Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

ID	Type	Stakeholder	Document	Page No	Line No	Comments	Developer's response
1	SH	Independent Age	Additional questions re COVID-19	General	General	Please tell us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication: Research we conducted in Spring/Summer 2021 involved interviews with older people about how the pandemic has affected their mental health. It suggested that a number of common challenges have caused distress and may have harmed older people's mental health including bereavement, long-term shielding (including voluntary shielding), long-term loneliness and isolation, and declining physical health and mobility. Some of these could have long-term impacts on mental health, such as bereavement, especially where compounded by restrictions on funerals, etc. In addition, some people have at various times reported barriers to accessing support from GPs, including difficulties getting appointments but also patient attitudes, e.g. 'I shouldn't take up GP time when other people need help more than me'. The committee should consider whether there are additions to the guidance that could help address these barriers. For example, greater consideration of identifying bereavement in patients as a risk factor for depression.	Thank you for your comment. The committee are aware of the impact of Covid-19 on mental health, and that this may have had an even greater impact on older people. The committee decided not to make Covid-specific recommendations as these may become outdated, but instead has increased the emphasis in the guideline on assessing the person, any factors that may be contributing to their depression and their needs on an individual basis.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

2	SH	Mind	All Evidence Reviews	General	General	Mind is a signatory of a stakeholder coalition position statement regarding these guidelines, following the draft document published in July 2017. We are pleased to see some of the changes highlighted have been addressed in these draft guidelines. Some methodological issues do still remain. Some are particular to this guideline (such as the categorisation of depression into the dichotomy of less/more severe), while other methodological issues are broader than these guidelines alone. These include an over reliance on Randomised Control Trials (RCTs) over broader, diverse sources of evidence important to people with lived experience (including qualitative and lived experience feedback).Within this guideline in particular, there are concerns that real world data collected within our NHS, through the IAPT dataset, is not included. This includes data from millions of patients treated within the NHS, and is concerning because a very large proportion of the treatments recommended in this guideline will be offered through IAPT services.	Thank you for your comment. The committee considered the current NICE classifications of mild to moderate and moderate to severe depression, and agreed that although these classifications have been adopted quite widely there is potential uncertainty with regards to the management of moderate depression. The committee agreed that a dichotomy of less and more severe depression was clearer, and the guideline includes definitions (that less severe depression includes the traditional categories of subthreshold symptoms and mild depression, and more severe depression includes the traditional categories of moderate and severe depression) in order to improve practical utility. The committee considered the distinction between less severe (subthreshold/mild) and more severe (moderate/severe) depression to be clinically meaningful in terms of supporting effective clinical decision making and being aligned with how clinicians conceptualize depression (in particular, GPs and other primary care staff, given that the majority of people with depression and almost all first line presentations of depression are managed in primary care). Based on this distinction, an anchor point of 16 on the PHQ-9 was selected as the cut-off between less severe and more severe depression, on the basis of alignment with the

							clinical judgement of the committee and eligibility criteria in the included studies. Published standardization of depression measurement crosswalk tables (Carmody 2006; Rush 2003; Uher 2008; Wahl 2014) were used in order to 'read-across' different symptom severity scales that were used in different studies. The committee considered RCTs as the most appropriate study design to assess clinical and cost effectiveness. This is consistent with the NICE guidelines manual which recognises RCTs as the most valid evidence of the effects of interventions, and this was outlined a priori in the review protocols. As specified in the scope, the experience of care section from the 2009 guideline was not included in this update. However, a new review question on patient choice was added to this update that includes a systematic review of primary qualitative studies that focus specifically on service user experience around choice of treatment. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context (including

							drawing on their knowledge of the IAPT dataset) so that the 'reality' for people experiencing depression was taken into consideration. In response to stakeholder comments, the committee have re-structured treatment recommendations in order to take into account implementation factors. In January 2020 NICE published a statement of intent signalling the ambition for the future use of wider sources of data and analytic methods (including sources commonly referred to as real-world data and evidence). To make decisions about the relative effectiveness of interventions, RCTs will continue to be prioritised in line with the NICE guidelines manual, in order to ensure that the populations treated with various interventions are equivalent. However it is possible that in the future, high-quality real-world datasets such as the IAPT dataset, could inform questions about access and engagement.
3	SH	Mind	All Evidence Reviews	General	General	We are concerned that 'partial recovery' is not included alongside full recovery as a critical outcome. Improvements to, for example severe depression, may not meet the criteria for full recovery but will be significantly meaningful for individuals. We are concerned that treatments that may assist someone to move from severe depression to moderate or mild depression may not be included, despite the fact this would have a	Thank you for your comment. The guideline includes continuous changes in scores on depression scales as a critical outcome for every treatment question, which will show changes for people who have both fully and partially recovered. This was agreed by the committee to be a better way to capture this data than the use of a dichotomous outcome for partial recovery.

						significant impact on the wellbeing of individuals. We are concerned that not including treatments that enable individuals to achieve 'partial recovery' means that certain treatment options may not have been included which people with lived experience value, such as arts and creative therapies. We recommend that 'partial recovery' is included as a critical outcome alongside full recovery.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

4	SH	The Association of Clinical Psychologists UK	All evidence reviews	General	General	Long-term follow-up data We welcome the recognition in this draft that long-term effectiveness is indeed an important outcome and applaud the efforts made to include such data where it was available. We regret to learn that very few studies of those included in the reviews report long-term follow-up data. We acknowledge, therefore, the decision that prioritisation of these outcomes is not possible. However, we notice that this was not consistently followed through. We do not think it appropriate and ethical practice to refer to some but not all of these outcomes and ask for this to be amended.For example, as highlighted in Table 13 on p.39 of Evidence Review B, for less severe depression, 4 studies showed a statistically significant effect at their respective follow-up point. However, only the two studies on group CBT and the one study on group problem-solving were considered whereas the study in STPP was not. Another example pertains to the further-line treatment recommendations, where the statistically significant benefit of LTPP at follow-up was not considered whilst for other treatments it was (Evidence Review D, p. 113).Moreover, it appears that only studies that yielded a statistically significant effect at the relevant follow-up point were considered, whilst those that did not find an effect were not, especially in the reviews for new episodes. Again, the findings of all of these studies	Thank you for your comment. The committee agree that long-term follow-up is important and share your disappointment that this is not more routinely measured and reported. Long-term follow-up is included in the research recommendations in the guideline. As highlighted in table 13 of Evidence report B and the corresponding 'committee discussion of the evidence' section, group CBT and group problem-solving showed benefits on depression symptoms at follow-up compared to treatment as usual, and CBT with antidepressants showed benefits compared to antidepressants alone. The committee agreed that this provided a useful indication that the results seen from the NMA for group CBT and group problem-solving may be maintained over a longer period. A 6-month follow-up of short-term psychodynamic psychotherapy (STPP) compared to non-directive counselling found a benefit for STPP for the outcomes of depression symptoms and remission at 6 months, but the committee noted that this small amount of evidence did not change their view, based on the NMA results, that these treatments had similar levels of effectiveness. In further-line treatment (Evidence report D),

						would need to be taken into account as they provide important information as to whether a treatment has been found to lose its effect after treatment ended. For example, for less severe depression, 55 out of 127 studies included in the NMA had follow-up data (43%). Of those, 4 were found to show statistically significant effects at their respective follow-up point (Evidence B, Table 13, p.39). This means that 51 studies did not show a statistically significant effect. Similarly, for those with more severe depression, 27 studies were identified with follow-up data and, out of those, 8 were found to have a statistically significant effect (Evidence Review B, Table 27, p.109). Again, this means that 19 studies showed no sustained effect. We cannot find where these important findings (of lack of treatment efficacy in longer-term follow ups) were both emphasised and considered in terms of the treatment recommendations.Given the importance of long term follow up data, both in demonstrating enduring clinical benefits and more accurate indications of cost effectiveness, we are concerned that it is not mentioned in the section on research recommendations. As stressed within the various documents of this draft, two thirds of patients do not currently benefit from treatments. This equates to more than 2 million individuals in the UK each year. As such we would want the guideline to stress that any studies	under the 'committee discussion of the evidence' section the committee highlight the sparsity of follow-up data from further-line treatment studies. The committee noted that a small number of studies could be combined in meta-analyses for outcomes up to 6 months after endpoint, however, beyond this point it was predominantly single-study analyses. The committee considered this limited evidence, and noted that a small number of studies showed evidence for sustained benefits on depression outcomes associated with augmenting antidepressants with CBT (up to 40 months), IPT (up to 12 months), short-term psychodynamic psychotherapy (up to 12 months), and long-term psychodynamic psychotherapy (up to 2 years). The committee agreed that the effects on depression outcomes at follow-up were generally in line with the effects observed at endpoint, and this strengthened their confidence in the recommendations.

						concerning depression should aim to include and report their outcomes over the long-term follow-up.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

5	SH	The Association of Clinical Psychologists UK	All evidence reviews	General	General	Quality of life and functioning outcomes We are particularly pleased about the inclusion of functioning and quality of life measures. We regret to learn that of those studies included in the reviews, only a few had reported on these outcomes.We would like to suggest that a sentence be added in the relevant sections in all documents referring to the importance of (a) future studies reporting on such outcomes, and (b) existing studies to publish these findings where the data was collected, especially given that these are the measures of greatest priority to service users.	Thank you for your comment. The committee agree that quality of life and functioning outcomes are important. The committee noted the limited evidence for these outcomes, and included quality of life and functioning outcomes for the research recommendations in the guideline. The importance of these outcomes is highlighted in the committee discussion of the evidence sections (as well as in the research recommendations). Risk of bias ratings also downgraded studies where these outcome measures were recorded but not reported (in the risk of selective reporting bias rating).

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

6	SH	The Association of Clinical Psychologists UK	All evidence reviews	General	General	Appropriate methods for determining treatment effect We are pleased that the third draft of the guideline includes continuous changes in scores on depression scales in every review question. However, we remain concerned that full recovery is still a critical outcome and that partial recovery, as we had advised, has not been added. It furthermore appears that the decisions for treatment recommendation have been influenced by these recovery rates. Moreover, the economic analysis focuses primarily on full remission. As previously pointed out, full remission or recovery from a severe depression baseline might be difficult or impossible to achieve, yet changes might still be clinically meaningful. Treatment which helps some service users move from severe depression to mild or moderate depression (i.e., 'partial recovery'), for example, would be worth recommending. Failing to do so risks the wellbeing of service users who may otherwise be denied these potentially transformative changes.We therefore recommend refining the interpretation of the evidence to inform treatment recommendation accordingly.	Thank you for your comment. The guideline includes continuous changes in scores on depression scales as a critical outcome for every treatment question, which will show changes for people who have both fully and partially recovered. This was agreed by the committee to be a better way to capture this data than the use of a dichotomous outcome for partial recovery. The economic analysis does not focus primarily on full remission. The economic analysis of treatments for a new episode of less severe depression has modelled only response (defined as at least 50% improvement in depressive symptoms) which may reflect full remission or not (depending on the starting point of depressive symptoms). Full remission was not considered in this population, due to lack of sufficient data in the respective NMA. The economic analysis of treatments for a new episode of more severe depression has considered full remission (i.e. a score on a depressive symptom scale that was below the cut-off point for a depression diagnosis) and also response that did not reach full remission (i.e. 50% improvement in depressive symptoms that was however not adequate to reach the scale cut-off point characterising full remission). The utility data attached to the model health states

							also reflected, as relevant, symptom improvement not reaching remission and/or symptom improvement reaching remission. Therefore, partial remission has been considered in the economic analysis for both populations.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

7	SH	Institute of Psychoanalysis	All reviews	General	General	Limiting evidence to RCTs only The NICE manual states that: “In order to formulate recommendations, the guideline Committee needs to consider a range of evidence about what works generally, why it works, and what might work (and how) in specific circumstances. The Committee needs evidence from multiple sources, extracted for different purposes and by different methods.” (p.67)It is further understood that the guideline committee follows the guidance set out in the NICE manual, in limiting evidence to RCTs in this guideline. However, we would like to stress that the various limitations of RCTs specifically in the field of mental health have been pointed out repeatedly by experts from many scientific disciplines and positions irrespective of therapeutic modality. To create sound policy requires drawing on a diverse range of evidence. We would like to stress that there exist important UK-based pragmatic trials and real-world data. Given the apparent lack of evidence from the UK (for example, on p.80 (l.21) of evidence review B only 34 of the included RCTs in the NMA were UK-based, and as emphasised throughout the various documents, the systematic search for UK-based health economic studies produced only a few relevant studies) it would only make sense to add important evidence from the studies that we have at our disposal, and that are	Thank you for your comment. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context (including drawing on their knowledge of the IAPT dataset) so that the 'reality' for people experiencing depression was taken into consideration. In response to stakeholder comments, the committee have re-structured treatment recommendations in order to take into account implementation factors. In January 2020 NICE published a statement of intent signalling the ambition for the future use of wider sources of data and analytic methods (including sources commonly referred to as real-world data and evidence). To make decisions about the relative effectiveness of interventions, RCTs will continue to be prioritised in line with the NICE guidelines manual, in order to ensure that the populations treated with various interventions are equivalent. However it is possible that in the future, high-quality real-world datasets such as the IAPT dataset, could inform questions about access and engagement. The committee were aware of pragmatic RCTs that were excluded from the NMA typically because the samples in the trials were <80%

						most relevant not only in terms of clinical evidence, but also in terms of providing important information about cost-effectiveness. We would like to point out that, as stated on p. 58, l 45f of the evidence review B document, the committee decided despite their exclusion to take some of the results of these "important and well known" pragmatic trials into account. However, it appears that the committee was rather partial with respect to which results they were taking into account when considering treatment recommendation, seemingly considering the effects of CBT and behavioural treatments in order to justify their superiority (see for example p. 141, l. 21f; p.146, l.31f). We therefore ask to amend this draft to include a more balanced consideration of pragmatic trials in order to adhere to the scientific principles of consistency and transparency.Given the lack of studies included in the guideline review from the UK/conducted within the NHS, it is particularly relevant that there is also real-world data collected through routine outcome monitoring (i.e. the IAPT data set) collected from millions of patients treated for depression within the NHS and carried out in the very setting where the evidence from the guideline will be applied. As such, it seems absurd/nonsensical/a missed opportunity not to include these in full in the present review, especially when this guideline	first-line treatment or <80% non-chronic depression. These were stipulations of the review protocol in order to create a homogenous data set, but the committee used their knowledge of these studies in the round when interpreting the evidence from the systematic review and making recommendations. By way of illustration some of these studies were listed in Evidence report B, however, in response to stakeholder comments the committee agree that it would be more consistent to name all UK-based studies which were excluded on this basis but which the committee were aware of when making recommendations, and this has now been done. Regarding the systematic review of economic evidence, it is noted that this was limited to UK studies only in Evidence reviews B (treatment of a new episode) and C (relapse prevention), because these areas were supported by guideline de-novo economic modelling. This approach yielded 6 UK economic studies of treatments for less severe depression (plus the guideline de-novo economic model), 11 UK economic studies of treatments for more severe depression (plus the guideline de-novo economic model), and 2 published UK economic studies of treatments for relapse prevention (plus the

						continues to emphasise the need to for health care professionals to collect ROM data (see p.59 of the draft guideline) We therefore suggest amending this draft by including such evidence from real-world data and pragmatic trials.	guideline de-novo economic model). The guideline de-novo economic models were informed by the guideline NMAs, assessed the whole range of effective treatments in respective areas, were directly relevant to current UK optimal routine care regarding resource use and unit costs, and were thus given higher priority over published economic evidence. In all other economic reviews non-UK studies were included in a hierarchic way, so that UK evidence was sought, and where this was not available, then non-UK studies were included. This approach is stated in Supplement 1 (Methods).

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

8	Individual	Individual 9	Equality Impact Assessment	General	General	The impact assessment does not appear to follow through into your recommendations, and the studies used to generate your new guidelines have not considered the impact or effectiveness of various treatments for people from minority groups and/ or for those with additional needs.	Thank you for your comment. You are correct that pre-specified sub-group analyses were not conducted to identify the effectiveness of treatments for people from minority groups or with additional needs. However, the equality impact assessment lists groups for whom there were likely to be inequalities in accessing treatment for depression or who would need special consideration when developing recommendations, and outlines the amendments that were made to recommendations to account for this.

9	SH	Parkinson's UK	Equality Impact Assessment	General	General	We welcome NICE's comprehensive consideration of the specific barriers faced by communities with certain protected characteristics and inclusion health groups. However, we are concerned that no mention is made within the Equality Impact Assessment or the Guideline, of the detrimental impact of discrimination and bias among health professionals on the treatment these groups receive. The impact of bias and discrimination on mental health cannot be understated. It has been evidenced that subjects of discrimination have a higher predisposition to suffer health problems, particularly those related to mental illness such as depression and anxiety (Alvarez-Galvez, J, Rojas-Garcia, A (2019). 'Measuring the impact of multiple discrimination on depression in Europe.' BMC Public Health 19, 435). The interplay of discrimination and depression is well-evidenced. Previous research on the effects of discrimination on health have highlighted the influence of ethnic and racial discrimination on mental and physical health outcomes (Bhui K, Stansfeld S, McKenzie K, Karlsen S, Nazroo J, Weich S (2005). 'Racial/ethnic discrimination and common mental disorders among workers: findings from the EMPIRIC study of ethnic minority groups in the United Kingdom.' Am J Public Health. 95(3):496–501). Discrimination based on gender, sexual orientation, language, religion, nationality, socioeconomic status, or	Thank you for your comment. The committee were aware of the potential impact of discrimination and stigma on access to mental health services, and have expanded the recommendations in the section of the guideline on principles of care to cover potential methods to overcome stigma , and added text regarding awareness and avoidance of discrimination to this section as well, and to the section on access to services. These changes have also been described in the Equality Impact Assessment (EIA).

						disabilities can also lead to poor health outcomes (Alvarez-Galvez J, Salvador-Carulla L (2010). 'Perceived discrimination and self-rated health in Europe: evidence from the European Social Survey.'. PLoS One. 2013;8(9):e74252). Health professionals and structures are not immune to bias, and this can lead to exceedingly poor outcomes for marginalised groups. For example, when it comes to psychosis, Black men experience it around 10 times more frequently than white men. But despite this, the latter are more than twice as likely to be receiving treatment for mental health problems (Mind. 'Discrimination in mental health services.' https://bit.ly/34B8Jnn, accessed 6 January 2022). We encourage NICE to include in its guidance the merits of and recommend bias and anti-discrimination training for health professionals supporting and caring for people with depression, this will be critical in achieving a productive relationship between practitioner and patient, based on trust.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

10	SH	Practice Plus Group	Equality Impact Assessment part	2	General	Technology remains a vital factor to support patient with learning disabilities and autism spectrum disorder , from evidence most patients rely on devices to enhance their communication as they have regular ritualistic behaviour pattern as part of their condition , the idea of interpreters remains relevant within the context of asylum seekers Remote consultation removes that regular mundane pattern patients have been use to over the years whereby they have face to face contact , we have seen an increase in violence and aggression with some Patients who prefer to have face to face contact rather than remote consultation	Thank you for your comment. The page of the EIA you refer to relates to the scope of this guideline. In the section relating to the guideline itself (3.2) the use of remote consolations has been discussed, with the caveat that alternatives to remote consultation must be available.

11	SH	British Beauty Council	Evidence review D	6	General	Depression evidence review I (nice.org.uk) - Patient choice review question - What are the facilitators and barriers that can enhance or inhibit choice of treatment for adults with depression? (p.6) "there are a range of pharmacological treatments and physical interventions such as electroconvulsive therapy and acupuncture. Many of these treatments are often used in combination, and may be delivered in a variety of settings (for example, individually or in groups, in primary care or secondary care), adding further complexity to the choice of treatment." There is significant evidence of the benefits to mental health from touch therapies. However, these therapies are not yet routinely used in the UK and Northern Ireland within the public and National Health Services (NHS), with access often triggered by the recipient rather than a medical professional. As highlighted earlier, NICE has previously stated that the existing body of evidence on the legitimacy and efficacy of touch therapy as a form of treatment is not robust enough with large enough sample sizes. It is therefore recommended that a number of trials are carried out which expect will demonstrate the benefits and value for money of these treatments versus those traditionally used in the UK. It is also recommended that integrated health improvements should be seen as part of the toolkit for solutions and social prescribing with existing	Thank you for your comment. The committee did not consider touch therapies to be interventions that were in regular clinical use for the treatment of depression. Therefore these interventions were not specified in any of the review protocols. As such the evidence on touch therapies has not been appraised and we are not able to make any recommendations on their use.

						medical services to support the NHS - with a clear strategy, policy and funding for Primary Care Trusts to access. Qualified therapists undertake in excess of 90 hours of training in anatomy physiology and pathologies as part of their nationally regulated qualification for entry into the workforce. They subsequently undertake additional continual professional development training in cancer touch therapy, stress management and other touch therapies. The sector is well placed to support the NHS and Public Health to relieve issues and symptoms relating to Functional neurological disorders (FND) and physical health and wellbeing through a range of therapies, improved selfcare and preventative healthcare.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

12	SH	UK Spa Association	Evidence review D	6	General	Depression evidence review I (nice.org.uk) - Patient choice review question - What are the facilitators and barriers that can enhance or inhibit choice of treatment for adults with depression? (p.6) "there are a range of pharmacological treatments and physical interventions such as electroconvulsive therapy and acupuncture. Many of these treatments are often used in combination, and may be delivered in a variety of settings (for example, individually or in groups, in primary care or secondary care), adding further complexity to the choice of treatment." There is significant evidence of the benefits to mental health from touch therapies. However, these therapies are not yet routinely used in the UK and Northern Ireland within the public and National Health Services (NHS), with access often triggered by the recipient rather than a medical professional. As highlighted earlier, NICE has previously stated that the existing body of evidence on the legitimacy and efficacy of touch therapy as a form of treatment is not robust enough with large enough sample sizes. Issues regarding sample size are also relevant to research into the benefits of aromatherapy and reflexology in treating depression.It is therefore recommended that a number of trials are carried out which expect will demonstrate the benefits and value for money of these treatments versus those traditionally used in the UK. It is also	Thank you for your comment. The committee did not consider touch therapies to be interventions that were in regular clinical use for the treatment of depression. Therefore these interventions were not specified in any of the review protocols. As such the evidence on touch therapies has not been appraised and we are not able to make any recommendations on their use. The number of research recommendations that the committee can develop is limited and unfortunately touch therapies were not prioritised for a research recommendation.

						recommended that integrated health improvements should be seen as part of the toolkit for solutions and social prescribing with existing medical services to support the NHS - with a clear strategy, policy and funding for Primary Care Trusts to access. Qualified therapists undertake in excess of 90 hours of training in anatomy physiology and pathologies as part of their nationally regulated qualification for entry into the workforce. They subsequently undertake additional continual professional development training in aromatherapy, reflexology, cancer touch therapy, stress management and other touch therapies. The sector is well placed to support the NHS and Public Health to relieve issues and symptoms relating to Functional Neurological Disorders (FND) and physical health and wellbeing through a range of therapies, improved selfcare and preventative healthcare.	
13	SH	Faculty of Public Health	Evidence Review	General	General	There needs to be greater recognition and evidence on addressing social factors alongside other treatment options e.g. practical and social support with debt, gambling, domestic violence, unemployment, poor housing etc.	Thank you for your comment. Additional considerations have been added into the recommendations on initial assessment, including factors such as the ones you suggest that might be contributing to depression. A recommendation to consider how other agencies

							may be able to provide support has also been added.
14	SH	Faculty of Public Health	Evidence Review	General	General	There needs to be greater evidence on individual physical activity, nature-based activity and other social and community interventions.	Thank you for your comment. In response to stakeholder comments, the committee supported less intense 'move more' exercise for general wellbeing (although not as a treatment for depression) and made a new recommendation to reflect this. The recommendation also emphasised the benefits of outdoors activities.

15	SH	Faculty of Public Health	Evidence Review	General	General	Research is needed on long term outcomes of skills and knowledge-based treatment v antidepressants.	Thank you for your comment. Outcomes were assessed at treatment endpoint, but in order to determine if treatments for depression had longer term benefits, follow-up measurements were also analysed and assessed by the committee as part of their decision-making process. However, the committee recognised that although these longer-term outcomes were very important to people with depression, as they were not available for all interventions they would be less useful to the committee to make recommendations. In general, very limited evidence provided some reassurance that classes of interventions that had shown beneficial results at endpoint, may have beneficial results at follow-up as well, but there was not enough evidence to develop recommendations based on follow-up data alone. Long-term follow-up is included in the research recommendations in the guideline.

16	Individual	Individual 4	Evidence review A	30	34	No distinction is made between studies that have used 'gold standard' diagnostic interviews to determine the prescence of depression according to DSM or ICD and those that have used only a psychometric tests. The former studies should be the foundation for recommendations, low quality studies should not be added to the mix.Service delivery assessments are almost invariably based solely on psychometric test scores alone and it should be made clear that any recommendations flowing from this data should be given much less weighting than given to therapies evaluated in rct's.	Thank you for your comment. As pre-specified in the review protocols, the population included adults with clinically important symptoms of depression (as defined by a diagnosis of depression according to DSM, ICD or similar criteria, or depressive symptoms as indicated by baseline depression scores on validated scales). Studies using depression symptom scales were included (in addition to studies that limited inclusion to those with a diagnosis of depression) on the basis that such scales are widely used in RCT research and clinical practice and are validated in the diagnosis of depression and the assessment of depression symptom severity. The committee also noted that excluding studies that did not use diagnostic interviews would result in the exclusion of a large number of studies (30% of studies included in Evidence review A would not be eligible) and would not allow examination of those with subthreshold symptoms of depression which were included in the review question and protocol.

17	Individual	Individual 4	Evidence review A	31	Table 1	Outcome is being assessed for service delivery purposes in terms of a psychometric test but this does not gauge what a patient cares about (the minimally important difference) e.g back to normal or best functioning. It should be made clear that the outcome measure used is deficient. Examining service delivery may be premature unless it has first been established that therapy/medication makes a real world difference in routine care.	Thank you for your comment. As pre-specified in the review protocol, critical outcomes for the service delivery model review (Evidence review A) included depression symptoms, but also remission (usually defined as no longer meeting criteria for depression on a validated symptom severity scale) and response (usually defined as at least 50% improvement from the baseline score on a depression scale). A number of different care models did not have available data on the outcomes of remission and response. Therefore when considering the evidence the committee placed the greatest emphasis on depression symptomatology and antidepressant use, as these provided the best point of comparison across different interventions.

18	Individual	Individual 6	Evidence Review B	General	General	The literature review is incomplete. Metacognitive therapy (MCT) is a psychotherapy which has a number of published RCT's for Depression and Metanalyses. There is one reference to a comparison with CBT (Jordon et al page 173 line 21 onwards). This reference is neither commented on in the text or reported in supplement B3 where analysis including Forrest plots are reported for other studies.	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. Metacognitive therapy (MCT) was included in the class of cognitive and cognitive behavioural therapies (as was CBT). Jordan 2014 was included in the NMA that informed the recommendations. However, because the study included a within-class comparison it is not included in the forest plots, and is not mentioned in the text as the within-class comparison of MCT versus CBT, was not regarded by the committee as a critical comparison.

19	Individual	Individual 6	Evidence Review B	General	General	The rationale for the use of condensing therapies into classes seems somewhat arbitrary. I appreciate that the authors have 100s of references to compare and condense however assumptions have been potentially made as to which therapies are grouped together. Some therapies which are not classified as cognitive such as psychodynamic or counselling could legitimately be placed in the same class but are not. One rationale presented for clustering is to reduce the impact of small sample sizes however this seems inconsistent with some of the analysis and later commentary when the 2 highest ranked interventions (Table 11 and 17) have relatively tiny sample sizes and potentially has implications as to how the reader could interpret what should be offered in a service or if one was a service user what one might request.	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. The classification system was developed based on the committee's expert advice, with psychological therapies been grouped according to common theoretical structure and methodological approach, and pharmacological treatments being grouped according to mechanism of action or chemical structure. Even after using this approach, some classes included a small number of interventions and/or people tested on each. However, it was not considered appropriate to group interventions within these classes with interventions in other classes, as their theoretical structure and methodological approach was not considered common enough, so such a grouping might bias and invalidate the results of the analyses. Regarding the two classes that have received highest rankings in the tables: these are indeed treatments tested on a very small number of people, which, nevertheless, met inclusion criteria for the NMA and were therefore

							included in the analysis. The NMA results for these two treatments reflected the findings of 2 single RCTs, respectively, with small study size (see Figure 354 in Supporting documentation B2 and Figure 390 in Supporting documentation B3 for the forest plots of these RCTs, which show very high effects reported by the RCTs). The committee did not take the NMA results for these two classes into account when they made recommendations. This is because they only took into account evidence on treatment classes tested on at least 50 participants across RCTs included in each NMA. This was the minimum amount of evidence that a treatment class should have in order to be considered for a practice recommendation. The committee looked at the total size of the evidence base in this area (treatment of a new episode of depression) and the large volume of evidence for some treatment classes relative to others, and decided not to consider treatment classes with a small size of evidence base (tested on <50 participants) as there were several treatment classes with much larger volume of evidence. This was stated in several places in the document, but it was not highlighted under 'The committee's discussion of the evidence'. This statement has now been included in this section in the final report. Therefore, this finding did not

							affect recommendations and should have no implications for clinical practice. The results of the NMA should not be read and interpreted in isolation from the committee's discussion of the evidence and have not exclusively determined the formulation of recommendations. The committee's discussion includes details on how the committee interpreted the results in light of their relevance, quality and uncertainty, along with other considerations, so that readers understand how the evidence, combined with further considerations, led to the formulation of guideline recommendations.

20	Individual	Individual 6	Evidence Review B	General	General	The presentation of the statistical analyses is challenging and would benefit from checking out how a lay person and ordinary clinicians would understand them.	Thank you for your comment. The statistical analyses undertaken were complex due to the amount and diversity of available data, including the consideration of two separate populations, the number of interventions and outcomes considered, and the statistical handling of diverse data reported in the RCTs considered in the systematic review. However, there was an attempt to simplify the presentation of the results as much as possible: first of all, under the section 'Methods and process', there is an overview of how results were presented, under 'Presentation of the NMA results'. There is also further explanation on the methods of presentation of the results under 'Evidence of network meta-analysis', under 'Base-case analysis' and 'Bias-adjusted analysis'. Regarding how results have been presented: network plots show how evidence was structured, and are an essential part of presenting results of a NMA. In the final report there is now text added under each plot to help interpretation. There are also tables for every outcome considered in the NMA, which reports all treatment classes and interventions and numbers randomised to each, so that readers are aware of the evidence base for each treatment class, intervention and outcome. Finally, results have been reported in two different ways: as forest plots, which is a

							standard way of presenting results of meta-analysis, and also in a tabulated form, where all treatment classes have been ranked from best to worst, along with the respective numbers randomised to each, their effects versus the reference treatment, and also the rankings in the analysis. Admittedly, there is a lot of information presented, but this has been simplified as much as possible, while retaining transparency and without omitting any crucial findings. Under the 'Committee's discussion of the evidence' there is also a description of results without numbers and complex statistical terms, explaining how the committee interpreted the results and reached recommendations, in a way that is more approachable to a lay person and clinicians alike.

21	SH	Greater Manchester Mental Health Services	Evidence Review B	General	General	The literature review is incomplete. Metacognitive therapy (MCT) is a psychotherapy which has a number of published RCT's for Depression and Metanalyses. There is one reference to a comparison with CBT (Jordon et al page 173 line 21 onwards). This reference is neither commented on in the text or reported in supplement B3 where analysis including Forrest plots are reported for other studies.	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. Metacognitive therapy (MCT) was included in the class of cognitive and cognitive behavioural therapies (as was CBT). Jordan 2014 was included in the NMA that informed the recommendations. However, because the study included a within-class comparison it is not included in the forest plots, and is not mentioned in the text as the within-class comparison of MCT versus CBT, was not regarded by the committee as a critical comparison.

22	SH	Greater Manchester Mental Health Services	Evidence Review B	General	General	The rationale for the use of condensing therapies into classes seems somewhat arbitrary. I appreciate that the authors have 100s of references to compare and condense however assumptions have been potentially made as to which therapies are grouped together. Some therapies which are not classified as cognitive such as psychodynamic or counselling could legitimately be placed in the same class but are not. One rationale presented for clustering is to reduce the impact of small sample sizes however this seems inconsistent with some of the analysis and later commentary when the 2 highest ranked interventions (Table 11 and 17) have relatively tiny sample sizes and potentially has implications as to how the reader could interpret what should be offered in a service or if one was a service user what one might request.	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. The classification system was developed based on the committee's expert advice, with psychological therapies been grouped according to common theoretical structure and methodological approach, and pharmacological treatments being grouped according to mechanism of action or chemical structure. Even after using this approach, some classes included a small number of interventions and/or people tested on each. However, it was not considered appropriate to group interventions within these classes with interventions in other classes, as their theoretical structure and methodological approach was not considered common enough, so such a grouping might bias and invalidate the results of the analyses. Regarding the two classes that have received highest rankings in the tables: these are indeed treatments tested on a very small number of people, which, nevertheless, met inclusion criteria for the NMA and were therefore

							included in the analysis. The NMA results for these two treatments reflected the findings of 2 single RCTs, respectively, with small study size (see Figure 354 in Supporting documentation B2 and Figure 390 in Supporting documentation B3 for the forest plots of these RCTs, which show very high effects reported by the RCTs). The committee did not take the NMA results for these two classes into account when they made recommendations. This is because they only took into account evidence on treatments tested on at least 50 participants across RCTs included in each NMA. This was the minimum amount of evidence that a treatment class should have in order to be considered for a practice recommendation. The committee looked at the total size of the evidence base in this area (treatment of a new episode of depression) and the large volume of evidence for some treatment classes relative to others, and decided not to consider treatment classes with a small size of evidence base (tested on <50 participants) as there were several treatment classes with much larger volume of evidence. This was stated in several places in the document, but it was not highlighted under 'The committee's discussion of the evidence'. This statement has now been included in this section in the final report. Therefore, this finding did not

							affect recommendations and should have no implications for clinical practice. The results of the NMA should not be read and interpreted in isolation from the committee's discussion of the evidence and have not exclusively determined the formulation of recommendations. The committee's discussion includes details on how the committee interpreted the results in light of their relevance, quality and uncertainty, along with other considerations, so that readers understand how the evidence, combined with further considerations, led to the formulation of guideline recommendations.

23	SH	Greater Manchester Mental Health Services	Evidence Review B	General	General	The presentation of the statistical analyses is challenging and would benefit from checking out how a lay person and ordinary clinicians would understand them.	Thank you for your comment. The statistical analyses undertaken were complex due to the amount and diversity of available data, including the consideration of two separate populations, the number of interventions and outcomes considered, and the statistical handling of diverse data reported in the RCTs considered in the systematic review. However, there was an attempt to simplify the presentation of the results as much as possible: first of all, under the section 'Methods and process', there is an overview of how results were presented, under 'Presentation of the NMA results'. There is also further explanation on the methods of presentation of the results under 'Evidence of network meta-analysis', under 'Base-case analysis' and 'Bias-adjusted analysis'. Regarding how results have been presented: network plots show how evidence was structured, and are an essential part of presenting results of a NMA. In the final report there is now text added under each plot to help interpretation. There are also tables for every outcome considered in the NMA, which reports all treatment classes and interventions and numbers randomised to each, so that readers are aware of the evidence base for each treatment class, intervention and outcome. Finally, results have been reported in two different ways: as forest plots, which is a

							standard way of presenting results of meta-analysis, and also in a tabulated form, where all treatment classes have been ranked from best to worst, along with the respective numbers randomised to each, their effects versus the reference treatment, and also the rankings in the analysis. Admittedly, there is a lot of information presented, but this has been simplified as much as possible, while retaining transparency and without omitting any crucial findings. Under 'The committee's discussion of the evidence' there is also a description of results without numbers and complex statistical terms, explaining how the committee interpreted the results and reached recommendations, in a way that is more approachable to a lay person and clinicians alike.

24	Individual	Individual 12	Evidence review B	General	General	In Table 2 (p. 18) I note that the treatment classes "Self-help without/with minimal support" includes "Computerised cognitive bias modification" and the class "Self-help with support" includes "Cognitive bias modification with support", and effect sizes etc. are calculated for these interventions as part of the NMA (e.g. Tables 4, 5 etc). The Ns for these interventions seemed very small, and when I checked the included studies there are only 3 (Baert 2010_study 1, Pictet 2016, Watkins 2009). There are many more studies in the Cognitive Bias Modification (CBM) literature addressing depression, see e.g. the 2020 network meta analysis in Lancet Psychiatry:Fodor, L. A., Georgescu, R., Cuijpers, P., Szamoskozi, Ş., David, D., Furukwa, T. A., & Cristea, I. A. (2020). Efficacy of cognitive bias modification interventions in anxiety and depressive disorders: A systematic review and network meta-analysis. Lancet Psychiatry, 7(6), 506–514. https://doi.org/10.1016/S2215-0366(20)30130-9And there are several studies published since then. From the search process and inclusion/exclusion criteria it is not at all clear why out of the many studies examining CBM on depression symptoms just these 3 were included. I wonder whether there was either a problem with either how the search was conducted, or with the specification of the inclusion/exclusion criteria, as it is difficult to see how it would make sense for	Thank you for your comment. The network meta-analysis review that you cite (Fodor 2020) was identified by the searches and has been checked for additional relevant primary studies. The systematic review (Fodor 2020) and any additional primary studies that were included in Fodor 2020 and were assessed at full-text for inclusion, are listed under excluded studies in Supplement B1. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models. Although the 3 studies cited target different biases (Baert 2010_study 1, Pictet 2016, Watkins 2009), the committee considered it appropriate to group them into a class as the interventions were considered to have broadly similar modes of action, treatment components, and approaches, and the interventions were expected to have similar (but not necessarily identical) effects.

						these 3 studies included out of all the studies out there, but no others. If how things are in the current draft guidance is correct, it would be good to document somewhere the exclusion reasons for other studies e.g., those listed in Fodor et a. 2020 (I could not find this information). Otherwise, it brings into question the credibility of the literature selection process and subsequent recommendations (e.g., it makes me wonder whether there might be similar situations for other intervention classes examined). Further, these three studies are investigating 3 very different interventions (one targeting attentional biases, one interpretation biases, and one concreteness) and it is questionable whether it makes sense to class them as one type of intervention. Normally these would be examined separately, otherwise it is a bit like classing all anti-depressants as 'medicine'.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

25	SH	Psychotherapy & Counselling Union	Evidence review B	General	General	Reliance on short-term outcomes Depression is often a long-term, re-occurring condition (cp. IAPT data in Hepgul et al., 2016, https://bmcpsychiatry.biomedcentral.com/track/pdf/10.1186/s12888-016-0736-6.pdf). The current draft guideline recognises some longer-term follow-up data (Evidence review B, p. 73), but it continues to rely heavily on very short-term outcomes, most commonly over a 6 to 12 week period. It also adopts a simple, binary model of recovery, ignoring partial recovery which in the real world may be very significant.	Thank you for your comment. The committee agree that long-term follow-up is important and share your disappointment that this is not more routinely measured and reported. Long-term follow-up is included in the research recommendations in the guideline. The guideline includes continuous changes in scores on depression scales as a critical outcome for every treatment question, which will show changes for people who have both fully and partially recovered. This was agreed by the committee to be a better way to capture this data than the use of a dichotomous outcome for partial recovery.

26	Individual	Individual 16	Evidence Review B	General	General	We are concerned that the research cited is limited and has a tendency for over reliance on computerised cognitive behavioural approaches.	Thank you for your comment. Different self-help approaches (with or without support) were searched for and were eligible for inclusion. In addition to computerised approaches, there are also RCTs of cognitive bibliotherapy, behavioural bibliotherapy, expressive writing, mindfulness meditation CD, relaxation training CD, and third-wave cognitive therapy CD, included in the network meta-analyses (NMAs) for treatment of a new episode of depression. One intervention per class was used as an exemplar in the economic analysis, as it was not feasible to model all interventions included in the NMA. Computerised CBT (cCBT) was selected as the exemplar from the class of self-help with support as it had a large evidence base and a high effect compared with other interventions in the same class. Thus, the clinical evidence and resource use data used to inform the economic analysis were specific to cCBT; consequently, the results of the economic analysis were specific to cCBT (but could also be extrapolated to any other intervention with similar acceptability, effectiveness and resource use). However, the treatment class effect size for self-help (with or without support) that was estimated from the NMA and reported in the clinical evidence sections of evidence review B, was informed by

							evidence from all interventions included in the treatment class. In addition, individual intervention effects have been reported in Evidence review B for all interventions within each class for the SMD outcome (for both less and more severe depression). In response to stakeholder comments, the self-help with support section has been relabelled as guided self-help and the description of guided self-help has been amended to clarify that this is not restricted to cCBT.

27	Individual	Individual 16	Evidence Review B	General	General	Within the research used we would like to express concern that the population demographics have some limitations and are not always representative of patient populations.	Thank you for your comment. The committee considered RCTs as the most appropriate study design to assess clinical and cost effectiveness. This is consistent with the NICE guidelines manual which recognises RCTs as the most valid evidence of the effects of interventions, and this was outlined a priori in the review protocols. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context so that the 'reality' for people experiencing depression was taken into consideration and recommendations were made that were relevant to the populations that clinicians typically encounter. The committees' discussions on this are documented in 'the committee's discussion of the evidence' sections

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

28	SH	Department for Environment, Food & Rural Affairs	Evidence Review B	General	General	There is no mention of the impact of interactions with green or blue space on treating depression in any of the research cited in this evidence review. We suggest that the scope of research for treatments is widened to include nature-based health interventions. There is a wealth of research which shows the positive impacts of time spent in green and blue space on depression which should be considered when developing recommendations on treating depression to ensure that interventions such as green social prescribing are not overlooked. Examples of evidence which could be reviewed are outlined below (please note this is not exhaustive): Public Health England (2020), Improving access to greenspace: A new review for 2020, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/904439/Improving_access_to_greenspace_2020_review.pdfDefra (2018), Health and the Natural Environment: A review of evidence, policy, practice and opportunities for the future, http://randd.defra.gov.uk/Document.aspx?Document=14290_HealthandtheNaturalEnvironment_FullReport_29.08.18.pdfUK Parliament Research Briefing (2020), Mental health statistics: prevalence, services and funding in England, Mental health statistics: prevalence, services and funding in England - House of Commons Library	Thank you for your comments. The committee did not consider nature-based activities to be interventions that were in regular clinical use for the treatment of depression. Therefore these interventions were not specified in any of the review protocols and consequently the studies that you cite would not have met the inclusion criteria for the reviews. However, in response to stakeholder comments, the committee supported less intense 'move more' exercise for general wellbeing (although not as a treatment for depression) and made a new recommendation to reflect this. The recommendation also emphasised the benefits of outdoors activities.

						(parliament.uk) ENCA Services Databook - ONS (2019) UK Natural Capital AccountsHealth matters: obesity and the food environment - GOV.UK (www.gov.uk)Natural England, A review of nature-based interventions for mental health care, A review of nature-based interventions for mental health care - NECR204 (naturalengland.org.uk)Natural England (2020), Nature connectedness among adults and children in England Mourato et al., Economic Analysis of Cultural Services (2010)Public Health England, Improving access to greenspace (2020)Cross government project on preventing and tackling mental ill health through green social prescribing (research on the effectiveness of green social prescribing included below):Willis et al, Green space and health benefits: a QALY and cost-effectiveness analysis of a mental health programme (2016)Maughan DL et al, Primary-care-based social prescribing for mental health: an analysis of financial and environmental sustainability (2016)Dayson and Bashir, The social and economic impact of the Rotherham Social Prescribing Pilot: main evaluation report (2014)Natural England, Good practice in social prescribing for mental health: the role of nature-based interventions' (2017) Cross government paper on 'Why society needs nature: Lessons learned from research during Covid-19'White et al,	

						'Would you be happier living in a green urban area?' (2013) Van den Berg et al, Health benefits of green spaces in the living environment (2015)Natural England, A rapid scoping review of health and wellbeing evidence for the Framework of Green Infrastructure Standards (2020)White et al, 'Spending at least 120 minutes a week in nature is associated with good health and wellbeing', (2019)Social Return on Investment analysis of the health and wellbeing impacts of Wildlife Trust programmeshttps://www.nature.com/articles/s41598-021-87675-0https://www.euro.who.int/en/health-topics/environment-and-health/urban-health/publications/2017/urban-green-space-interventions-and-health-a-review-of-impacts-and-effectiveness.-full-report-2017https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4410252/https://pubmed.ncbi.nlm.nih.gov/25631858/https://www.exeter.ac.uk/news/homepage/title_830601_en.htmlhttps://www.mentalhealth.org.uk/sites/default/files/MHAW21_NATURE%20REPORT_ENG_web.pdf (includes a number of studies)https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7688424/	

29	SH	The Mindfulness Initiative	Evidence review B	General	General	We note that the evidence for evidence-based mindfulness-based interventions has been grouped together and assessed alongside more general mindfulness meditation groups, and a 'meditation-relaxation' group.Mindfulness specifically encourages people to open up to all of their experience, and practice de-centring from their thoughts and ruminations. MBCT is a clinical programme incorporating elements of CBT that can be particularly useful for those with depression to manage and respond to the thoughts they are observing. Mindfulness is therefore not the same as 'relaxation' meditation, and we suggest that meditation is separated out from mindfulness in the evidence review to provide a more accurate picture of its effectiveness and ensure people are able to make a clear and informed choice over their treatment options.	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. However, the committee did agree that MBCT should be given as an exemplar of this class and in Table 1 of the recommendations, in considering how to deliver group mindfulness or meditation it is recommended that 'a programme such as mindfulness-based cognitive therapy specifically designed for people with depression' is used.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

30	SH	The Mindfulness Initiative	Evidence review B	General	General	We are disappointed not to see reference to more recent reviews of mindfulness-based interventions, having provided these in response to previous consultations of the draft guidelines. In particular, we note that Goldberg et al 2018, which is the most comprehensive meta-analysis to date of RCTs of mindfulness-based interventions for adults experiencing a current mental health problem, including sub-group analyses for people experiencing a current episode of depression.	Thank you for your comment. The systematic review that you cite (Goldberg et al. 2018) has been checked for additional relevant primary studies, and listed under excluded studies in Supplement B1 (as it was not appropriate to include in its entirety).

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

31	SH	The Association of Clinical Psychologists UK	Evidence review B	General	General	Network Meta-Analysis (NMA)We appreciate the inclusion of pair-wise meta-analyses alongside the NMA for the review of first episode depression. However, we remain very concerned about the fact that NMA continues to be the primary data analysis and that, in the end, pair-wise analyses were only used for comparison reasons. As stated on p.39 in evidence review B, the decision was made to utilise only the NMA results based on the finding that there were only very few differences in the comparison of findings between both. A problem with such a comparison, however, is that it can only be made for those comparisons for which direct evidence is available.As we have emphasised during all consultations on this guideline, the validity or trustworthiness of statistical evidence derived from NMA is highly controversial (Faltlinsen et al., 2018; Leucht et al., 2016). Given that it has no formal expert consensus, such an analytical approach can be viewed only as an experimental technique, and we believe that a national health treatment guideline should not be based on an experimental technique.In line with leading scientists, we strongly maintain that NMA should only be used when certain conditions are met. As repeatedly pointed out, these conditions seem not to have been met adequately here, showing evidence that transitivity and consistency assumptions are	Thank you for your comment. NMA was the main method used to synthesise evidence on pharmacological, psychological, psychosocial, physical and combined interventions, consistently with previous drafts of this guideline, in order to allow estimation of the relative effectiveness, acceptability and tolerability across all treatments for a new episode of less severe or more severe depression. Pairwise meta-analysis was employed to synthesise data on all critical outcomes of the clinical analysis in order to compare the results of the NMA with those of pairwise meta-analysis (MA) and explore any differences between them and possible reasons for any differences. Moreover, pairwise MA was used to synthesise follow-up data as well as data on functioning and quality of life. However, the decision was (right at the start rather than in the end of the process) that results of pairwise MAs on critical outcomes would not be considered as the primary source of evidence when formulating recommendations. This decision is stated under 'Summary of methods, Evidence synthesis', in Evidence review B. Nowhere on page 39 is it stated that there was a decision to utilise only the NMA results based on the finding that there were only very few differences in the comparison of findings between NMA and

						violated. Our concerns are supported by various statements within the draft guideline that point to these limitations. Moreover, given that the economic modelling carried out in this draft guideline is heavily influenced by the NMA (and therefore its limitations), we are similarly concerned about the trustworthiness of the outcome of the economic analysis of treatments. We therefore reiterate our advice that until there is consensus and evidence of the validity of such a statistical analysis for this type of complex dataset that combines three different modalities of treatment (pharmacological, psychological and physical), the primary method to synthesise the evidence should be through direct comparison (standard meta-analysis).	standard pairwise MA. It is only stated that, where relevant, results were overall consistent between the NMA and the pairwise meta-analysis. This finding was reassuring for the committee and increased its confidence in the NMA results. It is true that the comparison between NMA and pairwise MA results cannot be made for comparisons between treatments for which direct evidence is not available, and this is an important advantage of NMA over pairwise MA: that it allows estimation of effects between interventions that have not been directly compared in a head-to-head comparison via indirect comparisons. This is essential in order to estimate the relative effectiveness of all pairs of treatments assessed in the review. It also allows simultaneous comparison of the effects and ranking of all treatments. Interestingly, Faltinsen et al. (2018) report that WHO have started advocating the use of NMA to inform clinical guidelines and that the scientific production of network meta-analyses is increasing rapidly over the world. (They also report that NICE guidelines typically prefer direct evidence from RCTs and conventional meta-analyses to indirect evidence – this is not entirely true, as NICE prefer RCTs to indirect evidence, but “when multiple competing options are being

							appraised, a network meta-analysis should be considered" according to the NICE Guidelines Manual.) The authors recommend further methods for reporting and statistical testing of NMAs – which is fully agreed. Full reference to Leucht et al. (2016) could not be identified in your comments, but perhaps you refer to the paper "Network meta-analyses should be the highest level of evidence in treatment guidelines" (EUR ARCH PSY CLIN N 2016; 266, 477–480) where the authors conclude: "in our opinion, systematic reviews based on network meta-analyses should generally be the highest level of evidence in treatment guidelines, but we need to assess them carefully and in certain situations (such as if a meta-analysis is mainly composed of small trials)". In the area of mental health only, there are several NMAs published on treatments for depression, anxiety, PTSD, schizophrenia etc. NICE has used NMA in the past to inform other mental health guidelines, including PTSD, bipolar disorder, generalised anxiety, psychosis and social anxiety, and in several other diverse disease areas such as epilepsy, acne, and induction of labour. There are also several NMAs published in the area of psychotherapies for Depression (e.g. Barth et al, PLOS Medicine 2013, 10(5): e1001454; Cuijpers et al, JAMA Psychiatry 2019, 76(7):700-707;

							Cuijpers et al, World Psychiatry 2020, 19(1):92-107; Cuijpers et al, World Psychiatry 2021, 20(2):283-293; Zhou et al, World psychiatry 2015, 14(2):207–222; López-López et al, Psychological medicine 2019, 49(12):1937–1947), many of which have compared different types of therapy such as pharmacological vs psychological interventions, online vs. face-to-face interventions, etc. There are also published NMAs of psychotherapies for anxiety disorders (Mayo-Wilson et al, Lancet Psychiatry 2014, 1(5):368–376; Chen et al, Journal of psychiatric research 2019, 118:73–83), panic disorder (Pompoli et al, The Cochrane database of systematic reviews 2016, 4(4):CD011004), and PTSD (Merz et al, JAMA Psychiatry 2019, 76(9):904–913; Mavranezouli et al, Psychological medicine 2020, 50(4): 542–555; Coventry et al, PLoS medicine 2020, 17(8):e1003262; Mavranezouli et al, J Child Psychol Psychiatry 2020, 61(1):18-29). The above suggest that NMA is recognised as an established method of evidence synthesis and not as an experimental technique. Consistency between direct and indirect evidence and transitivity are met when the distribution of the effect modifiers is the same across treatment comparisons. It is correct that,

							for a valid analysis, due consideration must be given to the evaluation of effect modifiers across all comparisons. Balanced distribution of effect modifiers cannot happen when there is heterogeneity in populations and/or interventions. This heterogeneity, however, can be a problem in both pairwise MA and NMA and should be considered prior to conducting the meta-analysis, and when interpreting the results. In the guideline NMA a large part of heterogeneity was controlled by splitting populations with less and more severe depression, using detailed treatment definitions [including treatment intensity and mode of delivery for psychological interventions] and categorising them using a class random effects model. Heterogeneity was assessed by examining for model fit and checking for inconsistency between direct and indirect evidence. Other parameters, such as sex, socio-economic factors, therapist factors, may also contribute to heterogeneity, in particular in such a large and complex dataset, but this would also be a problem had exclusively pairwise MA of the 142 RCTs for less severe depression and 534 RCTs for more severe depression included in the systematic review been conducted. Considering heterogeneity when assessing the hundreds of pairwise, independent comparisons of this

							dataset would make interpretation of the findings and conclusions as to which interventions are the best options highly problematic. Between-study heterogeneity in the NMA was formally assessed for each network; results of this assessment were taken into account when interpreting the results of the NMA and making recommendations. Moreover, for the SMD outcome, a non-pharmacological subgroup of the overall dataset was analysed separately as a sensitivity analysis, to explore whether transitivity issues between pharmacological and non-pharmacological trials might have impacted on the results of the NMA. In addition, also for the SMD outcome, a sub-group analysis including only studies at low risk of bias for the attrition domain in the RoB tool has now been conducted. Detailed results of inconsistency checks and comparison between mixed (NMA) and direct evidence as well as additional sensitivity and sub-group analyses have been provided in Appendix M of Evidence review B, and supplements B5 and B6. The committee considered all these issues and additional analyses when making recommendations alongside the results of the pairwise MA, the economic modelling results and newly reviewed qualitative evidence. Recommendations take also into account

							individual patient needs and preferences, which might be argued to be an effect modifier the distribution of which could potentially differ across pharmacological, psychological and physical treatment trials. Consideration of cost-effectiveness is an essential element of NICE guidelines. The economic analysis assessed concurrently the relative cost-effectiveness of all effective treatments with an adequate evidence base for less and more severe depression. Economic modelling would not be possible to carry out had the guideline utilised only pairwise MA and not NMA. This is because, in order to assess the relative cost-effectiveness across all treatments, the economic model must be informed with data on the relative effects (discontinuation, response, remission in this particular model) across all treatments, and this simultaneous reference to relative effects is only possible with NMA and not with pairwise MA.

32	SH	Institute of Psychoanalysis	Evidence review B	General	General	Class modelsThe class models that have been adopted raises significant concern. The guideline states: “Each class consisted of interventions with a similar mode of action or similar treatment components or approaches so that interventions within a class were expected to have similar (but not necessarily identical) effects.” There is no evidence that this similarity is in fact the case. The lack of an explanation or definition as to how similarity between and within classes was assessed is striking and a serious omission. We recommend the inclusion of a more thorough and transparent explanation alongside a Table or Figure in the main document that summarises these. As far as we could discern, the only place where the information can be found is in the supplementary excel spreadsheet (Supplement B1).The decision that an estimate for variance was borrowed from other interventions where it was not available needs to be made more transparent and justified adequately. For example, Exercise borrowed variance from Counselling; Sort-term Psychodynamic Psychotherapy, Psychoeducation, and Interpersonal Psychotherapy, Self-help, and Behavioural Therapies borrowed variance from Cognitive Behavioural Therapy. It is currently not clear as to why this approach was chosen and we recommend the inclusion of a plausible rationale. We consider this especially crucial as treatment	Thank you for your comment. The committee drew on their clinical knowledge and experience to categorise interventions into classes. In response to your comment. a cross-reference to Supplement B1 has been added to the evidence report to highlight where the full list of intervention and class categorisations can be found. The decision about the borrowing of variance estimates was clearly stated in the protocol, which is available in PROSPERO (CRD42019151328) and also in Appendix A of Evidence review B. Details of the process are provided in the NMA report in Appendix M of Evidence review B under the 'Class models' section, which has now been slightly edited to further clarify the rationale for the adopted approach. As stated, the borrowing of variance from other classes was only needed for classes which did not have enough evidence to estimate within-class variability of effects (i.e. classes with just 1 or 2 interventions) and only for analyses where the evidence for a class did not allow estimation of within-class variability of effects. E.g. if a class included 3-4 interventions in one analysis and was thus possible to estimate its within-class variability of effect, then it did not borrow variance from another class. However, if

						costs were extrapolated from some interventions to others within a class for the economic analysis.	in another analysis (e.g. for a different population/outcome) it had inadequate evidence (1-2 interventions in the class), then it did borrow variance from another class with adequate relevant evidence. The assumptions around which classes to borrow variance from for classes with inadequate relevant evidence was made by the committee, based on their expertise on the expected variability of effects across interventions within a class (i.e. how similar or diverse effects interventions within a particular class were expected to have). It is noted that this process did not affect the mean class effect, but only the spread/uncertainty around the class effect and across the interventions within the class with inadequate evidence. It obviously did not affect in any way classes with adequate evidence regarding the estimation of the within-class variance of effects. Borrowing/sharing variance from/with another class was necessary to retain the individual treatment effects within classes formed by 1-2 interventions, and can be considered a conservative assumption, since the alternative would be to assume no variance within the class, which would mean that all interventions in the class would have the same treatment effect, which is a much stronger assumption. The fit of

							all models was tested and was found to be adequate so that there was no evidence that the data were in conflict with the assumptions underpinning the analysis. The process of borrowing variance for some classes in some of the NMAs is not related at all with processes and assumptions underpinning the economic modelling. Moreover, treatment costs were not extrapolated from any intervention to any other interventions within the class. It was conclusions on cost-effectiveness of an intervention within a class that, where appropriate (i.e. where interventions shared similar effectiveness and resource intensity), were extrapolated to other interventions within the class, as it was not feasible to model every single intervention in the class. This is stated in Appendix J of Evidence report B, under Discussion: “Specific interventions were used as exemplars within each class, so that results of interventions can be extrapolated to other interventions of similar effectiveness and resource intensity within their class."

33	SH	Institute of Psychoanalysis	Evidence review B	General	General	Network meta-analysis (NMA) It is unclear quite why the committee decided to utilise the NMA as the primary analysis, and only used the pair-wise analyses for comparison reasons.As stated on p.39, the decision was made to utilise only the NMA results was based on the finding that there were only very few differences in the comparison of findings between both. A problem with such a comparison, however is, that it can only be made for those comparisons for which direct evidence is available. In line with leading scientists, we strongly maintain that NMA should only be used when certain conditions are met. As shown, there are numerous violations of assumptions and other methodological shortcomings in this analysis plan that warrant our concerns that the resulting treatment recommendations have to be viewed with absolute caution and may not even be valid. Moreover, the health economic analyses are also impacted, given that they are based on the results derived from the NMA.Furthermore, the validity or trustworthiness of statistical evidence derived from NMA is controversial (Faltlinsen et al., 2018; Leucht et al., 2016). Given that it has no formal expert consensus, such an analytical approach can be viewed only as an experimental technique, and we believe that a national health treatment guideline should not be based on an experimental	Thank you for your comment. NMA was the main method used to synthesise evidence on pharmacological, psychological, psychosocial, physical and combined interventions, consistently with previous drafts of this guideline, in order to allow estimation of the relative effectiveness, acceptability and tolerability across all treatments for a new episode of less severe or more severe depression. Pairwise meta-analysis (MA) was employed to synthesise data on all critical outcomes of the clinical analysis in order to compare the results of the NMA with those of pairwise MA and explore any differences between them and possible reasons for any differences. Moreover, pairwise MA was used to synthesise follow-up data as well as data on functioning and quality of life. However, the decision was (right at the start rather than in the end of the process) that results of pairwise MAs on critical outcomes would not be considered as the primary source of evidence when formulating recommendations. This decision is stated under 'Summary of methods, Evidence synthesis', in Evidence review B. Nowhere on page 39 is it stated that there was a decision to utilise only the NMA results based on the finding that there were only very few differences in the comparison of findings between NMA and

						technique. Assumption of transitivity and consistency likely not met.Results drawn from indirect comparisons can only be valid when the assumptions of transitivity and consistency are met (e.g., Cipriani et al.,2013; Faltlinsen et al., 2018). Possible modifiers affecting the outcome need therefore to be controlled for between the studies. As with the previous two analyses, again, not all sensitivity analyses appeared to have been carried out in the current analyses. These were only conducted for participants in pharmacological vs. non-pharmacological treatments. Thus, whether the transitivity assumption holds, for example, for the comparison of different non-pharmacological treatments is not clear. A general limitation of NMA is that the statistical power to detect inconsistencies between direct and indirect evidence may be insufficient in comparisons including few studies with small samples, especially if heterogeneity is large (Faltinsen et al., 2018, Veroniki et al., 2014). Despite trying to circumvent the problem by including a class model, existing inconsistencies may still have not been detected as several studies included show small sample sizes, with N≤ 20 per condition (e.g., Albornoz, 2011, Bowman et al., 1995, Costa and Barnhofer, 2016, Covi and Lipman, 1987, Doyne et al., 1987, Gerber et al., 2020, Singh et al., 1997), also calling into question the effect of randomization (Hsu,	standard pairwise MA. It is only stated that, where relevant, results were overall consistent between the NMA and the pairwise meta-analysis. This finding was reassuring for the committee and increased its confidence in the NMA results. It is true that the comparison between NMA and pairwise MA results cannot be made for comparisons between treatments for which direct evidence is not available, and this is an important advantage of NMA over pairwise MA: that it allows estimation of effects between interventions that have not been directly compared in a head-to-head comparison, via indirect comparisons. This is essential in order to estimate the relative effectiveness of all pairs of treatments assessed in the review. It also allows simultaneous comparison of the effects and ranking of all treatments, without breaking randomisation and without making implicit assumptions and calculations. Another advantage of the NMA is that it increases precision by combining direct with indirect evidence. Interestingly, Faltinsen et al. (2018) report that WHO have started advocating the use of NMA to inform clinical guidelines and that the scientific production of network meta-analyses is increasing rapidly over the world. (They also

						1989).Treatment ranking If all assumptions are met, NMA is a useful technique for the purpose of ranking treatment outcome. As stressed in this guideline as well as in the NICE method guideline, it is one of the primary reasons as to why NICE recommends its usage. However, treatment ranking can be affected by small differences that are not clinically important (Faltinsen et al., 2018), which indeed seems to be the case in the current analyses.As noted in point 11, for severe depression, bias-adjusted analysis for comparison with placebo yielded a standardized mean difference (SMD) of -0.78 (rank: 17.28); for individual CBT/CT and of -0.58 (rank: 22.08); for short-term psychodynamic therapy (STPP). In other words, the difference between these three corresponds to a difference in effect sizes of -0.20. This difference is below the MID (minimally important difference) of SMD=0.50 defined by NICE as clinically important (Evidence file B, p.14). This in effect means that there is no clinically significant difference in efficacy between individual CBT/CT and STPP in the treatment of severe depression. This is true for less severe depression as well (individual CBT vs. TAU: bias-adjusted SMD=-0.73, STPP vs. TAU: bias-adjusted SMD=-0.48, e.g., below the SMD deemed clinically important by NICE). Ranking treatments for less severe depression according to clinically	report that NICE guidelines typically prefer direct evidence from RCTs and conventional meta-analyses to indirect evidence – this is not entirely true, as NICE prefer RCTs to indirect evidence, but “when multiple competing options are being appraised, a network meta-analysis should be considered” according to the NICE Guidelines Manual.) The authors recommend further methods for reporting and statistical testing of NMAs – which is fully agreed. Full reference to Leucht et al. (2016) could not be identified in your comments, but perhaps you refer to the paper “Network meta-analyses should be the highest level of evidence in treatment guidelines” (EUR ARCH PSY CLIN N 2016; 266, 477–480) where the authors conclude: “in our opinion, systematic reviews based on network meta-analyses should generally be the highest level of evidence in treatment guidelines, but we need to assess them carefully and in certain situations (such as if a meta-analysis is mainly composed of small trials)”. In the area of mental health only, there are several NMAs published on treatments for depression, anxiety, PTSD, schizophrenia etc. NICE has used NMA in the past to inform other mental health guidelines, including PTSD, bipolar disorder and schizophrenia, and in several other diverse disease areas such as epilepsy, acne, and

						insignificant differences in efficacy is (again) highly questionable. For CBT “good evidence” of efficacy was concluded by NICE, for STPP the conclusion was that there was only “some evidence” of efficacy. If this judgment is based on the number of studies available (which is not clear, indicating a lack of transparency), it is necessary to emphasize that a larger number of studies does not imply higher efficacy. Following, for example, Chambless and Hollon (1998), two RCTs are sufficient for a treatment to be classified as efficacious.In the Evidence file B, on p.61, the committee conceded that the 95% credible intervals (CrI) around the rankings of interventions were characterized by considerable uncertainty. For example, the mean ranking of group CBT, which was shown to be the most cost-effective intervention, was 2.76, however its 95% CrI were 1 to 12, suggesting high uncertainty around the result for group CBT. Similar uncertainty was shown for all interventions included in the analysis. In other words, the CrIs show that the NMA rankings are ‘uncertain’ and thus likely should be treated with significant caution.Head-to-head comparisonsIt is not clear whether the analyses included the comparisons between the different psychotherapies and as such whether these analyses found any statistically significant differences between them. From the documents provided, it seems that only effect sizes	induction of labour. There are also several NMAs published in the area of psychotherapies for Depression (e.g. Barth et al, PLOS Medicine 2013, 10(5): e1001454; Cuijpers et al, JAMA Psychiatry 2019, 76(7):700-707; Cuijpers et al, World Psychiatry 2020, 19(1):92-107; Cuijpers et al, World Psychiatry 2021, 20(2):283-293; Zhou et al, World psychiatry 2015, 14(2):207–222; López-López et al, Psychological medicine 2019, 49(12):1937–1947), many of which have compared different types of therapy such as pharmacological vs psychological interventions, online vs. face-to-face interventions, etc. There are also published NMAs of psychotherapies for anxiety disorders (Mayo-Wilson et al, Lancet Psychiatry 2014, 1(5):368–376; Chen et al, Journal of psychiatric research 2019, 118:73–83), panic disorder (Pompoli et al, The Cochrane database of systematic reviews 2016, 4(4):CD011004), and PTSD (Merz et al, JAMA Psychiatry 2019, 76(9):904–913; Mavranezouli et al, Psychological medicine 2020, 50(4): 542–555; Coventry et al, PLoS medicine 2020, 17(8):e1003262; Mavranezouli et al, J Child Psychol Psychiatry 2020, 61(1):18-29). The above suggest that NMA is recognised as an established method of evidence synthesis and not as an experimental technique.

						and their CrL´s resulting from the comparisons with placebo or TAU were calculated, which were then compared for the different treatments. No head-to-head comparisons of treatments were reported which are usually presented in the NMA tables including all comparisons. It is, however, a common statistical fallacy to assume difference between two treatments if, for example, one treatment is superior to a control condition but the other is not, without comparing them directly (Makin and Orban de Xivry, 2019). We therefore ask for an amendment of these incorrect statistical applications to allow more confidence in the conclusions being drawn from the analyses. Quality of NMA evidence It is not clear whether the quality of, and the confidence in, the results of the NMA were taken into account when discussing results and making treatment recommendations (Salanti et al., 2014). In Appendix F only results for a few specific treatments are reported (e.g., CBT couple therapy, CBT vs. waiting list).Impact of risk of bias on outcome (see page 41 evidence review B)Risk of bias seems to have only been tested for the impact of publication bias (small study bias) on outcome. The impact of other forms of bias seems to have been not addressed. This is the more important since other researchers have found that most studies of those therapies recommended as first	Consideration of cost-effectiveness is an essential element of NICE guidelines. The economic analysis assessed concurrently the relative cost-effectiveness of all effective treatments with an adequate evidence base for less and more severe depression. Economic modelling would not be possible to carry out had the guideline utilised only pairwise MA and not NMA. This is because, in order to assess the relative cost-effectiveness across all treatments, the economic model must be informed with data on the relative effects (discontinuation, response, remission in this particular model) across all treatments, and this simultaneous reference to relative effects is only possible with NMA and not with pairwise MA. Consistency between direct and indirect evidence and transitivity are met when the distribution of the effect modifiers is the same across treatment comparisons. Effect modifiers are factors that interact with intervention effects and should be distinguished from prognostic factors that predict outcomes but do not interact with intervention effects. NMA is robust to differences between studies in prognostic factors. As you have mentioned, the assumptions behind NMA cannot be met when there is heterogeneity in populations and/or

						rank treatments are highly biased (Cuijpers et al., 2016).	interventions in effect modifiers. Heterogeneity, can be a problem in both pairwise MA and NMA and should be considered prior to conducting the meta-analysis, and when interpreting the results. In the guideline NMA, a large part of heterogeneity was accounted for by splitting populations with less and more severe depression, using detailed treatment definitions [including treatment intensity and mode of delivery for psychological interventions] and categorising them using a class random effects model. Other parameters, such as sex, socio-economic factors, therapist factors, may contribute to heterogeneity, but only if they are effect modifiers. In such a large and complex dataset, these factors were inconsistently reported and thus the impact of them is difficult to explore. Of course, this would also be a problem had exclusively pairwise MA been conducted for all 142 RCTs for less severe depression and 534 RCTs for more severe depression that were included in the systematic review. Considering heterogeneity when assessing the hundreds of pairwise, independent comparisons of this dataset would make interpretation of the findings and conclusions as to which interventions are the best options highly problematic.

							A random class effects model was used for all NMAs to account for heterogeneity between treatments within class as well as between studies. In addition it was aimed to explain the heterogeneity by exploring the impact of a number of other potential effect modifiers and analytic decisions to assess their impact on model fit and heterogeneity for SMD, including: • the impact of small study bias (see bias-adjusted models) (pre-specified sensitivity analysis) • restricting analyses to non-pharmacological interventions only (pre-specified sensitivity analysis) • the impact of excluding studies that had fewer than 15 participants in any arm (post-hoc sensitivity analysis) • the impact of assuming additivity of control arms (e.g. assuming the relative effect of TAU vs TAU + CBT was equal to No treatment + CBT) (post-hoc sensitivity analysis) • the impact of excluding studies that had >5 points' contribution to the residual deviance (post-hoc sensitivity analysis) • the impact of restricting analyses to studies classified as "low risk of bias" for attrition (additional analysis performed post-consultation).

							Between-study heterogeneity in the NMA was formally assessed for each network and the results of this assessment and of potential impacts on transitivity and inconsistency were taken into account by the committee when interpreting the results of the NMA and making recommendations. It is correct that there is often low power to detect inconsistency, particularly when (as in several of the networks) there is high heterogeneity. This is essentially because heterogeneity and inconsistency are manifestations of the same problem – an imbalance of effect modifiers. Therefore, an exploration of the impact of potential effect modifiers on the results (e.g. using sensitivity analyses) and an understanding of their impact on both heterogeneity and inconsistency can help to determine whether they are indeed effect modifiers or not, and therefore whether assumptions of transitivity and consistency are likely to be reasonable. Note that whilst there may be baseline characteristics that differ between studies, the imbalance is only of concern if these are effect modifiers and is not of concern if these are only prognostic factors. Detailed results of inconsistency checks and

							comparison between mixed (NMA) and direct evidence as well as additional sensitivity analyses have been provided in Appendix M of Evidence review B, and supplements B5 and B6. The committee considered all these issues when making recommendations alongside the results of the pairwise MA, the economic modelling results and newly reviewed qualitative evidence. Recommendations take also into account individual patient needs and preferences, which might be argued to be an effect modifier the distribution of which could potentially differ across pharmacological, psychological and physical treatment trials. The committee agreed that treatment rankings in the NMA suggested uncertainty in the results. However, as explained above, the treatment rankings in the NMA was not the only criterion when assessing the evidence and making recommendations. The committee agreed that there are not very large difference in the effects sizes between individual CT/CBT and STPP, and this uncertainty in the NMA results is stated in several places in evidence review B, including the committee's discussion. It is noted that, for less severe depression, the effect on the SMD vs TAU was

							based on N=481 for individual CBT and N=49 for STPP. Also, the 95%CrI were much wider for STPP than for individual CBT. As stated in the evidence review B, the committee considered insufficient evidence on any treatment class that was derived from N<50 people across RCTs on each NMA outcome (after looking at the total size of the evidence base in the area of treatment of a new episode of depression and noticing that there were several treatment classes with larger volume of evidence), and did not consider those treatment classes for a practice recommendation, however, they made an exception for treatment classes already available on the NHS, such as STPP. For more severe depression, the effect on the SMD vs pill placebo was based on N=1044 for individual CBT and N=267 for STPP. There was evidence for effect vs pill placebo for individual CBT (as the 95%CrI did not cross the zero line) but not for the STPP class (however, effects for interventions within the STPP class did marginally show effect vs pill placebo). The recommendations and the ranking of treatments for a new episode of depression were also affected by the results of the guideline economic modelling, which was informed by additional outcomes, such as discontinuation, response in completers and remission in completers. The

							guideline economic analysis results, which were also characterised by uncertainty, suggested that individual CBT was more cost-effective than GP care but STPP was less cost-effective than GP care in both less and more severe depression. As repeated above, overall, when making recommendations, the committee considered the results of the NMA regarding the mean effects of each treatment class vs the reference treatment, the uncertainty around them (as expressed in 95%CrI), the volume of the evidence base for each treatment, and the evidence of effect or the lack of it (as shown by 95%CrI crossing or not the no effect line) of the classes but also of individual interventions within each class. They also considered the results of the pairwise meta-analysis of follow-up data and of quality of life and functioning data. The committee also considered the relative cost-effectiveness of interventions, as suggested by the guideline economic analysis. Other factors such as implementation issues (step 2 and current structure of IAPT services), treatment acceptability (expressed in discontinuation rates, which were incorporated into the economic analysis), side effects (drugs), and applicability of the evidence in the UK context (relating to problem solving, as well as acupuncture and

							antidepressant combination) were also taken into consideration. All this information on the evidence and committee's considerations are provided in Evidence review B. Judgements on 'good' evidence or 'some evidence' were made on the basis of 1) the magnitude of the effect and 2) the available evidence base regarding the number of people tested on each treatment, rather than the number of trials testing each treatment. The committee felt more confident to recommend treatments that had been tested on several hundreds of people and found to be effective (such as individual CT/CBT) rather than interventions tested on few people and found to be effective. For this reason, the committee decided not to consider interventions that had been tested on N<50 people, even though some of them (e.g. combined CT/CBT group + exercise group in less severe depression; mindfulness or meditation group in more severe depression) had shown very high effects in the NMA. In less severe depression, group CBT showed wide 95%CrI around its mean ranking in the economic analysis, however it is noted that these were very skewed and that in most iterations group CBT ranked in a high place

							among other treatments (since its mean ranking was 2.76 in an analysis involving 16 interventions). It is noted that group CBT was found to be dominant in its comparison with group BA (which ranked 2nd most cost-effective), i.e. it was less costly and more effective, and, in their in-between comparison, group CBT had a 85% probability of being more cost-effective than group BA (data not shown in the report). Similarly, it was shown to have an ICER of £1,466/QALY versus group exercise (3rd most cost-effective option), which is well below the NICE lower cost-effectiveness threshold of £20,000/QALY, and a probability of being cost-effective of 81% in their in-between comparison. Therefore, the uncertainty expressed in the rankings reflects uncertainty in the overall results across the 16 interventions included in the analysis, but not necessarily uncertainty in the relative cost-effectiveness of each intervention and comparison within the analysis. Comparisons were made between all treatment classes and all interventions, on every outcome examined in the NMA. However, it was not feasible to include all these results and/or comment on the differences in effect between all pairs of treatments examined in the main evidence report (this was also one of the reasons

							why NMA was employed, in order to synthesise available evidence and summarise results by ranking treatments and providing effects of each treatment versus a common reference treatment). Nevertheless, full results on the relative effects between all pairs of classes and interventions from the NMA are provided in Supplements B5 and B6, for less and more severe depression, respectively. Results from pairwise MA that have included all available head-to-head trial comparisons are reported in Supplements B2 and B3. The quality of the evidence underpinning the NMA was assessed by examining the factors considered in a GRADE profile (risk of bias, publication bias, inconsistency, indirectness and imprecision). The Cochrane risk of bias tool for RCTs was used to assess potential bias in each study included in the review. Risk of bias ratings for each RCT included in the NMA are provided in Supplement B1. The model goodness of fit and inconsistency were assessed for each NMA. Bias-adjusted models were run to explore and adjust for potential bias associated with small study size. Transitivity between populations participating in pharmacological and non-pharmacological studies was assessed in a sensitivity analysis which excluded

							pharmacological trials, as well as several other post-hoc sensitivity analyses that were run (see above). Finally, indirectness was considered by qualitatively assessing potential differences across the populations, interventions and outcomes of interest, and those included in the relevant studies that informed the NMA. Details of quality assessment, which were considered by the committee when interpreting the results of the NMAs, are provided under 'Quality assessment of studies included in the evidence review' separately for less and more severe depression, in Evidence review B. These factors were considered by the committee when making recommendations. A threshold analysis was also planned, as an alternative to GRADE for assessing confidence in guideline recommendations based on the NMA (Phillippo et al., Ann Intern Med 2019, 170(8):538-546). However, it was noted that, in addition to the results of the NMA, the committee took other pragmatic factors into consideration when making recommendations, including the uncertainty and limitations around the clinical and cost-effectiveness data, and the need to provide a wide range of interventions to take into account individual needs and allow patient choice. For this reason, it was difficult to identify a clear decision rule to link the

							recommendations directly to the NMA results. Therefore, conducting a threshold analysis would not add value to decision making. This is reported under 'Quality assessment of studies included of studies included in the evidence review and the evidence' and also 'The committee's discussion of the evidence -> Interpreting the evidence -> The quality of the evidence'. In principle adjusting for risk of bias in individual trials would be something that could be explored as a potential effect modifier. However, for these analyses to work, a good spread of "good" and "bad" studies across the network is needed, which is not the case, as it can be seen in the risk of bias assessments. To make this clear, a table of the number of studies with different risk of bias domains in both more and less severe depression for SMD has now been added in Appendix M of evidence review B. The committee were also presented with the risk of bias assessments for all the studies, and took account of this when making their recommendations. The subgroup of studies rated as low risk of bias for attrition was investigated as a sensitivity analysis but found no evidence that this was an

							effect modifier. Although there are sufficient studies to analyse a low risk of bias subgroup for Blinding (participants), Blinding (care administrator) and Performance, these studies are almost exclusively pharmacological studies, and the analysis is equivalent to performing a subgroup analysis of pharmacological studies only. Given that a pre-specified sensitivity analysis of non-pharmacological studies only was conducted and found that results were not sensitive to this, it would be unlikely to detect any differences that might arise from a subgroup of pharmacological only (equivalent to low risk of bias for Blinding or Performance). Adjusting for small study effects captures a range of potential biases that are associated with smaller studies, including, but not restricted to, publication bias. Sensitivity analyses to risk of bias domains where it was possible / informative to do so have now been included (see above). However, in the absence of sufficient information to explore other risk of bias domains, the best proxy available was to explore the effect of study size which is often associated with risk of bias indicators. Boxplots of the risk of bias domains by the number of participants randomised per study arm have now been included in Appendix M of Evidence review B,

							which shows smaller studies to be at higher risk of bias across almost all domains in both more and less severe depression. The analysis of small study effects has the benefit that all studies can be included in the analyses simultaneously, thus increasing power to detect any effect. Cuijpers et al. (2016) assessed the quality of individual trials of psychotherapies for adults with depression and found that individual trials did not have enough power to identify small differences in effect. The authors concluded that 'Meta-analyses may be able to solve the problem of the low power of individual trials. However, many of these studies have considerable risk of bias, and if we only focused on trials with low risk of bias, there would no longer be enough studies to detect clinically relevant effects.' This is a limitation of the evidence base and not of the NMA per se and confirms the findings of the guideline risk assessment, according to which, most studies included in the review were at high risk of bias. This would also be a problem had a pairwise meta-analysis been conducted.

34	Individual	Individual 4	Evidence review B	063 - 079148 - 203	General	In neither the references for less severe depression or severe depression do you cite or consider the Scott and Stradling (1990) Behavioural Psychotherapy, 18, 1-19 study comparing individual and group CBT in Toxteth, Liverpool. Had you done so you may have realised that delivering group CBT in routine practice is problematic and there should not be a binary individual and group CBT as you indicate. This would have been to properly take account of the S, settings in PICOTS. Other important studies are not included on group cognitive behavioural activation [Kellet et al (2019)].	Thank you for your comment. Scott and Stradling (1990) was identified by the searches and considered for inclusion. However, it did not meet study design eligibility criteria (pre-specified in the review protocol) as the assignment of participants to conditions was not random but was made by the therapist in advance of patient contact using a predetermined sequential allocation modified by the flow of referrals and therapist time constraints. The study is listed under excluded studies in Supplement B1 . Unfortunately the Kellet et al (2019) reference that you cite could not be identified, and so it is not possible to respond as to why it may not have been identified and included. Based on the clinical and cost-effectiveness data, the committee decided to recommend group CBT or group behavioural activation (BA) as treatments of choice for a new episode of less severe depression in adults, as they had shown a beneficial effect compared to treatment as usual, and appeared to be the most cost-effective classes in the egconomic analysis. However, the committee noted that both these treatments were group therapies, and group treatments might not always be suitable. The

							committee noted that there was evidence of clinical and cost-effectiveness for guided self-help, individual CBT and individual BA, and these interventions could be offered as alternatives to group therapy. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The self-help with support section has been relabelled as guided self-help, placed earlier in the treatment pathway, and the description of guided self-help has been amended to recommend that printed or digital materials that follow the principles of guided self-help are used including structured CBT, structured BA, problem solving or psychoeducation materials, delivered face-to-face or by telephone or online. The full review protocol in Appendix A, provides detail on all PICOTS dimensions including study setting (primary, secondary, tertiary and social care settings) and timepoints (endpoint and follow-up [data for all available follow-up

							periods of at least 1-month post-intervention was extracted]).

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

35	SH	EMDRIA	Evidence review B	206 - 215	General	In all the guideline review protocols (eg. Review B, Appendix A, p206), EMDR for depression is included as an intervention of interest for treatment of adults. However, in Appendix B - literature search strategies – the search term "EMDR" does not appear anywhere (searches updated 4/6/2020). We would have expected it to appear after search line 14 and before search line 16 (p215) for the Embase etc searches, and between #22 and #23 in the Cochrane library search (p218). This omission is replicated in the other search strategies. Hence it is unclear if, or how, EMDR trial data has been extracted for the NMA and evidence reviews – have the relevant papers been identified from searches or extracted from systematic reviews? We wondered whether relevant EMDR papers might therefore been accidentally omitted from the NICE reviews, and ask the committee to clarify this omission and re-run the review searches.	Thank you for your comment and for drawing our attention to this omission. In response to your comment a specific supplementary search has been run for EMDR. However, no eligible studies were identified, apart from the Ostacoli 2018 study that was already included in the further-line treatment review. The excluded studies lists of Supplement B and Supplement D have now been updated with the additional studies which were identified, and the reason for exclusion.
36	Individual	Individual 10	Evidence review B	8	4	Couple-based interventions were not included in the network meta-analysis due to the incorrect assumption that they are only relevant to people who are experiencing relationship distress. A recent meta-analysis found that they were equally effective in the treatment of depression for people in distressed and non-distressed relationships (Barbato, A. & D'Avanzo, B. (2020). The findings of a Cochrane Meta-Analysis of couple therapy in	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in

						adult depression: Implications for research and clinical practice. Family Process, 59 (2), 1-15).	pairwise comparisons (and not included in the NMA).
37	Individual	Individual 10	Evidence review B	8	4	Couple-based interventions were not included in the network meta-analysis due to the incorrect assumption that they are only relevant to people who are experiencing relationship distress. A recent meta-analysis found that they were equally effective in the treatment of depression for people in distressed and non-distressed relationships (Barbato, A. & D'Avanzo, B. (2020). The findings of a Cochrane Meta-Analysis of couple therapy in adult depression: Implications for research and clinical practice. Family Process, 59 (2), 1-15).	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA).
38	SH	British Psychological Society	Evidence Review B	8	4	Couple interventions, including behavioural couple's therapy, were considered only in pairwise comparisons (and not included in the network meta-analysis) due to the incorrect assumption that they were considered more appropriate for subgroups of adults with depression, namely for people with problems in their relationship with their partner. We request that the studies excluded on this basis are included in the analysis.	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA).

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

39	SH	Tavistock Relationships	Evidence Review B	8	4	Couple interventions, including behavioural couple's therapy, were considered only inpairwise comparisons (and not included in the network meta-analysis) due to the incorrect assumption (see earlier comment 8) that they were considered more appropriate for subgroups of adults with depression, namely for people with problems in their relationship with their partner. We request that the studies excluded on this basis are included and that couples therapy.	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA).

40	Individual	Individual 4	Evidence review B	8	11	The evidence review is based around PICO and not around PICOTS used by the American Psychological Association to assess reviews, see Tolin et al (2015) Empirically Supported treatment: Recommendations for a New Model Clinical Psychology Science and Practice. The T refers to timeline, including posttreatment and at least 3 months follow up, the S refers to settings. The APA recommends that at least one study has to be conducted in a real world setting with routine as opposed to highly-trained practitioners. In this context it is remiss not to consider in the Guidance the effectiveness studies Ross, M., & Scott, M. (1985). An evaluation of the effectiveness of individual and group cognitive therapy in the treatment of depressed patients in an inner city health centre. The Journal of the Royal College of General Practitioners, 35(274), 239–242 and Scott and Stradling (1990)https://doi.org/10.1017/S014134730001795X] comparing individual CBT, group CBT and treatment as usual conducted in an area of high deprivation (Toxteth, Liverpool). This failure to look at Settings is apparent also in the neglect of the pandemic, the Guidelines recommend group interventions to be canvassed first despite their impracticality over most of the last 2 years and the forseeable future. A consideration of Settings would also have highlighted that the	Thank you for your comment. Based on the clinical and cost-effectiveness data, the committee decided to recommend group CBT or group behavioural activation (BA) as treatments of choice for a new episode of less severe depression in adults, as they had shown a beneficial effect compared to treatment as usual, and appeared to be the most cost-effective classes in the economic analysis. However, the committee noted that both these treatments were group therapies, and group treatments might not always be suitable. The committee noted that there was evidence of clinical and cost-effectiveness for guided self-help, individual CBT and individual BA, and these interventions could be offered as alternatives to group therapy. The guideline also includes a recommendation that commissioners and providers of mental health services should ensure that pathways have a range of different methods in place to deliver treatments in addition to face-to-face meetings, including online delivery. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the

						recommendations cannot flourish in the soil of IAPT's modus operandi. This, the largest service provider does not make diagnosis, as such its's clinicians are not aware of comorbidity or of what the treatment implications might be. The Guidance fails to acknowledge that depression is most commonly found in a setting of comorbidity. It is essential that recommendations from NICE have a real world feel. Had you used PICOTS your findings would be based on a small number of high-quality studies that nevertheless take account of routine practice.Studies in which psychometric tests have been the sole gateway are accorded the same status as those that have used 'gold standard' diagnostic interviews and blind assessors. The 2 are of very different methodological quality. Conclusions should not rest on studies that have used solely psychometric tests which are subject to demand characteristics, pleasing the therapist, not wanting to feel time wasted etc	principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The self-help with support section has been relabelled as guided self-help, placed earlier in the treatment pathway, and the description of guided self-help has been amended to recommend that printed or digital materials that follow the principles of guided self-help are used including structured CBT, structured BA, problem solving or psychoeducation materials, delivered face-to-face or by telephone or online. The full review protocol in Appendix A, provides detail on all PICOTS dimensions including study setting (primary, secondary, tertiary and social care settings) and timepoints (endpoint and follow-up [data for all available follow-up periods of at least 1-month post-intervention was extracted]). As specified in the scope, the recognition, assessment and initial management section from the 2009 guideline was not included in this update. In line with NICE processes, the 2009 content has been carried across to this updated guideline. However, the evidence on recognition, assessment and initial management has not been reviewed, and recommendations could not

							be made about comorbidities in the context of diagnosis. As pre-specified in the review protocols, the population included adults with clinically important symptoms of depression (as defined by a diagnosis of depression according to DSM, ICD or similar criteria, or depressive symptoms as indicated by baseline depression scores on validated scales). Studies using depression symptom scales were included (in addition to studies that limited inclusion to those with a diagnosis of depression) on the basis that such scales are widely used in RCT research and clinical practice and are validated in the diagnosis of depression and the assessment of depression symptom severity. The committee were concerned that excluding studies that did not use diagnostic interviews would result in the exclusion of a large number of studies, would have a disproportionate impact on the evidence base for some interventions for example for self-help studies, and would not allow examination of those with subthreshold symptoms of depression which were included in the review question and protocol.

41	SH	Oxford Health NHS Foundation Trust	Evidence review B	8	Table 1	cCBT is not listed as a separate intervention, but research evidence included is nearly all specific to cCBT. How is this evidence being considered?	Thank you for your comment. Different self-help approaches (with or without support) were searched for and were eligible for inclusion. In addition to computerised approaches, there are also RCTs of cognitive bibliotherapy, behavioural bibliotherapy, expressive writing, mindfulness meditation CD, relaxation training CD, and third-wave cognitive therapy CD, included in the network meta-analyses (NMAs) for treatment of a new episode of depression. One intervention per class was used as an exemplar in the economic analysis, as it was not feasible to model all interventions included in the NMA. Computerised CBT (cCBT)was selected as the exemplar from the class of self-help with support as it had a large evidence base and a high effect compared with other interventions in the same class. Thus, the clinical evidence and resource use data used to inform the economic analysis were specific to cCBT; consequently, the results of the economic analysis were specific to cCBT (but could also be extrapolated to any other intervention with similar acceptability, effectiveness and resource use). However, the treatment class effect size for self-help (with or without support) that was estimated from the NMA and reported in the clinical evidence sections of Evidence review B, was informed by

							evidence from all interventions included in the treatment class. In addition, individual intervention effects have been reported in the evidence review B for all interventions within each class for the SMD outcome (for both less and more severe depression). In response to stakeholder comments, the self-help with support section has been relabelled as guided self-help, moved to the beginning of Table 1, and the description of guided self-help has been amended to clarify that this is not restricted to cCBT.

42	SH	Psychological Professions Network	Evidence review B	8	Table 1	Computerised CBT is not listed as a separate intervention being considered, but research included is nearly all specific to cCBT, How is this evidence being considered?	Thank you for your comment. Different self-help approaches (with or without support) were searched for and were eligible for inclusion. In addition to computerised approaches, there are also RCTs of cognitive bibliotherapy, behavioural bibliotherapy, expressive writing, mindfulness meditation CD, relaxation training CD, and third-wave cognitive therapy CD, included in the network meta-analyses (NMAs) for treatment of a new episode of depression. One intervention per class was used as an exemplar in the economic analysis, as it was not feasible to model all interventions included in the NMA. Computerised CBT (cCBT) was selected as the exemplar from the class of self-help with support as it had a large evidence base and a high effect compared with other interventions in the same class. Thus, the clinical evidence and resource use data used to inform the economic analysis were specific to cCBT; consequently, the results of the economic analysis were specific to cCBT (but could also be extrapolated to any other intervention with similar acceptability, effectiveness and resource use). However, the treatment class effect size for self-help (with or without support) that was estimated from the NMA and reported in the clinical evidence sections of evidence review B, was informed by

							evidence from all interventions included in the treatment class. In addition, individual intervention effects have been reported in the evidence review B for all interventions within each class for the SMD outcome (for both less and more severe depression). In response to stakeholder comments, the self-help with support section has been relabelled as guided self-help, and the description of guided self-help has been amended to clarify that this is not restricted to cCBT.
43	SH	British Psychological Society	Evidence Review B	9	11	Table 1: Summary of the protocol (PICO table) contains what appear to be an error. Behavioural couple therapy, instead of being listed as a psychological intervention, was listed as a psychosocial intervention.	Thank you for your comment. This was a copy and paste error in creating the summary of the protocol from the full protocol in Appendix A. It has now been amended.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

44	SH	Tavistock Relationships	Evidence Review B	9	11	Table 1: Summary of the protocol (PICO table) contains what appear to be an error. Behavioural couple therapy instead of being listed as a psychological intervention was listed as a psychosocial intervention.	Thank you for your comment. This was a copy and paste error in creating the summary of the protocol from the full protocol in Appendix A. It has now been amended.

45	Individual	Individual 4	Evidence review B	9	General	It should be pointed out that not all comparisons are equal, emphasis should be given to those involving credible placebos. The measures of outcome need differentiation e.g. loss of diagnostic status as assessed by diagnostic interview should have a much greater weighting than psychometric test result. This will yield a more smaller pool of studies but this should lead to greater humility about recommendations.	Thank you for your comment. The committee agree that not all comparators are equally desirable. However, all relevant comparators were included, as restricting the review to only studies with a placebo would considerably limit and potentially bias the evidence base. Different comparators were categorised separately in the network, and the committee considered comparators when assessing risk of bias and quality of the evidence using GRADE, and when interpreting the evidence and making recommendations. As pre-specified in the review protocol, critical outcomes included depression symptomatology, remission (that could include loss of diagnosis but was more commonly defined as scoring below a cut off on a depression scale) and response (usually defined as at least 50% improvement from the baseline score on a depression scale). Studies reporting depression symptomatology outcomes were included on the basis that such scales are widely used in RCT research and clinical practice and are validated in the diagnosis of depression and the assessment of depression symptom severity. The committee were concerned that excluding studies that did not use diagnostic interview outcomes would result in the exclusion of a large number of

							studies, would have a disproportionate impact on the evidence base for some interventions for example for self-help studies, and would not allow examination of those with subthreshold symptoms of depression which were included in the review question and protocol.
46	Individual	Individual 10	Evidence review B	9	General	Couple therapy should be in the 'psychological intervention' category instead of the 'psychosocial intervention' one..	Thank you for your comment. This was a copy and paste error in creating the summary of the

							protocol from the full protocol in Appendix A. It has now been amended.
47	Individual	Individual 10	Evidence review B	9	General	Couple therapy should be in the 'psychological intervention' category instead of the 'psychosocial intervention' one..	Thank you for your comment. This was a copy and paste error in creating the summary of the protocol from the full protocol in Appendix A. It has now been amended.

48	SH	Psychotherapy & Counselling Union	Evidence review B	10	15	Two-level categorisation of depression The categories of depression in the draft guideline are significantly out-of-step with generally accepted classifications. On the one hand the guideline condenses the generally-accepted four categories of severity into just two ("less severe" and "more severe", Evidence review B, p. 10), partly in order to simplify the application of Network Meta-Analysis (NMA). On the other hand it distinguishes "depression in people with a diagnosis of personality disorder" (previously labelled "complex depression") and "psychotic depression", from "chronic depression" (Guideline, pp. 45-49), contrary to guidance from the European Psychiatric Association (Jobst et al., 2016, pp. 19-20, https://research.vu.nl/ws/portalfiles/portal/26038326/2016_Jobst_Eur_Psychiatry_chronic_depression.pdf).	Thank you for your comment. The committee considered the current NICE classifications of mild to moderate and moderate to severe depression, and agreed that although these classifications have been adopted quite widely there is potential uncertainty with regards to the management of moderate depression. The committee agreed that a dichotomy of less and more severe depression was clearer, and the guideline includes definitions (that less severe depression includes the traditional categories of subthreshold symptoms and mild depression, and more severe depression includes the traditional categories of moderate and severe depression) in order to improve practical utility. The committee considered the distinction between less severe (subthreshold/mild) and more severe (moderate/severe) depression to be clinically meaningful in terms of supporting effective clinical decision making and being aligned with how clinicians conceptualize depression (in particular, GPs and other primary care staff, given that the majority of people with depression and almost all first line presentations of depression are managed in primary care). For the further-line treatment review, studies were sought that included adults with depression showing an inadequate response to

							at least one previous intervention for the current episode and this included the further-line treatment of psychotic depression, depression with coexisting personality disorder and chronic depression. First-line treatment or relapse prevention of chronic depression (including dysthymia), and first-line treatment or relapse prevention of depression with coexisting personality disorder were separate reviews, as the committee did not feel that it was appropriate to combine these populations for first-line treatment or relapse prevention. The committee reviewed the European Psychiatric Association classification but considered that the grouping together of psychotic depression, depression with coexisting personality disorder and chronic depression for the further-line treatment review should allow the effectiveness of interventions for a more clinically complex population to be considered.

49	SH	Institute of Psychoanalysis	Evidence review B	10	15	The distinction between less severe and more severe depression The categorisation system of first episode depression into 'less severe' and 'more severe' is very concerning as there is no evidence of either the methodological/statistical or clinical validity of such a dichotomisation of individuals suffering from depression. We agree with the guideline authors that many years of clinical practice and research have yielded that depression is not a unitary phenomenon. And while, as one of the authors you cite put it: "no standardized nomenclature for different depression severity levels is agreed on" most researchers and clinicians have a common understanding that depression severity levels fall into the three broad categories of mild, moderate and severe (Wahl et al., 2014, p. 82). Indeed, the guideline itself refers to these as "traditional subcategories" (e.g., p.10, l.26). So why would the guideline divert from a tradition that has found both some clinical resonance as well as psychometric validity and reliability? We stress again, that any treatment recommendations based on methodological choices that have not been validated need to be viewed with caution.	Thank you for your comment. The committee considered the current NICE classifications of mild to moderate and moderate to severe depression, and agreed that although these classifications have been adopted quite widely there is potential uncertainty with regards to the management of moderate depression. The committee agreed that a dichotomy of less and more severe depression was clearer, and the guideline includes definitions (that less severe depression includes the traditional categories of subthreshold symptoms and mild depression, and more severe depression includes the traditional categories of moderate and severe depression) in order to improve practical utility. The committee considered the distinction between less severe (subthreshold/mild) and more severe (moderate/severe) depression to be clinically meaningful in terms of supporting effective clinical decision making and being aligned with how clinicians conceptualize depression (in particular, GPs and other primary care staff, given that the majority of people with depression and almost all first line presentations of depression are managed in primary care). Based on this distinction, an anchor point of 16 on the PHQ-9 was selected as the cut-off between less severe and more severe

							depression, on the basis of alignment with the clinical judgement of the committee and eligibility criteria in the included studies. Published standardization of depression measurement crosswalk tables (Carmody 2006; Rush 2003; Uher 2008; Wahl 2014) were used in order to 'read-across' different symptom severity scales that were used in different studies.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

50	Individual	Individual 4	Evidence review B	10	20	Using a PHQ9 score of 16 to distinguish severe from less severe depression, is inadequate, it is based on consensus not, evidence. The PHQ9 was validated in a US outpatient setting against the Prime MD, but the questions on the latter are identical to those on the former thus it falls foul of the STARD requirements. The PRIME MD is not a 'gold standard' diagnostic interview. There are therefore major external validity issues with the PHQ9, the fact that its usage is commonplace, does not increase its validity.	Thank you for your comment. An anchor point of 16 on the PHQ-9 was selected as the cut-off between less severe and more severe depression, on the basis of alignment with the clinical judgement of the committee and eligibility criteria in the included studies. Published standardization of depression measurement crosswalk tables (Carmody 2006; Rush 2003; Uher 2008; Wahl 2014) were used in order to 'read-across' different symptom severity scales that were used in different studies, and thresholds to distinguish between less severe and more severe depression were outlined for all eligible scales (including but not limited to the PHQ-9) in the review protocols.

51	SH	Psychotherapy & Counselling Union	Evidence review B	10	29	Use of Network Meta-Analysis (NMA)One major change in the draft guideline (as compared to the currently approved 2009 document) is the use of Network Meta-Analysis (see Dias, Welton, Sutton, & Ades, 2016, http://nicedsu.org.uk/wp-content/uploads/2016/03/A-general-linear-modelling-framework-for-pair-wise-and-network-meta-analysis-of-randomised-controlled-trials..pdf), combined with economic modelling, to generate an ordered list of interventions ranked by clinical and cost-effectiveness (Guideline, pp. 23-30, 31-37).NMA is a new and sophisticated method of analysis drawn from the field of operational research, and it can undoubtedly yield valuable insights. However, it is very sensitive to inconsistencies between different studies, particularly variations in uncontrolled factors (effect modifiers), which can result in a form of Simpson's paradox and a failure of transitivity (see Baker and Kramer, 2002, https://link.springer.com/content/pdf/10.1186/1471-2288-2-13.pdf, and Cipriani, Higgins, Geddes, & Salanti, 2013, https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.689.7412&rep=rep1&type=pdf), meaning that NMA will generate invalid results. Unfortunately in psychotherapy outcome research it is increasingly recognised that there can be many different factors (effect modifiers), and it is very	Thank you for your comment. In this guideline update, NMA was the main method used to synthesise evidence on pharmacological, psychological, physical and combined interventions in order to allow simultaneous estimation of the relative effectiveness, acceptability and tolerability across all treatments for a new episode of less severe or more severe depression. This is in line with the NICE Guidelines Manual, according to which "when multiple competing options are being appraised, a network meta-analysis should be considered". An important advantage of NMA over pairwise meta-analysis is that it allows estimation of effect between treatments that have not been directly compared in a head-to-head comparison, via indirect comparisons. This is essential in order to estimate the relative effectiveness of all pairs of treatments assessed in the review. It also allows simultaneous comparison of the effects and ranking of all treatments. This approach was also necessary in order to inform the economic model so as to concurrently assess the relative cost-effectiveness across the whole range of effective treatments for a new episode of depression. It is noted that assessment of cost-effectiveness is an essential element of NICE guidelines. Since the 2009 guideline on Depression was published,

						difficult to control for them. This is the basic rationale for component studies and the on-going common factors debate (see Wampold, 2015, https://onlinelibrary.wiley.com/doi/pdf/10.1002/wps.20238, and Cuijpers, Reinjnders, & Huibers, 2019, https://research.vu.nl/ws/portalfiles/portal/105340005/annurev_clinpsy_050718_095424_The_Role_of_Common_Factors_in_Psychotherapy_Outcomes.pdf). And whether or not one agrees with the common factors model, the implication for NMA is that there is a very high risk that extraneous uncontrolled factors will lead to invalid results (which will be practically impossible to detect).In short, given the current state of knowledge, psychotherapy outcome research is probably one of the least suitable fields for the application of NMA. The use of NMA could be justified in the context of small-scale pilot research, but for a mainstream guideline which will be used regularly by thousands of practitioners, the use of such an unproven technology seems highly inappropriate and completely unjustified.	NMA techniques have considerably developed and have been used to support several NICE guidelines in the area of mental health (e.g. bipolar disorder, PTSD, generalised anxiety disorder, psychosis, social anxiety) and other diverse disease areas (e.g. acne, induction of labour, epilepsy). NMA is a well proven and established technology used to inform WHO (World Health Organization) guidelines (see https://apps.who.int/iris/handle/10665/271991) as well as Cochrane Reviews (see https://methods.cochrane.org/cmi/network-meta-analysis). There are also several NMAs published in the area of psychotherapies for Depression (e.g. Barth et al, PLOS Medicine 2013, 10(5): e1001454; Cuijpers et al, JAMA Psychiatry 2019, 76(7):700-707; Cuijpers et al, World Psychiatry 2020, 19(1):92-107; Cuijpers et al, World Psychiatry 2021, 20(2):283-293; Zhou et al, World psychiatry 2015, 14(2):207–222; López-López et al, Psychological medicine 2019, 49(12):1937–1947), many of which have compared different types of therapy such as pharmacological vs psychological interventions, online vs. face-to-face interventions, etc. There are also published NMAs of psychotherapies for anxiety disorders (Mayo-Wilson et al, Lancet Psychiatry 2014, 1(5):368–376; Chen et al, Journal of psychiatric research 2019, 118:73–83),

							panic disorder (Pompoli et al, The Cochrane database of systematic reviews 2016, 4(4):CD011004), and PTSD (Merz et al, JAMA Psychiatry 2019, 76(9):904–913; Mavranezouli et al, Psychological medicine 2020, 50(4): 542–555; Coventry et al, PLoS medicine 2020, 17(8):e1003262; Mavranezouli et al, J Child Psychol Psychiatry 2020, 61(1):18-29). Regarding heterogeneity that can be caused when the distribution of effect modifiers is not the same across treatment comparisons, it is correct that, for a valid analysis, due consideration must be given to the evaluation of effect modifiers across all comparisons. This is relevant to both pairwise meta-analysis and NMA and should be considered prior to conducting the meta-analysis, and when interpreting the results. In the guideline NMA a large part of heterogeneity was controlled by splitting populations with less and more severe depression, using detailed treatment definitions [including treatment intensity and mode of delivery for psychological interventions] and categorising them using a class random effects model. Heterogeneity was assessed by examining for model fit and checking for inconsistency between direct and indirect evidence. Other parameters, such as sex and

							socio-economic factors, may also contribute to heterogeneity, in particular in such a large and complex dataset, but this would also be a problem had exclusively pairwise meta-analysis of the 142 RCTs for less severe depression and 534 RCTs for more severe depression included in the systematic review been conducted. Similarly, where factors related to the intervention, such as intervention components and therapist factors, were inconsistently reported or had not been measured in primary studies, these were not possible to assess for their impact in the NMA, but this is true had we conducted exclusively pairwise meta-analysis. Considering heterogeneity and likely distribution of potential effect modifiers when assessing the hundreds of pairwise, independent comparisons of this dataset would make interpretation of the findings and conclusions as to which interventions are the best options highly problematic. Between-study heterogeneity in the NMA was formally assessed for each network; results of this assessment were taken into account when interpreting the results of the NMA and making recommendations. Moreover, for the SMD outcome, a non-pharmacological subgroup of the overall dataset was analysed separately as a sensitivity analysis, to explore whether transitivity issues between

							pharmacological and non-pharmacological trials might have impacted on the results of the NMA. In addition, also for the SMD outcome, an analysis including only studies at low risk of bias for the attrition domain in the RoB tool has now been conducted. Detailed results of inconsistency checks and comparison between NMA and direct evidence as well as additional sensitivity and sub-group analyses have been provided in Appendix M of Evidence review B, and supplements B5 and B6. The committee considered all these issues and additional analyses when making recommendations alongside the results of the pairwise MA, the economic modelling results and newly reviewed qualitative evidence. Recommendations take also into account individual patient needs and preferences, which might be argued to be an effect modifier the distribution of which could potentially differ across pharmacological, psychological and physical treatment trials.

52	SH	British Psychological Society	Evidence Review B	13	39	Here again it is wrongly stated that couple interventions are only appropriate for sub-groups of people with depression, specifically those with problems in the relationship with their partner, leading to the inappropriate exclusion of some studies.	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA).
53	SH	Tavistock Relationships	Evidence Review B	13	39	Here again it is wrongly stated that couple interventions are only appropriate for sub-groups of people with depression specifically those with problems in the relationship with their partner leading to the inappropriate exclusion of some studies and the couple evidence not being included in the NMA.	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA).
54	SH	British Psychological Society	Evidence Review B	14	23	Here again it is wrongly stated that couple interventions are only appropriate for sub-groups of people with depression, specifically those with problems in the relationship with their partner, leading to the inappropriate exclusion of some studies.	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in

							pairwise comparisons (and not included in the NMA).
55	SH	Tavistock Relationships	Evidence Review B	14	23	As comment above	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA).
56	Individual	Individual 6	Evidence Review B	17	26	Figure 1- Network plot- This statistical presentation of information is confusing and the purpose unclear. This comment would apply to all subsequent Network plots. This has implications for clinicians and patients if they choose to read this document.	Thank you for your comment. Network plots are an essential element of presenting NMA-related information. Text has now been added under 'Evidence from the network meta-analysis' to explain what network plots represent. In addition, explanatory text has been added under each network plot in this report, to help readers interpret the information depicted in the plots.

57	SH	Greater Manchester Mental Health Services	Evidence Review B	17	26	Figure 1- Network plot- This statistical presentation of information is confusing and the purpose unclear. This comment would apply to all subsequent Network plots. This has implications for clinicians and patients if they choose to read this document.	Thank you for your comment. Network plots are an essential element of presenting NMA-related information. Text has now been added under 'Evidence from the network meta-analysis' to explain what network plots represent. In addition, explanatory text has been added under each network plot in this report, to help readers interpret the information depicted in the plots.

58	Individual	Individual 9	Evidence review B	18	Table 2	Why has the evidence used to examine guided self-help been taken from predominantly CCBT studies, whose demographics either aren't stated or are not reflective of the population. The studies that do state ethnicity and age have not provided a sample that reflects the demographic of the population, and they fail to consider or identify whether recovery is impacted depending on either of these factors. These studies on CCBT use redundant CCBT packages no longer used in IAPT services like Beating the Blues.	Thank you for your comment. Different self-help approaches (with or without support) were searched for and were eligible for inclusion. In addition to computerised approaches, there are also RCTs of cognitive bibliotherapy, behavioural bibliotherapy, expressive writing, mindfulness meditation CD, relaxation training CD, and third-wave cognitive therapy CD, included in the network meta-analyses (NMAs) for treatment of a new episode of depression. One intervention per class was used as an exemplar in the economic analysis, as it was not feasible to model all interventions included in the NMA. Computerised CBT (cCBT) was selected as the exemplar from the class of self-help with support as it had a large evidence base and a high effect compared with other interventions in the same class. Thus, the clinical evidence and resource use data used to inform the economic analysis were specific to cCBT; consequently, the results of the economic analysis were specific to cCBT (but could also be extrapolated to any other intervention with similar acceptability, effectiveness and resource use). However, the treatment class effect size for self-help (with or without support) that was estimated from the NMA and reported in the clinical evidence sections of evidence review B, was informed by

							evidence from all interventions included in the treatment class. In addition, individual intervention effects have been reported in the evidence review B for all interventions within each class for the SMD outcome (for both less and more severe depression). In response to stakeholder comments, the self-help with support section has been relabelled as guided self-help, and the description of guided self-help has been amended to clarify that this is not restricted to cCBT. The committee agree that participant demographics are often poorly reported, and the relationship between baseline factors (with the possible exception of severity) and outcome is not well understood. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context so that the 'reality' for people experiencing depression was taken into consideration and recommendations were made that were relevant to the populations that clinicians typically encounter. The committees' discussions on this are documented in 'The committee's discussion of the evidence' sections

59	Individual	Individual 6	Evidence Review B	36	6	Table 11- A treatment with a sample of 25 participants was ranked highest of all the treatments analysed. This raises clinical questions for services such IAPT. The review does not report on whether this result has been replicated and given the small sample size if this result is stable. This raises questions for services and clinicians as to what should be being offered to patients accessing services.	Thank you for your comment. This was indeed a treatment tested on a very small number of people. The NMA result reflected the finding of a RCT with small study size (see Figure 354 in Supporting documentation B2 for the forest plot of this RCT). This was the only study included in the systematic review and the NMA that assessed this treatment and reported relevant data that allowed estimation of SMD. The committee did not take this result into account when they made recommendations. This is because they only took into account evidence on treatments tested on at least 50 participants across RCTs included in each NMA. This was the minimum amount of evidence that a treatment class should have in order to be considered for a practice recommendation. The committee looked at the total size of the evidence base in this area (treatment of a new episode of depression) and the large volume of evidence for some treatment classes relative to others, and decided not to consider treatment classes with a small size of evidence base (tested on <50 participants) as there were several treatment classes with much larger volume of evidence. This was stated in several places in the document, but it was not highlighted under 'The committee's discussion of the evidence'. This statement has now been included in this section

							in the final report. Therefore, this finding did not affect recommendations and has no immediate implications for clinical practice. If this finding is replicated in a larger sample in future research, and there is confidence in the finding, then the treatment may be recommended in the future and may thus have an impact on services.

60	SH	Greater Manchester Mental Health Services	Evidence Review B	36	6	Table 11- A treatment with a sample of 25 participants was ranked highest of all the treatments analysed. This raises clinical questions for services such IAPT. The review does not report on whether this result has been replicated and given the small sample size if this result is stable. This raises questions for services and clinicians as to what should be being offered to patients accessing services.	Thank you for your comment. This was indeed a treatment tested on a very small number of people. The NMA result reflected the finding of a RCT with small study size (see Figure 354 in Supporting documentation B2 for the forest plot of this RCT). This was the only study included in the systematic review and the NMA that assessed this treatment and reported relevant data that allowed estimation of SMD. The committee did not take this result into account when they made recommendations. This is because they only took into account evidence on treatments tested on at least 50 participants across RCTs included in each NMA. This was the minimum amount of evidence that a treatment class should have in order to be considered for a practice recommendation. The committee looked at the total size of the evidence base in this area (treatment of a new episode of depression) and the large volume of evidence for some treatment classes relative to others, and decided not to consider treatment classes with a small size of evidence base (tested on <50 participants) as there were several treatment classes with much larger volume of evidence. This was stated in several places in the document, but it was not highlighted under 'The committee's discussion of the evidence'. This statement has now been included in this section

							in the final report. Therefore, this finding did not affect recommendations and has no immediate implications for clinical practice. If this finding is replicated in a larger sample in future research, and there is confidence in the finding, then the treatment may be recommended in the future and may thus have an impact on services.
61	Individual	Individual 10	Evidence review B	41	4	This section states that no relevant outcome studies were found evaluating couple interventions for less severe depression and problems in the partner relationship.	Thank you for your comment. No relevant (and eligible) studies were identified for couple interventions for adults with less severe depression and problems in the relationship with their partner.
62	Individual	Individual 10	Evidence review B	41	4	This section states that no relevant outcome studies were found evaluating couple interventions for less severe depression and problems in the partner relationship.	Thank you for your comment. No relevant (and eligible) studies were identified for couple interventions for adults with less severe depression and problems in the relationship with their partner.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

63	SH	British Psychological Society	Evidence Review B	41	5	Here again it is wrongly stated that couple interventions are only appropriate for sub-groups of people with depression, specifically those with problems in the relationship with their partner, leading to the inappropriate exclusion of some studies.	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA).
64	SH	Tavistock Relationships	Evidence Review B	41	5	As comment above	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA).

65	Individual	Individual 4	Evidence review B	47	25	It is noted that when applying the Cochrane risk of bias tool to studies of less severe depression that 'Generally the standard of reporting in studies was quite low'. If this is the case rather than clinicians relying on 'evidence base', leg of the 3 legged stool for evidence based practice they should rely at least as much on their own audit and clients preferences. This point should be made.	Thank you for your comment. In addition to the results of the network meta-analysis (NMA), the committee took other pragmatic factors into consideration when making recommendations, including the uncertainty and limitations around the clinical and cost-effectiveness data, and the need to provide a wide range of interventions to take into account individual needs and allow patient choice. The committee agreed that decisions on treatment should be made in discussion with the person with depression, and recommended that a shared decision should be made. The committee cross-referred to the guideline recommendations on choice of treatment which provided more detailed recommendations on how this shared decision should be made and what should be included in the discussion. It was recognised by the committee that people who have had prior episodes of depression may also have preferences for their treatment based on prior experience or insight into their own depression patterns.

66	SH	EMDRIA	Evidence review B	62	19	We supported the committee's position that, to allow choice of treatments, a wider range of treatments should be offered – as these provide alternatives to people who did not wish to have CBT or BA, or had tried them for a previous episode of depression and not found them to be effective. This meant that some treatments, including counselling, IPT, and short-term psychodynamic psychotherapy, were recommended as further-line treatments despite relatively low-quality evidence.	Thank you for your comment. In addition to the results of the network meta-analysis (NMA), the committee took other pragmatic factors into consideration when making recommendations, including the uncertainty and limitations around the clinical and cost-effectiveness data, and the need to provide a wide range of interventions to take into account individual needs and allow patient choice. The committee agreed that decisions on treatment should be made in discussion with the person with depression, and recommended that a shared decision should be made. The committee cross-referred to the guideline recommendations on choice of treatment which provided more detailed recommendations on how this shared decision should be made and what should be included in the discussion. It was recognised by the committee that people who have had prior episodes of depression may also have preferences for their treatment based on prior experience or insight into their own depression patterns.

67	SH	Institute of Psychoanalysis	Evidence review B	67	7	Differentiation between interventions – the role of qualitative evidence The committee call for 'identifying the mode of action of psychological interventions' for less severe depression as this would 'allow greater differentiation between the interventions and aid patient choice.' We welcome this call and recognise the need for greater differentiation between the interventions. Furthermore, we argue that a greater differentiation would be welcome for treatments for other, more severe forms of depression. What are described as modes of action in the draft Guideline, may be translated in psychotherapy research as 'mechanisms of action', or 'mechanisms of change' (Kazdin, 2007; 2009). We believe that qualitative evidence and evidence from case reports may be utilised to this end, in the form of a discrete evidence synthesis, such as performed for Evidence Review I. Section 6.2 of 'Developing NICE guidelines: the manual' identifies different approaches to qualitative evidence synthesis including the use of meta-ethnography and meta-synthesis which would be appropriate vehicles for incorporating qualitative evidence including case study to identify modes of action, and these approaches are already established in psychology and psychotherapy research (Timulak, 2009; Iwakabe and Gazzola, 2009; Levitt, 2018). The subsequent results could be distilled into	Thank you for your comment. The experience of care section from the 2009 guideline was not included in this update (as specified in the scope). However, as your comment recognises, a new review question on patient choice was added to this update that includes a systematic review of primary qualitative studies that focus specifically on service user experience around choice of treatment. The committee agree that the research recommendation on 'identifying the mode of action of psychological interventions' should include those with both less and more severe depression and have clarified this in the guideline. The committee considered RCTs as the most appropriate study design to assess clinical and cost effectiveness. This is consistent with the NICE guidelines manual which recognises RCTs as the most valid evidence of the effects of interventions, and this was outlined a priori in the review protocols. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context so that the 'reality' for people experiencing depression was taken into consideration and recommendations were made

						talking points to be presented alongside the existing ‘menu’ of treatments set out in the Guideline, adding context to the dialogue between practitioner and patient in their arrival at a collaborative decision. This is a recommendation we make not only for the current Guideline but for future Guidelines which present psychological therapies as treatments.	that were relevant to the populations that clinicians typically encounter. The committees' discussions on this are documented in 'The committee’s discussion of the evidence' sections. The committee considered that the contextual features that you describe as requiring qualitative evidence to address, are taken into account by this interpretation of the clinical context by the committee.

68	SH	Institute of Psychoanalysis	Evidence review B	102-032	Table 23Table 9	No effect size differences noted. For severe depression, bias-adjusted analysis for comparison with placebo yielded a standardized mean difference (SMD) of -0.78 (rank: 17.28) for individual CBT/CT and of -0.58 (rank: 22.08) for short-term psychodynamic therapy (STPP), corresponding to a difference in effect sizes of -0.20. We feel that it is important that this is noted. Additionally, for less depression, similar observation is found. The bias-adjusted analysis for comparison for individual CBT vs. TAU is MD=-0.73, and for STPP vs. TAU, the bias-adjusted is SMD=-0.48.	Thank you for your comment. The committee agreed that there are not very large differences in the effects sizes between individual CT/CBT and STPP vs the reference treatment, and this uncertainty in the NMA results is stated in several places in evidence review B, including the committee's discussion. It was not feasible to comment on the differences in effect between all pairs of treatments examined (this was also one of the reasons why NMA was employed, in order to synthesise available evidence and summarise results by ranking treatments and providing effects of each treatment versus a common reference treatment). However, full results on the relative effects between all pairs of classes and interventions are provided in Supplements B5 and B6, for less and more severe depression, respectively. It is noted that, for less severe depression, the effect on the SMD vs TAU was based on N=481 for individual CBT and N=49 for STPP. Also, the 95%CrI were much wider for STPP than for individual CBT. As stated in the evidence review B, the committee considered insufficient evidence on any treatment class that was derived from N<50 people across RCTs on each NMA outcome (after looking at the total size of the evidence base in the area of treatment of a new episode of depression and noticing that there were several

							treatment classes with larger volume of evidence), and did not consider those treatment classes for a practice recommendation, however, they made an exception for treatment classes already available on the NHS, such as STPP. For more severe depression, the effect on the SMD vs pill placebo was based on N=1044 for individual CBT and N=267 for STPP. There was evidence for effect vs pill placebo for individual CBT (as the 95%CrI did not cross the zero line) but not for the STPP class (however, effects for interventions within the STPP class did marginally show effect vs pill placebo). The recommendations and the ranking of treatments for a new episode of depression were also affected by the results of the guideline economic modelling, which was informed by additional outcomes, such as discontinuation, response in completers and remission in completers. The guideline economic analysis results, which were also characterised by uncertainty, suggested that individual CBT was more cost-effective than GP care but STPP was less cost-effective than GP care in both less and more severe depression. For less severe depression, this result was partly attributable to the fact that the effects modelled in the economic analysis for each intervention were achieved with fewer CBT sessions (8 for individual CBT vs. 12 for STPP, reflecting

							reported resource use in the trials informing the NMA and the economic analysis – see new Appendix N added in evidence review B for more details). [In more severe depression, 16 sessions were modelled for both interventions based on reported resource use in respective RCTs.]

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

69	Individual	Individual 6	Evidence Review B	82	1	Figure 9 - Network plot- This statistical presentation is confusing and does not clearly communicate information. This has implications for clinicians and patients who may choose to read the document.	Thank you for your comment. Network plots are an essential element of presenting NMA-related information. Text has now been added under 'Evidence from the network meta-analysis' to explain what network plots represent. In addition, explanatory text has been added under each network plot in this report, to help readers interpret the information depicted in the plots.
70	SH	Greater Manchester Mental Health Services	Evidence Review B	82	1	Figure 9 - Network plot- This statistical presentation is confusing and does not clearly communicate information. This has implications for clinicians and patients who may choose to read the document.	Thank you for your comment. Network plots are an essential element of presenting NMA-related information. Text has now been added under 'Evidence from the network meta-analysis' to explain what network plots represent. In addition, explanatory text has been added under each network plot in this report, to help readers interpret the information depicted in the plots.

71	SH	Greater Manchester Mental Health Services	Evidence Review B	82	001-003	NMA by Cipriani et al seems to have been omitted from the evidence review base for antidepressants. Agomelatine studies are missing. Comparisons of better tolerated and higher efficacy molecules versus completion rates for psychological therapies and effect size would be helpful.	Thank you for your comment. The NMA that you cite (Cipriani et al. 2018) has been checked for additional relevant primary studies, and listed under excluded studies in Supplement B1 as it was not appropriate to include in its entirety due to different review questions. As pre-specified in the review protocol, agomelatine was not included. For inclusion in this review, the committee agreed that pharmacological interventions needed to be licensed in the UK and in routine clinical use for the first-line treatment of depression. The national prescription data for England in 2017 (Prescribing & Medicines Team, Health and Social Care Information Centre, 2017) was used to define routine usage of drugs: if a drug appeared in the top 15 antidepressants prescribed by volume it was included, with the exception of dosulepin which the BNF indicates should be initiated by a specialist. As you identify in your comment, one of the benefits of the NMAs conducted for this review is that both antidepressants and psychological interventions are included in the same NMA allowing a comparison of relative efficacy.

72	SH	Greater Manchester Mental Health Services	Evidence Review B	82	001-003	Newer pharmacological treatments both for severe depression and TRD e.g. Ketamine have nit been reviewed , even considering the costs of esketamine , there is significant evidence for Iv ketamine in addressing severe suicidal ideation and risk in depressed patients which would impact on the LOS for inpatient population admitted for that reason .It has been omitted even for research recommendations.	Thank you for your comment. For inclusion in this review, the committee agreed that pharmacological interventions needed to be licensed in the UK and in routine clinical use for the first-line treatment of depression. The national prescription data for England in 2017 (Prescribing & Medicines Team, Health and Social Care Information Centre, 2017) was used to define routine usage of drugs: if a drug appeared in the top 15 antidepressants prescribed by volume it was included, with the exception of dosulepin which the BNF indicates should be initiated by a specialist. Ketamine was not prioritised for investigation by this guideline as it is not a currently available first line intervention for depression, it is not licensed for use in depression and it is a widely abused drug. In these circumstances the committee did not think it was appropriate to review it or include it in a research recommendation. Esketamine is the subject of a NICE technology appraisal and in line with NICE processes on linking to technology appraisals within NICE guidelines, the evidence on esketamine was intentionally not searched for or appraised by this guideline.

73	Individual	Individual 6	Evidence Review B	86	1	Table 17- A treatment with a sample size of 15 is ranked 1st. This has implications for services as it is unclear that this result is replicable and stable given the very small sample. It affects clinicians and patients as it is unclear if we should be offering this rather than another intervention.	Thank you for your comment. This was indeed a treatment tested on a very small number of people. The NMA result reflected the finding of a RCT with small study size (see Figure 390 in Supporting documentation B3 for the forest plot of this RCT). This was the only study included in the systematic review and the NMA that assessed this treatment and reported relevant data that allowed estimation of SMD. The committee did not take this result into account when they made recommendations. This is because they only took into account evidence on treatments tested on at least 50 participants across RCTs included in each NMA. This was the minimum amount of evidence that a treatment class should have in order to be considered for a practice recommendation. The committee looked at the total size of the evidence base in this area (treatment of a new episode of depression) and the large volume of evidence for some treatment classes relative to others, and decided not to consider treatment classes with a small size of evidence base (tested on <50 participants) as there were several treatment classes with much larger volume of evidence. This was stated in several places in the document, but it was not highlighted under 'The committee's discussion of the evidence'. This statement has now been included in this section

							in the final report. Therefore, this finding did not affect recommendations and has no immediate implications for clinical practice. If this finding is replicated in a larger sample in future research, and there is confidence in the finding, then the treatment may be recommended in the future and may thus have an impact on services.

74	SH	Greater Manchester Mental Health Services	Evidence Review B	86	1	Table 17- A treatment with a sample size of 15 is ranked 1st. This has implications for services as it is unclear that this result is replicable and stable given the very small sample. It affects clinicians and patients as it is unclear if we should be offering this rather than another intervention.	Thank you for your comment. This was indeed a treatment tested on a very small number of people. The NMA result reflected the finding of a RCT with small study size (see Figure 390 in Supporting documentation B3 for the forest plot of this RCT). This was the only study included in the systematic review and the NMA that assessed this treatment and reported relevant data that allowed estimation of SMD. The committee did not take this result into account when they made recommendations. This is because they only took into account evidence on treatments tested on at least 50 participants across RCTs included in each NMA. This was the minimum amount of evidence that a treatment class should have in order to be considered for a practice recommendation. The committee looked at the total size of the evidence base in this area (treatment of a new episode of depression) and the large volume of evidence for some treatment classes relative to others, and decided not to consider treatment classes with a small size of evidence base (tested on <50 participants) as there were several treatment classes with much larger volume of evidence. This was stated in several places in the document, but it was not highlighted under 'The committee's discussion of the evidence'. This statement has now been included in this section

							in the final report. Therefore, this finding did not affect recommendations and has no immediate implications for clinical practice. If this finding is replicated in a larger sample in future research, and there is confidence in the finding, then the treatment may be recommended in the future and may thus have an impact on services.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

75	SH	Institute of Psychoanalysis	Evidence review B	143	General	Couples psychotherapy. In line with the previous guideline couples' psychotherapy has been considered as a treatment option and we welcome this. Based on a wealth of empirical research (e.g. Beach, Fincham, & Katz, 1998; Benazon & Coyne, 2000; Coyne, Thompson, Palmer, 2002; Johnson & Jacob, 1997, 2000; Scott & Cordova, 2002; Whisman, 2007), the direct pathway between couple relationship distress and depression has been well documented. However, we are surprised to learn that a very narrow definition and as such narrow inclusion criteria has been used. This led to the identification of only one study, which dates from 1992 and includes cognitive therapy (Beech, 1992, see page 111)We are surprised by the inconsistency here to recommend a treatment on the review of one study alone, that has in addition been rated as a "very weak study". To further specify, it is inconsistent to include a treatment on the basis of one study while excluding (not recommending in the guideline) other treatments that have been shown to be effective in single studies. The fact that only one study was identified reflects the methodology chosen rather than available evidence and this provides further support for our request that the exclusion/inclusion criteria for the analysis is amended.	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA). The committee considered the pairwise analysis of behavioural couples therapy for people with depression and problems in the relationship with their partner. As you indicate in your comment, this evidence was based on a small, single study which indicated that compared to waitlist, couples' therapy demonstrated benefits in terms of depression symptoms and marital adjustment, but when compared to CBT it did not show a benefit in depression symptoms, but did with marital adjustment. CBT compared to waitlist demonstrated benefits only in terms of depression symptoms. The committee discussed that although this was limited evidence, behavioural couples therapy was included in the range of interventions offered by the IAPT services and that it was useful in the specific

							population and so recommended its use for this group of people.

76	Individual	Individual 5	Evidence Review B	173	21	One study of MCT versus CBT (Jordan et al) is currently listed, however it is not stated how this has been classified and treated in the analysis. Specifically, how was MCT categorised and was it included as a condition? Discussion and specific analysis of MCT against CBT (e.g. Forrest plots in supplement B3) is warranted, but missing. On the basis of this referenced study such analysis should be included as a matter of equipoise and analysis should incorporate the large-scale comparison trial of MCT against CBT that was published in 2020, but is not currently reviewed.	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. Metacognitive therapy (MCT) was included in the class of cognitive and cognitive behavioural therapies (as was CBT). Jordan 2014 was included in the NMA that informed the recommendations. However, because the study included a within-class comparison it is not included in the forest plots, and is not mentioned in the text as the within-class comparison of MCT versus CBT, was not regarded by the committee as a critical comparison.

							Unfortunately, without a reference for the large-scale comparison trial of MCT and CBT published in 2020 that you refer to in your comment, it is not possible to respond as to why it may not have been identified and included.

77	SH	Greater Manchester Mental Health Services	Evidence Review B	173	21	One study of MCT versus CBT (Jordan et al) is currently listed, however it is not stated how this has been classified and treated in the analysis. Specifically, how was MCT categorised and was it included as a condition? Discussion and specific analysis of MCT against CBT (e.g. Forrest plots in supplement B3) is warranted, but missing. On the basis of this referenced study such analysis should be included as a matter of equipoise and analysis should incorporate the large-scale comparison trial of MCT against CBT that was published in 2020, but is not currently reviewed.	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. Metacognitive therapy (MCT) was included in the class of cognitive and cognitive behavioural therapies (as was CBT). Jordan 2014 was included in the NMA that informed the recommendations. However, because the study included a within-class comparison it is not included in the forest plots, and is not mentioned in the text as the within-class comparison of MCT versus CBT, was not regarded by the committee as a critical comparison.

							Unfortunately, without a reference for the large-scale comparison trial of MCT and CBT published in 2020 that you refer to in your comment, it is not possible to respond as to why it may not have been identified and included.

78	SH	EMDRIA	Evidence review B(and original review protocol, p.2)	205	General	The decision to exclude from the review scope research trials "that specifically recruit participants with a physical health condition in addition to depression." (e.g. Review protocol, p2; Evidence review B, p205) is, in our view, a serious omission that limits the utility of the guideline. We struggled to understand the rationale for omitting this research. We felt it was a somewhat strange decision given that in 1.4.1, the guideline recommends that "when considering treatments, make sure to consider any physical health problems" – yet all this trial evidence has been excluded from the review. It also meant several relevant psychological treatment trials, including some trials of EMDR – were omitted from the review. We ask the committee to explain more coherently the decision to exclude research evidence on treatments for depression in those suffering with physical health problems (and make this clear in the guidance itself); or reconsider and review this data with a view to making specific recommendations for this group.	Thank you for your comment. There is separate NICE guidance on Depression in adults with a chronic physical health problem (CG91), and that is the rationale for excluding trials that specifically recruit participants with a physical health condition in addition to depression. Recommendation 1.4.1 includes considerations for delivering treatments. However, in response to your comment a cross-reference to the CG91 guideline has been added to this recommendation.
79	SH	British Psychological Society	Evidence Review B	207	Appendix A	Couple therapy is again listed as a psychosocial intervention when it is a psychological intervention and again incorrectly described as more appropriate for sub-groups of people with depression specifically those with problems in the relationship with their partner.	Thank you for your comment. This was not intended to be listed as a psychosocial intervention but was in a separate section at the end. However, in response to your comment, it has been moved under the psychological interventions heading for greater clarity.

80	SH	Tavistock Relationships	Evidence Review B	207	Appendix A	Couple therapy is again listed as a psychosocial intervention when it is a psychological intervention and again incorrectly described as more appropriate for sub-groups of people with depression specifically those with problems in the relationship with their partner.	Thank you for your comment. This was not intended to be listed as a psychosocial intervention but was in a separate section at the end. However, in response to your comment, it has been moved under the psychological interventions heading for greater clarity.
81	SH	Oxford Health NHS Foundation Trust	Evidence review B	326	General	The rationale for assuming high intensity interventions are delivered by a Band 5 PWP is not described. This is a significant omission because high intensity interventions would not be delivered by Band 5 PWPs. High Intensity interventions are expected to be delivered by High Intensity Therapists at Band 7. If a Band 5 PWP was trained in delivering these then they would in fact be delivering the role of a B7 not a B5 and this would have significant cost implications. The implications of this are that it skews the results away from low intensity interventions. There is no explicit consideration of low intensity interventions (BA/Problem Solving/ Cognitive restructuring/Graded Exposure) separate to these interventions being delivered as high intensity interventions. This seems again to be a reflection of the lack of detailed knowledge of IAPT service provision in the committee.	Thank you for your comment. Delivery of high intensity interventions by a Band 5 PWP was an assumption tested only in a sensitivity analysis, and this was clear in the text ("in order to explore the impact of therapist unit cost on the results of the economic analysis, in deterministic sensitivity analysis high-intensity psychological interventions were assumed to be delivered by band 5 PWPs"). This sensitivity analysis has now been omitted from the report, as the committee agreed it is not relevant. The base-case analysis (which was the one that informed recommendations) assumes delivery of high intensity interventions by a band 7 therapist, and, in the case of group interventions, by a band 7 high intensity therapist, who leads the delivery of the group intervention, supported by a band 6 therapist; this reflects optimal practice, based on the committee's expert advice. Therefore results (and recommendations) were not skewed away from low intensity interventions. BA was modelled as a high intensity intervention, in accordance with the

							evidence informing the economic analysis. Problem solving was modelled as a low intensity intervention and was assumed to be delivered by Band 5 therapists in the base-case economic analysis and all sensitivity analyses. Cognitive restructuring and Graded Exposure were not included in the NMA and/or economic analysis as no relevant evidence that met inclusion criteria for the systematic review was identified.

82	SH	Psychological Professions Network	Evidence review B	326	General	The rationale for assuming high intensity interventions are delivered by a Band 5 PWP is not described. High intensity interventions would not be delivered by B5 PWP staff as high intensity interventions are expected to be delivered by High Intensity Therapists at B7. If a B5 PWP was trained in this then they would not be delivering the role of a B5. The implications of this is that it skews the results away from low intensity interventions. There is no explicit consideration of low intensity interventions (BA/Problem Solving/ Cognitive restructuring/Graded Exposure) separate to these interventions as high intensity interventions	Thank you for your comment. Delivery of high intensity interventions by a Band 5 PWP was an assumption tested only in a sensitivity analysis, and this was clear in the text ("in order to explore the impact of therapist unit cost on the results of the economic analysis, in deterministic sensitivity analysis high-intensity psychological interventions were assumed to be delivered by band 5 PWPs"). This sensitivity analysis has now been omitted from the report, as the committee agreed it is not relevant. The base-case analysis (which was the one that informed recommendations) assumes delivery of high intensity interventions by a band 7 therapist, and, in the case of group interventions, by a band 7 high intensity therapist, who leads the delivery of the group intervention, supported by a band 6 therapist; this reflects optimal practice, based on the committee's expert advice. Therefore results (and recommendations) were not skewed away from low intensity interventions. BA was modelled as a high intensity intervention, in accordance with the evidence informing the economic analysis. Problem solving was modelled as a low intensity intervention and was assumed to be delivered by Band 5 therapists in the base-case economic analysis and all sensitivity analyses. Cognitive restructuring and Graded Exposure were not

							included in the NMA and/or economic analysis as no relevant evidence that met inclusion criteria for the systematic review was identified.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

83	SH	Oxford Health NHS Foundation Trust	Evidence Review B	331	Table 88	CBT group assumption that it is delivered by 1 band 7 and 1 band 6 – not clear why this would be the case what is the evidence?	Thank you for your comment. This assumption was based on the committee's expert advice, considering optimal practice. It was assumed that the CBT group therapy was led by a high intensity Band 7 therapist, supported by a Band 6 therapist, who might be, for example, a trainee clinical psychologist. This support may be of particular importance in larger groups of participants, although it is not an essential element of delivery. The text has now been reworded to clarify that delivery is led by a band 7 HI therapist, supported by a band 6 therapist.
84	SH	Psychological Professions Network	Evidence Review B	331	Table 88	CBT group assumption that it is delivered by 1 band 7 and 1 band 6 – not clear why this would be the case. Band 6 is usually trainee HIT.	Thank you for your comment. This assumption was based on the committee's expert advice, considering optimal practice. It was assumed that the CBT group therapy was led by a high intensity Band 7 therapist, supported by a Band 6 therapist, who might be, for example, a trainee clinical psychologist. This support may be of particular importance for larger groups of participants, although it is not an essential element of delivery. The text has now been reworded to clarify that delivery is led by a band 7 HI therapist, supported by a band 6 therapist.

85	SH	The Mindfulness Initiative	Evidence review B	335	Table	The costs given for MBCT are based on 2 therapists and 8 participants. There have been significant effects in RCTs using MBCT with one therapist and up to 15 participants. Almost all MBCT RCTs have been with 1 teacher and up to 15 participants per group[1].	Thank you for your comment. The economic analysis modelled the number of sessions of psychological interventions based on relevant information reported in the RCTs that informed the guideline NMA and economic analysis, supplemented by the committee's clinical experience on optimal delivery of interventions within the NHS. This information has now been added in evidence review B, under Appendix N. Few studies reported the number of participants in group interventions and even fewer made specific reference to the number of therapists per group. For MBCT, only one study on the treatment of a new episode of less severe depression reported the number of participants per group as 8-15. The committee expressed the view that group interventions should be optimally delivered by two therapists, one leading the delivery of the intervention and another one observing, and that the optimal number of participants is around 8. This has been reflected in the economic modelling and the respective recommendations. The committee has now modified the recommendation for MBCT, based on their clinical expertise and available evidence. The suggested delivery is now 'preferably by 2 practitioners at least one of whom has therapy-specific training and competence' with 'usually 8-

							15 participants per group'. Studies on MBCT for relapse prevention have more consistently reported numbers of participants and therapists. The economic analysis on relapse prevention has thus included a sensitivity analysis where the intervention is delivered by 1 high intensity therapist to 12 participants.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

86	SH	Oxford Health NHS Foundation Trust	Evidence Review B	355	64	It is unclear what the rationale is to assume that High Intensity Interventions are delivered by B5 PWP – see above. This would not be the case in practice and will likely have the impact of suggesting that CBT group is less expensive than it is in practice as there are a number of factors to consider.	Thank you for your comment. Delivery of high intensity interventions by a Band 5 PWP was an assumption tested only in a sensitivity analysis, and this was clear in the text ("in order to explore the impact of therapist unit cost on the results of the economic analysis, in deterministic sensitivity analysis high-intensity psychological interventions were assumed to be delivered by band 5 PWPs"). This sensitivity analysis has now been omitted from the report, as the committee agreed it is not relevant. The base-case analysis (which was the one that informed recommendations) assumes delivery of high intensity interventions by a band 7 therapist, and, in the case of group interventions, by a band 7, supported by a band 6 therapist, reflecting optimal practice in the NHS, based on the committee's expert advice. Therefore the cost of CBT group has not been underestimated in the analysis. Please note that the cost of group interventions has taken into account drop-outs, assuming that participants who leave a group are not replaced by other participants, thus the cost of a group therapy remains the same whether participants attend all sessions or not.

87	SH	Psychological Professions Network	Evidence Review B	355	064-065	It is unclear what the rationale is to assume that High Intensity Interventions are delivered by B5 PWP. This would not be the case in practice and will likely have the impact of suggesting that CBT group is less expensive than it is in practice. This is incorrect and should be changed, as it will underestimate the cost of group CBT and other high intensity interventions	Thank you for your comment. Delivery of high intensity interventions by a Band 5 PWP was an assumption tested only in a sensitivity analysis, and this was clear in the text ("in order to explore the impact of therapist unit cost on the results of the economic analysis, in deterministic sensitivity analysis high-intensity psychological interventions were assumed to be delivered by band 5 PWPs"). This sensitivity analysis has now been omitted from the report, as the committee agreed it is not relevant. The base-case analysis (which was the one that informed recommendations) assumes delivery of high intensity interventions by a band 7 therapist, and, in the case of group interventions, by a band 7, supported by a band 6 therapist, reflecting optimal practice in the NHS, based on the committee's expert advice. Therefore the cost of CBT group has not been underestimated in the analysis. Please note that the cost of group interventions has taken into account drop-outs, assuming that participants who leave a group are not replaced by other participants, thus the cost of a group therapy remains the same whether participants attend all sessions or not.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

88	SH	Oxford Health NHS Foundation Trust	Evidence Review B	361	67	It is unclear why there is an assumption that all psychological interventions would be assumed to be delivered by a Band 5 PWP when this would not be the case. The figures used may be interpreted to suggest that this is what the intervention should cost. This is not true in practice where interventions for more severe depression are more likely to be delivered by Band 7 and above psychological therapists.	Thank you for your comment. Delivery of high intensity interventions by a Band 5 PWP was an assumption tested only in a sensitivity analysis, and this was clear in the text ("in order to explore the impact of therapist unit cost on the results of the economic analysis, in deterministic sensitivity analysis high-intensity psychological interventions were assumed to be delivered by band 5 PWPs"). This sensitivity analysis has now been omitted from the report, as the committee agreed it is not relevant. The base-case analysis (which was the one that informed recommendations) assumes delivery of high intensity interventions by a band 7 therapist, and, in the case of group interventions, by a band 7, who leads the delivery, supported by a band 6 therapist, reflecting optimal practice in the NHS, based on the committee's expert advice. The figures reported in the economic appendix under intervention costs reflect delivery of interventions by Band 7 therapists (with support from Band 6 therapists for group interventions) as described above.

89	SH	Psychological Professions Network	Evidence Review B	361	67	It is unclear why there is an assumption that all psychological interventions would be assumed to be delivered by a Band 5 PWP when this would not be the case. The figures used may be interpreted to suggest that this is what the intervention should cost. This is incorrect and needs changing, as psychological interventions for more severe depression in practice are more likely to be delivered by Band 7 and above psychological professionals.	Thank you for your comment. Delivery of high intensity interventions by a Band 5 PWP was an assumption tested only in a sensitivity analysis, and this was clear in the text ("in order to explore the impact of therapist unit cost on the results of the economic analysis, in deterministic sensitivity analysis high-intensity psychological interventions were assumed to be delivered by band 5 PWPs"). This sensitivity analysis has now been omitted from the report, as the committee agreed it is not relevant. The base-case analysis (which was the one that informed recommendations) assumes delivery of high intensity interventions by a band 7 therapist, and, in the case of group interventions, by a band 7, who leads the delivery, supported by a band 6 therapist, reflecting optimal practice in the NHS, based on the committee's expert advice. The figures reported in the economic appendix under intervention costs reflect delivery of interventions by Band 7 therapists (with support from Band 6 therapists for group interventions) as described above.

90	SH	Oxford Health NHS Foundation Trust	Evidence review B	364	029-021	Not clear why this assumption has been used as it does not reflect current service delivery nor design.	Thank you for your comment. Delivery of high intensity interventions by a Band 5 PWP was an assumption tested only in a sensitivity analysis, and this was clear in the text ("in order to explore the impact of therapist unit cost on the results of the economic analysis, in deterministic sensitivity analysis high-intensity psychological interventions were assumed to be delivered by band 5 PWPs"). This sensitivity analysis has now been omitted from the report, as the committee agreed it is not relevant. The base-case analysis (which was the one that informed recommendations) assumes delivery of high intensity interventions by a band 7 therapist, and, in the case of group interventions, by a band 7, supported by a band 6 therapist, reflecting optimal practice in the NHS, based on the committee's expert advice.

91	SH	Psychological Professions Network	Evidence review B	364	029-021	Not clear why this assumption has been used as it does not reflect current service delivery nor design. This needs changing as it leads to incorrect cost-effectiveness calculations	Thank you for your comment. Delivery of high intensity interventions by a Band 5 PWP was an assumption tested only in a sensitivity analysis, and this was clear in the text ("in order to explore the impact of therapist unit cost on the results of the economic analysis, in deterministic sensitivity analysis high-intensity psychological interventions were assumed to be delivered by band 5 PWPs"). This sensitivity analysis has now been omitted from the report, as the committee agreed it is not relevant. The base-case analysis (which was the one that informed recommendations) assumes delivery of high intensity interventions by a band 7 therapist, and, in the case of group interventions, by a band 7, supported by a band 6 therapist, reflecting optimal practice in the NHS, based on the committee's expert advice. As explained, this assumption (delivery of high intensity interventions by a Band 5 PWP) was only used in a sensitivity analysis that has now been omitted. Therefore, the base-case cost-effectiveness calculations (which informed recommendations) were not based on this assumption; they were based on the salary Bands of the professionals delivering the interventions in the NHS and are, thus, not incorrect.

92	SH	Oxford Health NHS Foundation Trust	Evidence review B	366	032-034	Less specialised therapists e.g. B5 PWPs would not be delivering high intensity therapists. If they had received suitable training then they would be employed at B7. The economic analysis is flawed on this basis and this seems to be a very significant issue given the nature of the proposals resulting from this.	Thank you for your comment. Delivery of high intensity interventions by a Band 5 PWP was an assumption tested only in a sensitivity analysis, and this was clear in the text ("in order to explore the impact of therapist unit cost on the results of the economic analysis, in deterministic sensitivity analysis high-intensity psychological interventions were assumed to be delivered by band 5 PWPs"). This sensitivity analysis has now been omitted from the report, as the committee agreed it is not relevant. The base-case analysis (which was the one that informed recommendations) assumes delivery of high intensity interventions by a band 7 therapist, and, in the case of group interventions, led by a band 7, supported by a band 6 therapist, reflecting optimal practice in the NHS, based on the committee's expert advice. The economic analysis was therefore not flawed by the assumption of Band 5 PWPs delivering high intensity interventions. Nor did any recommendations result from this assumption.

93	SH	Psychological Professions Network	Evidence review B	366	032-034	Less specialised therapists e.g. B5 PWPs would not be delivering high intensity therapies. If they had received suitable training then they would be employed at B7. The economic analysis is flawed on this basis.	Thank you for your comment. Delivery of high intensity interventions by a Band 5 PWP was an assumption tested only in a sensitivity analysis, and this was clear in the text ("in order to explore the impact of therapist unit cost on the results of the economic analysis, in deterministic sensitivity analysis high-intensity psychological interventions were assumed to be delivered by band 5 PWPs"). This sensitivity analysis has now been omitted from the report, as the committee agreed it is not relevant. The base-case analysis (which was the one that informed recommendations) assumes delivery of high intensity interventions by a band 7 therapist, and, in the case of group interventions, led by a band 7, supported by a band 6 therapist, reflecting optimal practice in the NHS, based on the committee's expert advice. The economic analysis was therefore not flawed by the assumption of Band 5 PWPs delivering high intensity interventions. Nor did any recommendations result from this assumption.

94	SH	British Psychological Society	Evidence Review B	374	10	In this table on suggestions for research to understand the mechanisms of psychological therapies for acute depression, there is a claim that “very little evidence is available…” This does not appear to take into account a large literature suggesting common factors for therapies for common mental health difficulties (e.g. see review: Budd, R., & Hughes, I. (2009). The Dodo Bird Verdict - controversial, inevitable and important: A commentary on 30 years of meta-analyses. Clinical Psychology and Psychotherapy, 16(6), 510–522. https://doi.org/10.1002/cpp.648). This research suggests three key factors: A good therapeutic alliance, therapist belief in the approach, and therapist characteristics. Furthermore, any research on how and why psychological therapies help people experiencing depression needs to take into account (a) the social determinants and maintainers of depression, and (b) the interpersonal nature of psychological therapy, which cannot be entirely reduced to a list of techniques because a technique is always used within this interpersonal interaction, with an active client contribution, which modifies what it looks like. Both client and therapist social context also modify the way any ‘therapy technique’ works. Randomised trials are aimed at filtering out such contextual variables, but context is part of why something works or fails to work in a given locality	Thank you for your comment. A focus on mechanisms of action should not be confused with specific therapeutic techniques. Different techniques, including those taking account of the interpersonal interaction, may nevertheless operate through the same underlying psychological mechanism. The committee considered RCTs as the most appropriate study design to assess clinical and cost effectiveness. This is consistent with the NICE guidelines manual which recognises RCTs as the most valid evidence of the effects of interventions, and this was outlined a priori in the review protocols. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context so that the 'reality' for people experiencing depression was taken into consideration and recommendations were made that were relevant to the populations that clinicians typically encounter. The committees' discussions on this are documented in 'The committee’s discussion of the evidence' sections. The committee considered that the social and interpersonal features that you describe as requiring realist research/review or case study research to address, are taken into account by

						and with a given client and therapist, so it needs to be included in the research. Trials tell us what works, but not why it works, for whom and in what contexts. For approaches quintessentially designed to understand these issues, we recommend realist research or a realist review (Pawson & Tilley 1997; Pawson, 2013; Wong et al., 2013). It is possible that there is already sufficient extant research on CBT for depression to carry out a realist review to understand the key mechanisms. However, it is important to accept that (a) success is likely to be about more than putting together certain 'components', and that (b) there are aspects of depression that cannot be addressed with either medication or psychotherapy aimed only at changing the individual. Whilst individuals can gain support and acquire new strategies to improve their relationships and environment, there are limits imposed by societal structures and the reality that individuals only ever have limited control over these. Some causes and maintainers of depression must be addressed at a societal and policy level. Another way to unpack causal links would be via systematic multiple explanatory case study research (Yin, R. (2018). Case study research and applications: design and methods. Sage) on therapy as it progresses. References for realist research and reviewing: Pawson, R. (2013). The Science of Evaluation: A Realist Manifesto. Sage.	this interpretation of the clinical context by the committee.

						Pawson, R. & Tilley, N (1997). Realistic evaluation. Sage. Wong, G., Greenhalgh, T., Buckingham, J., Westhorp, G., & Pawson, R. (2013). RAMESES publication standards: realist synthesis: BMC Medicine 2013, 11:21	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

95	Individual	Individual 5	Evidence Review B, E	General	General	There is published evidence of the effect of metacognitive therapy in mild and severe (treatment resistant depression) in 3 important eligible trials that are not considered in the evidence review and analysis. It is recommended that these 3 studies be included.	Thank you for your comment. Unfortunately, without references, it is not possible to respond as to why these studies may not have been identified and included.
96	SH	Greater Manchester Mental Health Services	Evidence Review B, E	General	General	There is published evidence of the effect of metacognitive therapy in mild and severe (treatment resistant depression) in 3 important eligible trials that are not considered in the evidence review and analysis. It is recommended that these 3 studies be included.	Thank you for your comment. Unfortunately, without references, it is not possible to respond as to why these studies may not have been identified and included.

97	SH	Greater Manchester Mental Health Services	Evidence Review B, E	General	General	Subgroup analysis should include a comparison of metacognitive therapy with CBT, two published studies are available (Jordan et al, 2014; and Callesen et al, 2020).	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. Metacognitive therapy (MCT) was included in the class of cognitive and cognitive behavioural therapies (as was CBT). Jordan 2014 was included in the NMA that informed the recommendations. However, because the study included a within-class comparison it is not included in the forest plots, and is not mentioned in the text as the within-class comparison of MCT versus CBT, was not regarded by the committee as a critical comparison.

							Callesen et al. (2020) was identified by the searches but did not meet inclusion criteria as less than 80% of participants were receiving first-line treatment (35% receiving psychiatric medication at baseline). This study is in the excluded studies list of Supplement B1.

98	SH	The Mindfulness Initiative	Evidence review C	General	General	We note the comments on cost effectiveness of MBCT vs maintenance anti-depressant treatment but as noted in our report on Mindfulness-based alternatives to long-term prescription drugs[2], Public Health England concluded in their 2019 report that:there are nearly 1 million people who have been using for at least three years. PHE said this suggested those with mild-to-moderate depression may have become dependent.long-term use on such a scale could not be justified and was a sign of patients becoming dependent.Cost effectiveness whilst important therefore can not be the determining barometer when it comes to giving people a choice over evidence-based treatment. MBCT has the advantage of being a non-stigmatised and non-invasive treatment option.Taking a longer-term perspective, people learning skills to understand and manage their fluctuating mental states is likely to be more cost effective and have a stronger effect on a person's wellbeing and quality of life than long-term anti-depressant use.	Thank you for your comment. The recommendations on relapse prevention are for people at a higher risk of relapse, as indicated by a number of clinical and socioeconomic factors, and not specifically for people who have remitted from mild-to-moderate depression alone. The committee took into account clinical and cost-effectiveness along with other considerations when making recommendations. The committee agreed that recommendations on relapse prevention should remain unchanged as there is a risk from moving people from one type of treatment to another, so if people had remitted with antidepressant treatment and were assessed as at higher risk of relapse it would be optimal for them to continue with the treatment they had achieved remission with. MBCT is also recommended as an option for people who do not wish to continue on antidepressants. The committee did consider the low benefit:risk ratio of antidepressant use especially for people with less severe depression, and for this reason they made a recommendation to not routinely offer antidepressant medication as first-line treatment for people with less severe depression, unless that is the person's preference. Furthermore, the committee acknowledged the withdrawal symptoms associated with discontinuation of

							antidepressant use, and made specific recommendations to support people stopping antidepressants.

99	SH	The Mindfulness Initiative	Evidence review C	9	General	We recommend that mindfulness is separated out from 'meditation and relaxation' to avoid confusion between these different types of treatment. Mindfulness specifically encourages people to bring awareness to their present moment experience with compassion, care and curiosity, and to de-centre from their thoughts. It is not the same as relaxation training or meditation, which is a much broader categorisation.	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. Mindfulness and meditation approaches were combined into group and individual classes, and progressive muscle relaxation (individual and group) interventions were considered as distinct classes. The committee agreed that mindfulness based cognitive therapy (MBCT) should be given as an exemplar of this class and in Table 1 of the recommendations, in considering how to deliver group mindfulness or meditation it is recommended that 'a programme such as

							mindfulness-based cognitive therapy specifically designed for people with depression' is used.

100	SH	Institute of Psychoanalysis	Evidence review D	General	General	Exclusion of important bona-fine studies of long-term psychodynamic psychotherapy for further line treatmentWe have noticed that two important RCTs investigating long-term treatments have been omitted in the further-line treatment review. Both provided crucial evidence of the effectiveness of long-term psychodynamic psychotherapy, a treatment modality that is currently offered within NHS services and UK tertiary sector and therefore should have been included, in addition to the Fonagy et al (2015) NHS study. These omitted studies that need to be included under the further-line treatment review are:1.The Leuzinger-Bohleber et al 2019, which investigated long-term psychodynamic therapy and long-term CBT and found both to be effective. It was considered under the chronic depression review and excluded because >20% were not first-line treatment. However, we cannot see a valid reason for excluding it under further-line treatment as either chronic or treatment-resistant as the study population fulfil criteria for both.2. Knekt et al 2008/2013/2016), which investigated the effectiveness of long-term psychodynamic. It was for inexplicable reasons considered under first-line treatment only, excluded due to the population <80% first-line treatment. Again, it should have been included under further-line treatment as the study population fulfils the criteria.All three studies	Thank you for your comment. As you point out Leuzinger-Bohleber et al 2019 was considered for the chronic depression review and was excluded. This study also did not meet eligibility criteria for the further-line treatment review as the inclusion criteria of the study was not limited to those receiving further-line treatment, participants were not randomised at the point of non-response, and it could not be regarded as an augmentation study following limited or no response to antidepressants as only 36% of participants were taking antidepressants at baseline. This study has now been added to the excluded studies list in supplement D. Knekt et al 2008/2013/2016 was considered under first-line treatment as detailed in your comment, and did not meet criteria. It also did not meet criteria for the further-line treatment review as the inclusion criteria of the study was not limited to those receiving further-line treatment (in fact those receiving psychotherapy within the previous 2 years were excluded), participants were not randomised at the point of non-response, and it could not be regarded as an augmentation study following limited or no response to antidepressants as only 22% of participants were receiving psychotropic medication at baseline. This study has now been

						provide evidence that effects are sustained, even improved, over the long-term (2-3 year) follow-up.As stated previously, Individuals with enduring and complex forms of depression often report a background of developmental adversity and trauma. As this draft acknowledges, the problems experienced are multi-faceted and often severe and hugely debilitating. Research and clinical practice have shown that many individuals with chronic or complex forms of depression have tried the available and recommended first or second-line short-term treatments without success (e.g., Leichsenring & Rabung 2011; Maj et al. 2020). Moreover, systematic reviews have repeatedly shown that in complex mental disorders, longer-term psychotherapy has been found to be superior to short-term psychotherapy (Leichsenring & Rabung, 2011, Leichsenring et al., 2013).Recommendation for psychological interventions for further line treatment (and chronic depression) defaults to the recommendations of the 'more severe' first episode list for no clear reasons. The evidence at hand, however, may provide different options of treatments are already available within our NHS.	added to the excluded studies list in supplement D. The further-line treatment recommendation that cross-refers to psychological treatment options for more severe depression is for people whose depression has had no or a limited response to treatment with antidepressant medication alone. There was no evidence that specifically examined switching to a psychological intervention for those who have not responded to initial antidepressant treatment, however, the committee drew on the evidence for first-line treatments in more severe depression. The committee agreed that the psychological interventions that had been identified as effective and cost-effective for first-line treatment of more severe depression could be used for people who had not responded to antidepressants and wished to try a psychological therapy instead. There was only single-study evidence (Fonagy et al. 2015) for augmenting antidepressant treatment with long-term psychodynamic psychotherapy, and the committee considered the evidence too limited to make a recommendation for long-term psychodynamic psychotherapy specifically. However, a

							treatment option in the recommendation for people whose depression has had no or a limited response to treatment with antidepressant medication alone, includes changing to a combination of psychological therapy and medication, which could include long-term psychodynamic psychotherapy although it is not listed as an example due to the limited evidence.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

101	SH	EMDRIA	Evidence review D	200 - 208	General	In all the guideline review protocols (eg. Review D, Appendix A, p200), EMDR for depression is included as an intervention of interest for treatment of adults. However, in Appendix B - literature search strategies – the search term "EMDR" does not appear anywhere (searches updated 4/6/2020). We would have expected it to appear after search line 14 and before search line 16 (p208) for the Embase etc searches, and between #22 and #23 in the Cochrane library search (p211). This omission is replicated in the other search strategies. Hence it is unclear if, or how, EMDR trial data has been extracted for the NMA and evidence reviews – have the relevant papers been identified from searches or extracted from systematic reviews? We wondered whether relevant EMDR papers might therefore been accidentally omitted from the NICE reviews, and ask the committee to clarify this omission and re-run the review searches.	Thank you for your comment and for drawing our attention to this omission. In response to your comment a specific supplementary search has been run for EMDR. However, no eligible studies were identified, apart from the Ostacoli 2018 study that was already included in the further-line treatment review. Details of the additional EMDR search have been added to Appendix B of the relevant evidence reports (Evidence reports B, C, D, E, and F). The excluded studies lists of Supplement B and Supplement D have now been updated with the additional studies which were identified, and the reason for exclusion.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

102	SH	Janssen	Evidence Review D	176-177	General	We acknowledge and note the limited evidence available to inform later line of treatment recommendation and economic modelling. We note that a number of recommendations in this section have no evidence or have required their evidence to be generalised from early lines of treatments, especially for psychological treatments. We strongly suggest that in future reviews of the guideline that an attempt is made to look at the cost effectiveness of depression treatment strategies to identify the most appropriate choice of treatments along the pathway. However, we note that the guideline committee have done their best with the evidence available in coming up with recommendation here.	Thank you for your comment. As with all other review questions, a systematic review of economic literature for interventions for further line treatment of depression was also conducted. Regarding primary economic modelling, in accordance with NICE guideline methods and due to time constraints, an economic plan was prepared in collaboration with the committee, which prioritised review questions for primary economic analysis, using as criteria the expected resource implications as well as the quality and the relevance of available clinical and economic evidence. Using these criteria, the area of further line treatment was not prioritised, however, the committee agreed this is an area that needs to be considered for primary economic analysis in future guideline updates. It is noted, though, that this area is expected to require complex economic modelling that may not be possible to capture all relevant sub-groups, as it includes a heterogeneous population that may follow very diverse treatment sequences and pathways.

103	SH	Institute of Psychoanalysis	Evidence review D	367-368	Table 75	Inaccurate quality assessment of the Tavistock Adult Depression study (Fonagy et al., 2015) As something of an example of point 12 above, Table 75 reports the GRADE assessment for the study as “very low”. This appeared based on several inaccuracies which need to be corrected and include:Risk of bias: It is rated ‘serious’ on the grounds that there are “group differences at baseline”. We consider this an unreasonable down-rating because the differences were on education and receiving state benefits and not on any of the clinical characteristics or with respect to critical and additional outcomes. The study utilised a minimization protocol of those variables that are known to affect outcome, including gender, baseline severity and receiving/not receiving medication. Furthermore, as clearly stated in the paper, when the chance imbalance in education was moderated for by the statistical analysis, the effect remained and was robust.Imprecision: The study is rated ‘serious’ for 24 months follow up on grounds that the “CI crosses thresholds for both clinically important benefit and no effect”. This is incorrect. (N.B. this is a SMD not an odds ratio so the line of no effect is zero). This criterion appears to have been applied inconsistently between studies. The 95% CI is 0.26 to 1.1. The SMD is 0.68. If the threshold for clinically important benefit is 0.5, then this would need to be stated and justified	Thank you for your comment. For the Fonagy et al. (2015) study, risk of bias was rated as serious due in part to the significant difference between groups at baseline. Almost regardless of what this difference is, it suggests that there is a problem with randomisation as randomisation is intended to balance out potentially confounding variables. The non-blinding of participants and intervention administrators also presents a risk of bias, however, the rating reflects the blinding of outcome assessors (otherwise the risk of bias would have been very serious). With regards to the imprecision rating highlighted in your comment. The thresholds for clinically important SMD effects are -0.5 and 0.5. The 95% CI of -1.1 to -0.26 crosses the threshold of no effect (although it does not cross the line of no effect), and so it has been downgraded once. This is consistent with the methods outlined in Supplement 1. In response to the additional information provided regarding the rating of ‘publication bias’s due to funding from the International Psychoanalytic Association. This source of funding represents a potential interest. The committee agreed that it is important to rate equivalently across psychological and

						(in particular for a group of patients with such complex and severe form of depression).Other consideration: reporting bias: The study was not partially funded by the International Psychoanalytic Association (IPA). The IPA had no input into the design, conduct, analysis, or interpretation of the findings of the study. The RCT was funded by the NHS. A qualitative arm was included into the study in 2009 (6 years after it was launched) and it was for this that the study received two small grands from the IPA. Taking the above inaccuracies into account, the risk criteria for the study will need to be reviewed and adjusted accordingly. It should then also be amended in other part of the documents (e.g. p. 113) and recommendations need to be re-considered in light of this.	pharmacological trials, and as a pharmacological trial would be downgraded for publication bias if it was partially funded by a pharmaceutical company, then it is also consistent to do so here. It is important to note that the GRADE system 'quality' rating is not a value judgement on the quality of an individual study but rather an estimate of confidence that an estimate of the effect is correct and is unlikely to change with further research. Given that the evidence for long-term psychodynamic psychotherapy comes only from this single study, which has a moderate-to-small sample size, it is not possible to assert with a great degree of confidence that the addition of another study would not change the effect.

104	SH	UK ECT Improving Standards campaign group	Evidence review E	009 –084 – 088	General	ECT is listed as an intervention (p 9) to be considered for chronic depression. The Committee's literature search has not produced any ECT studies supporting the use of ECT in severe depression. This should be noted in the Committee's Discussion of the Evidence section (pp. 84-88).	Thank you for your comment. No relevant (and eligible) studies were identified for ECT for the first-line treatment or relapse prevention of chronic depression. However, the committee's discussion of the evidence section is concerned with how the committee interpreted the evidence that was reviewed. The committee therefore did not feel it appropriate to mention ECT in this section, consistently other interventions for which no eligible evidence was identified (behavioural therapies, psychodynamic psychotherapies, art therapy, music therapy, eye movement desensitization and reprocessing, peer support, mianserin, bupropion, mirtazapine, acupuncture, exercise, light therapy) are also not listed here.

105	SH	University of Essex	Evidence review D	114	General	Evidence review D: Fonagy 2015 – quality of life and functioning outcomesReview on p114 states that Fonagy 2015 reports no QOL or functioning outcome data. This is incorrect. Fonagy 2015 reportsFunctioning at 24 months follow-up (GAF): SMD= 0.69Both GAF (t=3.3, P<0.001) and QLESQ (t=3.1, P<0.001) at 24 month follow up show significant differences in favour of LTPP. Moderate-strong effect sizes can be extrapolated for QLESQ based on similar sample sizes for both measures.Additional details (on group sample sizes) are readily available on request from us or directly from Prof Fonagy as PI (as noted above, this study has University of Essex co-authors). These enable more precise effect size calculations (Hedges g) at each time point. Some of these are provided below. QLESQ at endpoint may be deemed imprecise as the CI crosses the zero line but other effect size estimates do not show any serious imprecision and indicate promising effects at 24 months follow up.GAFEndpoint LTPP: n=67; mean=57.3; SD=9.8Endpoint TAU: n=62; mean=52.5; SD=9.2Endpoint Hedges g=0.504 (95% CI: 0.154 to 0.855)24 months follow-up LTPP: n=67; mean=60; SD=12.924 months follow-up TAU: n=62; mean=52.4; SD=8.124 months follow-up Hedges g=0.7 (95% CI: 0.344 to 1.055)QLESQEndpoint LTPP: n=45; mean=38.8; SD=18Endpoint TAU: n=37; mean=32.6; SD=19.9Endpoint Hedges	Thank you for your comment. Data could not be extracted from the Fonagy et al. (2015) study for quality of life or functioning outcomes as Ns were not reported by arm. Given the size of the evidence base it was not possible to contact all authors for missing data.

						g=0.328 (95% CI: -0.109 to 0.766)24 months follow-up LTPP: n=42; mean=45.6; SD=19.924 months follow-up TAU: n=32; mean=32; SD=1924 months follow-up Hedges g=0.698 (95% CI: 0.25 to 1.147)These outcomes are promising and should be included in the review of further-line and chronic depression and taken into account in relation to evidence statements.	

106	SH	University of Essex	Evidence review D	133	General	Further line treatments: Evidence statements (p113 - critical outcomes)It is stated: “Very low quality evidence from 1 RCT (N=92) shows a clinically important and statistically significant benefit of augmenting antidepressant treatment with long-term psychodynamic psychotherapy, relative to continuing with antidepressants-only, on depression symptomatology at 2-year follow-up for adults with depression who have shown an inadequate response to at least 2 previous treatments for the current 20 episode”. If NICE accept that the quality assessment is incorrect (as per point 1 above), this statement should be revised and the treatment reconsidered in terms of recommended list of treatment choices. Note also that Fonagy 2015 meets criteria for chronic depression to and therefore an evidence statement for chronic depression should also follow suit.	Thank you for your comment. The Fonagy et al. (2015) study was downgraded for risk of bias due in part to the significant difference between groups at baseline. Almost regardless of what this difference is, it suggests that there is a problem with randomisation as randomisation is intended to balance out potentially confounding variables. The non-blinding of participants and intervention administrators also presents a risk of bias, however, the rating reflects the blinding of outcome assessors (otherwise the risk of bias would have been very serious). The Fonagy 2015 study was also downgraded for imprecision. The thresholds for clinically important SMD effects are -0.5 and 0.5. The 95% CI for the depression symptomatology outcome at 2-year follow-up is -1.1 to -0.26 and this crosses the threshold of no effect (although it does not cross the line of no effect). This is consistent with the methods outlined in Supplement 1. The Fonagy 2015 study was also downgraded due to potential reporting/publication bias due to funding from the International Psychoanalytic Association. This source of funding represents a potential interest. The committee agreed that it is important to rate equivalently across

							psychological and pharmacological trials, and as a pharmacological trial would be downgraded for publication bias if it was partially funded by a pharmaceutical company, then it is also consistent to do so here. It is important to note that the GRADE system 'quality' rating is not a value judgement on the quality of an individual study but rather an estimate of confidence that an estimate of the effect is correct and is unlikely to change with further research. Given that the evidence for long-term psychodynamic psychotherapy comes only from this single study, which has a moderate-to-small sample size, it is not possible to assert with a great degree of confidence that the addition of another study would not change the effect.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

107	SH	UK ECT Improving Standards campaign group	Evidence Review D	178	036-039	'There was some very limited evidence that ECT may be beneficial as a further-line treatment, either alone or in combination with exercise. The committee used this evidence to recommend that ECT may be considered for use as further-line treatment when other treatments have been unsuccessful.' The 'very limited' evidence of ECT being beneficial alone was one small RCT (with no placebo control) of 'low/very low' quality, in comparison to ADs (Comparisons 60 and 61), finding mixed outcomes in relation to 'depression symptomatology', only one of the two comparisons finding an advantage for ECT in terms of 'response', and no evidence at all relating to Quality of Life or remission. There was also no evidence beyond the end of treatment. Comparison 62 found that ECT was no more effective than exercise re symptoms or remission (moderate/low quality). Even the two comparisons (63 & 64) finding ECT to be effective in combination with exercise relied on just one RCT with no placebo control group, no response data, no Quality of Life data, and no follow up data beyond the end of treatment. This would seem to fall well short of any reasonable criteria for recommending use of a treatment . We therefore request that this recommendation be revoked.	Thank you for your comment. The committee noted the limitations of the evidence for ECT for further-line treatment, both in terms of quantity and quality in the committee discussion of the evidence section. However, the committee were also aware that ECT may be beneficial for some people and that removing it as an option would be detrimental to some people with depression. The recommendations on ECT limit its use (to when a rapid response is needed, when other treatments have failed, or based on patient preference). On this basis, the committee did not consider it appropriate to remove this recommendation, but did amend the wording to emphasise that ECT should generally not be used, and should only be considered in the limited circumstances described.

108	SH	UK ECT Improving Standards campaign group	Evidence Review D	178	039 - 041	'However, the committee were aware that there may be other situations where ECT could be considered: when a rapid response is needed (and the committee provided an example of when this might be the case)' It is not clear what this 'awareness' was based on or whether it should inform recommendations. There is no evidence that ECT is effective in the case of the example given in the Draft Guidance (…' if the depression is life threatening because the person is not eating or drinking'). Furthermore, a person refusing to eat or drink for any period of time would be in hospital and would surely not be allowed to die by medical staff. If 'life threatening' is intended, however, to include risk of suicide (and that needs clarifying) that would not be evidence-based. There is no evidence that ECT prevents suicide. In a recent study 14,810 ECT patients were 16 times more likely to try to kill themselves than a matched control group of 58,369 (Peltzman, et al., 2020). Even after controlling for 'demographic, clinical, and service use characteristics,' including psychiatric diagnoses and inpatient admissions, the ECT patients were 1.3 times more likely to have killed themselves (a non-significant difference). Another recent study, using the Swedish national registry, claimed its findings 'support the continued use of ECT to reduce suicide risk in hospitalized patients who are severely depressed' (Ronnqvist,	Thank you for your comment. The committee's awareness of the limited circumstances in which ECT may be beneficial for some people with depression was based on their clinical experience. The recommendation does not specify the use of ECT to prevent suicide, and an example is provided to clarify what is meant by life threatening. The committee did not review non-RCT evidence for benefits or harms (such as the papers cited: Peltzman et al. 2020; Ronnqvist et al. 2021; Tsai et al. 2021), as this was outside the scope of this update.

						et al.,, 2021). The overall difference in suicides over 12 months between the ECT group (1.1%) and the non-ECT group (1.6%) was small. The difference was significant, but only for patients who were psychotic, not for those who were depressed but not psychotic. Nor did the difference hold for people under 45. Furthermore, at three months (at which point any difference might more reasonably be attributed to ECT than at 12 months) there had been no significant overall difference. More importantly, 'Suicide was defined as death caused by intentional self-harm (ICD-10 codes X60-X80) or by an event of undetermined intent (ICD-10 codes Y10-Y35).' The most recent study found that 1,524 homeless US veterans who received ECT had made significantly more suicide attempts, at 30 days follow up, than 3,025 matched homeless veterans who hadn't had ECT. The difference remained significant at 90 days and one year (Tsai, et al., 2021). PELTZMAN, T. et al. (2020). Effects of Electroconvulsive Therapy on short-term suicide mortality in a risk-matched patient population. Journal of ECT, 36(3), 187-192RONNQVIST, I. et al. (2021). Electroconvulsive therapy and the risk of suicide with major depressive disorder. JAMA Network Open, 4(7), e2116589. TSAI, J. et al. (2021). Effects of Electroconvulsive Therapy on suicidal behavior and emergency department use among homeless veterans: a propensity score-	

						matched study. Journal of Clinical Psychiatry, 82(6), 21m13935.	

109	SH	University of Essex	Evidence review D	179	General	Further-line treatments – quality of life and functioning outcomes The committee concluded that recommendations for further line treatments would not be adjusted in light of sparse evidence of QOL outcomes across the set of studies. In our opinion this is an inappropriate conclusion to draw because: Where there is evidence complementing symptom outcomes for a severely disadvantaged population (long term/resistant depression), this additional evidence should be used to enhance patient choice rather than limit choices to the lowest common denominator (symptom outcomes). There is evidence that many pharmaceutical trials collect QOL or functioning outcomes but do not report them (e.g. see Paludan-Muller et al, 2021 who conclude that "regulatory agencies should refuse to approve drugs or new indications based on incomplete reporting"); this also appears true of several psychological therapy trials in this review Studies collecting but not reporting QOL/functioning outcomes carry a significant additional risk of bias which is currently not being captured by NICE GRADE assessments. NICE GRADE assessments take the only reported outcomes as a starting point and ignore instances where other outcomes were clearly collected according to the trial protocols but not reported. This is a very serious risk of bias over and above the risks currently scored in the	Thank you for your comment. Selective reporting bias is included under risk of bias in GRADE, and assessments have been made by study in Supplement D. If a study reported a protocol this was checked against reported outcomes and rated as at high risk of bias if all the outcomes specified a priori were not reported. Studies were also rated as at high risk of selective reporting bias if outcomes were not reported (in an extractable form) for all measures mentioned in the paper. If a protocol was not registered risk of selective reporting bias was rated as unclear. Data could not be extracted from the Fonagy et al. (2015) study for quality of life or functioning outcomes as Ns were not reported by arm. Given the size of the evidence base it was not possible to contact all authors for missing data. Therefore, the committee did not consider it appropriate to add a clinical evidence statement in support of long-term psychodynamic psychotherapy.

						GRADE system because in some instances, the non-reporting of QOL outcomes may be due to the QOL findings contradicting the positive findings on symptoms. Together, the widespread collection but non-reporting of secondary outcome points to the serious limitations to the evidence base in this review. Therefore where QOL outcomes are reported and indicate promise in line with symptom indications, these should be employed to increase patient choice, not to limit it.As a minimum, we request that NICE add a clinical evidence statement in support of LTPP based on the reported effect size for the GAF at 24 months follow up; and that this informs further considerations and recommendations.	

110	SH	Janssen	Evidence Review D	181	General	We are concerned that the guideline committee relaxed their criteria for looking at treatment resistant depression and mixed evidence from population that had no or limited response to treatment. We are understanding of the challenges associated with the sparse evidence base, but we do note that the effectiveness of treatments is significantly determined by the number of previous failures, as demonstrated by the STAR*D study (Rush et al, 2006). We are concerned that this approach may not be reflective of identifying appropriate treatments for different places in the pathway, especially with a view to the future when new treatments are available that specifically target people with treatment resistant depression. We would ask NICE and the guideline committee to keep this in mind for future updates of the guideline so that an appropriate review based on the number of failed treatments can be conducted and appropriately modelled to look at the sequencing of further lines of treatments in the pathway could be conducted in the future.	Thank you for your comment. When reviewing the evidence for further line treatment the committee had originally decided to separately examine the evidence base for treatment resistant depression (usually defined as no or limited response to two adequate courses of an antidepressant) from no or limited response to treatment. However, after carefully reviewing the trial populations and the variation in the criteria used to identify both no or limited response and treatment resistance the committee came to the view that there were considerable similarities and overlaps between the two populations and therefore decided to use the same data sets for both questions to inform the development of recommendations for no or limited response. The committee were also aware of problems in defining/categorising treatment resistant depression, particularly with regards to non-pharmacological interventions, as there does not appear to be a similarly accepted definition of failure to 2 adequate courses of psychological therapy. In the current evidence base, the number of failed treatments is frequently not reported. Where this data is available in the future it would be reasonable to assume that a NICE guideline could consider this, either in the

							context of a subgroup analysis or stand-alone review question. However, that will be a matter for future scoping and review protocol development.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

111	SH	EMDRIA	Evidence review D/supporting documentation D1	116	28	In Evidence review D (Supporting documentation D1) – further line treatment – one EMDR trial was included but no weight appears to have been placed on it, and it receives no mention in the committee's discussion of the evidence (p116, line 28 onwards):Ostacoli (2018) N=82 CBT vs EMDR augmentation – clinically important and significant benefit of augmenting with EMDR relative to individual CBT.This trial includes 6 month follow up data and an active control – CBT. Although it was not intended as a non-inferiority trial, it found that EMDR was at least as effective as CBT for further line treatment, with 22/40 patients achieving remission (17 for CBT). Given that CBT is a recommended further line treatment, we would ask the committee to look again at this evidence alongside the other EMDR trial evidence that we highlight, and review whether a 'consider' recommendation may be warranted for EMDR as a further line treatment.	Thank you for your comment. In response to your other comments, a specific supplementary search has been run for EMDR. However, no eligible studies were identified, apart from the Ostacoli 2018 study that was already included in this review. Details of the additional EMDR search have been added to Appendix B of the relevant evidence reports (Evidence reports B, C, D, E, and F). The excluded studies lists of Supplement B and Supplement D have now been updated with the additional studies which were identified, and the reason for exclusion. The committee decided not to recommend EMDR for further-line treatment as there was only data from a single study, the effects on remission (at endpoint and 6-month follow-up) were not statistically significant, and the trial was not sufficiently powered to conclude non-inferiority compared to CBT.

112	SH	University of Essex	Evidence review D: further line	025 - 367	Tables 7 and 75	Evidence review D: further line treatments The study "Fonagy 2015" involved University of Essex co-authors/researchers. We have concerns about the interpretation and assessment of this study which has led to the misrepresentation of this research in the draft guideline. We would ask that you correct these misrepresentations given that many audiences rely on the factual correctness of NICE guidelines and may not refer back to the original source to check accuracy: Table 7 (p25) states that the comparison group is "any antidepressants" whereas the comparison group is in fact Treatment as Usual (which was highly varied and included, in some cases, CBT)Table 7 omits functioning and quality of life outcomes that are reported in the study. Table 75 reports an unfair and inaccurate GRADE assessment of the study – see details belowGRADE assessment for Fonagy 2015 (Table 75) – "very low" Imprecision: rated 'serious' for 24 months follow up on grounds that the "CI crosses thresholds for both clinically important benefit and no effect". The 95% CI is 0.26 to 1.1. The SMD is 0.68. The CI does not cross the line of no effect so this is incorrect (N.B. this is a SMD not an odds ratio so the line of "no effect" is zero, not 1). In terms of the threshold for 'clinically important benefit', what is this? If it is 0.5, this needs stating and justifying (particularly for what is a severe and chronic group of patients). Further,	Thank you for your comment. With regards to the imprecision rating in Table 75 that is highlighted in your comment. The thresholds for clinically important SMD effects are -0.5 and 0.5. These thresholds are outlined in Supplement 1. The 95% CI of -1.1 to -0.26 crosses the threshold of no effect (although it does not cross the line of no effect), and so it has been downgraded once. This is consistent with the methods outlined in Supplement 1. In Table 72, the lower confidence bound is 0.21 and the higher is 0.33. This is therefore rated as 'no serious imprecision' as the confidence interval does not cross any threshold for a clinically important effect, and is consistent with no effect wherever the true point estimate is in this 95% confidence interval. This estimate of outcome demonstrates ineffectiveness but is not imprecise. The same is true for the example you cite in Table 71 where confidence intervals include -0.39 to 0.04 and -0.36 to 0.07. The Fonagy 2015 study was downgraded for risk of bias due in part to the significant difference between groups at baseline. Almost regardless of what this difference is, it suggests that there is a problem with randomisation as randomisation

						the threshold (if it is 0.5) appears to have been applied inconsistently between studies. Compare, for example to Table 72 in which imprecision is rated as 'no serious imprecision' with a lower confidence bound of 0.21. In Table 71 a rating of 'no serious imprecision' is given for a lower CI bound of 0.04 and another of 0.07. What is the clinical decision threshold being applied in these GRADE evaluations and why does it appear to be inconsistently applied to different RCTs? Is the down rating on grounds of Optimal Information Size? In which case what is the OIS being applied and is it being applied consistently across studies? Note that other precision parameters such as variances and standard errors for Fonagy 2015 are among the lowest reported in the pool of studies, which contradicts the suggestion that the effect size is not relevant or precise.Reporting bias: reporting bias is noted as a concern on grounds of partial funding by the International Psychoanalytic Association. We stated very clearly in our stakeholder response to NICE in 2017 that this was incorrect. We request that this be corrected. As we stated in 2017, the total funding received from this organisation was ≤ $20K over a ten-year period. This represented less than 2% of the overall research programme budget. More importantly, this income was received to support sub-projects linked to the research programme and not for the	is intended to balance out potentially confounding variables. The non-blinding of participants and intervention administrators also presents a risk of bias, however, the rating reflects the blinding of outcome assessors (otherwise the risk of bias would have been very serious). In response to the additional information provided regarding the rating of 'publication bias's due to funding from the International Psychoanalytic Association. This source of funding represents a potential interest. The committee agreed that it is important to rate equivalently across psychological and pharmacological trials, and as a pharmacological trial would be downgraded for publication bias if it was partially funded by a pharmaceutical company, then it is also consistent to do so here.

						RCT itself. The International Psychoanalytic Association had no input into the design, conduct, analysis, or interpretation of the findings of RCT. We offered to provide supporting documentation around this issue on request and no request was received.Risk of bias: recorded as “serious” because of group difference at baseline. As we stated in our 2017 stakeholder response, we consider this an unreasonable down rating. The baseline differences were on education and benefits and not on any clinical characteristic. The variables most likely to affect responsiveness were those used in the Fonagy 2015 minimization protocol - namely gender, baseline severity and on/off medication. No imbalances between the groups were found in respect of these or any other clinical/prognostic variables. Moreover, when the chance imbalance in education was moderated for by the statistical analysis, the effect remained and was robust. We consider this an unreasonable down-rating of the study. It is also inevitable that down-rating on this basis will have been applied inconsistently within the review since many RCTs in the reviews do not report baseline education or benefits.	

113	SH	Institute of Psychoanalysis	Evidence review D: further-line treatment	025 367-368	Table 7 and Table 75	Miss-classifying of the Tavistock Adult Depression study (Fonagy et al., 2015)We note that as stated in Table 7 and Table 75, the study is classified erroneously as augmenting any antidepressant with a psychological intervention versus continuing with the antidepressant only. As clearly indicated this study investigated the treatment of long-term psychoanalytic psychotherapy + TAU versus TAU. The study was designed as a pragmatic trial in order to reflect common NHS practice treatment guidelines. As such, TAU consists of a range of short-term treatments as recommended by NICE (2009), including CBT, counselling, IPT, CMHT, to which the primary care provider referred the patients to. The study did not follow an augmentation strategy. The study used a fundamentally different definition of TRD than proposed in this guideline that uses an exclusively pharmacological definition that requires operationalising of dose and duration monitoring.Furthermore, quality of life and functioning outcomes that are reported in the published paper are not included in Table 7 and we ask you to add them. The study used the GAF, and the QlesQ.	Thank you for your comment. The interventions in the Fonagy 2015 study were classified as long-term psychodynamic psychotherapy + any antidepressant versus any antidepressant, as over 80% of participants were receiving antidepressants at baseline in both arms. The committee agreed that where this was the case categorising as 'any antidepressant' was more informative than the ill-defined treatment as usual which can be used to refer to a vast range of interventions or no treatment at all. The further-line treatment review includes studies of both those with no or limited response and those with treatment resistance. The decision to use the same data sets for both questions to inform the development of recommendations for no or limited response was based on considerable similarities and overlaps between the two populations. The committee were also aware of problems in defining/categorising treatment resistant depression, particularly with regards to non-pharmacological interventions, as there does not appear to be a similarly accepted definition of failure to 2 adequate courses of psychological therapy. Data could not be extracted from the Fonagy

							2015 study for quality of life or functioning outcomes as Ns were not reported by arm. Given the size of the evidence base it was not possible to contact all authors for missing data.

114	SH	Institute of Psychoanalysis	Evidence review D: further-line treatment	111112	010-040006-013 018-030032-033	Furthermore and in relation to the above, Should say: 'relative to continuing with antidepressants and community treatment'.Should say: 'relative to continuing with antidepressants and community treatment'Should say: 'discontinuation of antidepressant medications'.Should say 'continuing with antidepressants and community treatment as usual'This is incorrect: The effect was in fact significant and spoke to less need for medication after ISTDP	Thank you for your comment. The interventions in the Fonagy 2015 study were classified as long-term psychodynamic psychotherapy + any antidepressant versus any antidepressant, as over 80% of participants were receiving antidepressants at baseline in both arms. The committee agreed that where this was the case categorising as 'any antidepressant' was more informative than the ill-defined treatment as usual which can be used to refer to a vast range of interventions or no treatment at all. Receipt of antidepressant medication after initiation of the intervention was not an outcome of interest and so evidence for this was not reviewed.
115	SH	LivaNova	Evidence review E	9	General	Although Electroconvulsive therapy (ECT) is listed in the final scope1 and multiple places in the evidence review2 as an intervention, no other treatment modalities are listed for assessment, like Transcranial magnetic stimulation (TMS) or Vagus Nerve Stimulation (VNS). Given the inclusion of TMS in the draft guideline3 and the cessation of NICE Pathways4, we would like to request that a hyperlinked reference to the Vagus Nerve Stimulation (VNS) Interventional Procedure Guidance (IPG 6795) be added.Reference:https://www.nice.org.uk/guidance/gid-cgwave0725/documents/final-scope	Thank you for your comment. ECT was included as in intervention in a number of evidence reviews, as you state, but very little evidence relating to its use was identified for inclusion. TMS and VNS were not included as interventions as they have both been subject to separate NICE appraisals. A link to the NICE guidance on TMS is already included as you note, and a link to the NICE interventional procedure guidance on VNS has now been included as well.

						Depression evidence review E (nice.org.uk)Depression guideline for consultation (nice.org.uk)We are withdrawing our NICE Pathways service | NICE Pathways | Our programmes | What we do | About | NICEImplanted vagus nerve stimulation for treatment-resistant depression (nice.org.uk)	

116	SH	Wellmind Health	Evidence review H	61	10	5. 'Evidence review H: Access' did not include research studies into digital therapeutic (DTx) courses and the benefits they provide in improving access to and uptake of treatments for underserved groups. In addition, digital delivery can also help improve wider access for less underserved groups that have access to and the capability to use digital devices, through reduced waiting times and their on-demand nature. They are also proven to reduce costs and waiting lists.	Thank you for your comment. No eligible evidence was identified that examined digital interventions to promote access. However, there was evidence for benefits, in terms of uptake and acceptance of treatment, associated with delivering interventions using different methods in order to promote access, for example using telephone delivery of treatment or services to older adults or black, Asian or minority ethnic groups. The committee discussed that, in addition to the telephone, there is now an increased use of other methods of communication in the NHS, particularly since the Covid-19 pandemic. This can include text messages, emails or video consultations. While this is welcomed by many people, the committee also discussed the importance of patient choice and problems associated with digital exclusion or digital poverty: some people may prefer a face-to-face intervention either because they are not comfortable using technology, because they lack the appropriate device or internet connection, lack a private and confidential space, or because of wider issues associated with difficulties in accessing services that intersect with the vulnerable groups identified in this review. The committee therefore recommended interventions be available via a range of different methods, and the methods of delivery should be

							guided by patient choice, with remote consultations only being used for people who wish to access and are able to access services in this way.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

117	SH	Mind	Evidence Review I	General	General	While we very much welcome the inclusion of a greater emphasis on patient choice within these guidelines, we recommend that a greater focus within this evidence review is placed on evidence of people's experience of treatments as part of this broader review of patient choice.	Thank you for your comment. The committee agreed that a qualitative evidence review identifying the factors that can promote choice and act as barriers to choice, would enable recommendations to be made that improved the implementation of shared decision-making and ensured the people's preferences were taken into consideration, better than qualitative review looking at people's experiences of individual treatments.

118	SH	University of Essex	Evidence review I	General	General	Evidence review I: patient choice As part of a very large group of stakeholders, we have previously advised on the need for a review of 'patient experience' to be included in the guideline. The joint stakeholder response to the previous draft guideline was very explicit that this means qualitative research in which people with depression were asked about their experiences of specific treatments; and that this should inform treatment recommendations. The joint stakeholder group also advised (in direct correspondence in early 2020 following NICE publication of the new Scope) that a review of 'patient choice' as proposed in the scope would not adequately address our concerns. See McPherson & Beresford's 2019 article in Disability & Society "Semantics of patient choice" for a fuller rationale for our advice on this issue.While we are disappointed that our specific advice, along with that of the wider stakeholder group has been disregarded, we acknowledge that the review of 'patient choice' included in the draft guideline represents a large volume of detailed work and has generated some useful insights. Nevertheless, in our view and as per our original advice, the review question chosen for this review was the wrong starting point for this element of the guideline. As such, the resulting set of included studies represents a very disparate set of studies. The	Thank you for your comment. As specified in the scope, the experience of care section from the 2009 guideline was not included in this update. However, a new review question on patient choice was added to this update that includes a systematic review of primary qualitative studies that focus specifically on service user and practitioner experience around choice of treatment. As outlined in the protocol, the committee agreed that it was important to include both service user and practitioner perspectives given the roles that both play in shared decision-making. Although the studies might have been disparate in their aims and focus, only findings relevant to choice of treatment were extracted and included in this review. Thus, although studies may have included experiences of depression itself, these were not extracted unless they had a bearing on choice and decision-making. Similarly, studies may have included experiences of treatments, for instance, antidepressants or self-help, however, only retrospective experiences of how these treatments were offered, initially discussed, and initial preconceptions and preferences were relevant to this review. The predominance of antidepressants and

						decision to include and exclude certain studies does not appear to be systematic or consistent as a systematic review should be. The majority of included studies seem to fall into the following 4 domains:A handful of studies specifically about choice or shared decision making as per the aims of the review (Badger 2007, Garfield 2004, Lawrence 2006, Simon 2007, van Grieken 2014)Studies about the experience of depression i.e. experience of illness (e.g. Stark 2008, Sterner, 2020, Ward 2014, Poleshuck 2013). Whilst of some general interest and relevance, experience of illness per se is not directly relevant to patient choice of treatment and hence the aims of the review. Moreover, there is a vast literature about experiences of depression and those included in the present review are a very tiny minority of these, meaning those included here are in no way and could not possibly be comprehensive or systematic.Studies about the experience of certain treatments such as antidepressants or combined med/psych or self help or support groups (e.g. Anderson 2013; 2015; Badger 2006; Bayliss 2015; Buus 2012, Chew Graham 2018, Cramer 2014, Green 2017, Jaffray 2014, MacDonald 2007, Schofield 2011, van Geffen 2011). Our original advice was to focus on these types of study for all treatment types. Having included these only for some types of treatment is wholly inconsistent	primary care experiences is driven by the eligible studies available. The population included adults with clinically important symptoms of depression (who may or may not have a diagnosis of depression). The committee agree that diagnostic status was under reported in these studies. However, this was reflected in the GRADE CERQual ratings and taken into account when interpreting the evidence. The McPherson et al. (2020) and McPherson & Armstrong (2012) reviews were checked for any relevant primary studies. However, meta-synthesis results were not appropriate to extract due to differences in the review questions. These studies are listed in the excluded studies in Supplement I. As outlined in the review protocol, the perspectives of carers was not included in this review, and therefore Priestley et al. (2016) was not eligible for inclusion.

						with having excluded studies of patient experiences of psychological treatments – particularly given the draft guideline focuses on psychological treatments as first line options.Studies of clinician experiences of managing depression or clinician experiences/views on certain treatments (Anthony, 2010, Bouroughs 2006, Chew Graham 2002, Dickinson 2010, Dumesnil 2018, Iglesias-Gonzalez 2021 , Johnson 2017, Jones 2013, Keeley 2014, Kirkpatrick 2020, Maxwell 2005, Mercier 2011, Parker 2020, Patel 2014, Pollock 2003, Railton 2000, Wilhelmsen 2014, Wittink 2011). These studies of mainly GP experiences of managing depression in primary care dominate the review. Yet they are not directly relevant to understanding how patients might experience treatments or choose between them. Moreover the set of studies in this category is not comprehensive and leaves out other studies on the topic including a University of Essex systematic review on the topic (see below).In spite of the inconsistency and unclear focus of the review there are some useful insights generated from these different domains of research. However, given the limits of the RCT evidence base in some parts of the draft guideline along with the heavy reliance on committee knowledge and experience, it is vital that this element of the guideline is of high quality and	

						makes best use of the qualitative evidence available. The review as it stands is limited because:It is heavily weighted towards GP experiences instead of prioritising patient and carer experiencesIt is heavily focused on experiences of antidepressants (excluding psychological treatments) which is inconsistent in terms of inclusion criteria and not particularly helpful to inform patient choice given the new draft guideline is focusing on prioritising psychological treatments.In many of the studies involving patient views or experiences, the diagnostic status of participants is unclear, meaning that we cannot even be certain if participants in these studies had major depressive disorderWe would recommend that the review is refined to focus more clearly on patient experiences of treatments and carer experiences and to accommodate studies on patient experience of psychological treatments. We recommend studies of patient experience be included only where there is clear indication that participants had depression via a diagnosis or a score on a validated scale. Specifically we advise that the following University of Essex research should be included:McPherson et al (2020) Patient experiences of psychological therapy for depression: a qualitative metasynthesis. This review is precisely the sort of qualitative review	

						recommended by the joint stakeholder group focusing on patient experiences of treatments. It includes 37 studies representing the experiences of 671 patients. All studies had to demonstrate that participants met criteria for depression using a formal mechanism for diagnosis. This review contains important insights relevant to patient choice of psychological treatments.Priestley et al (2016) Experiences of adults providing care to a partner or relative with depression: A meta-ethnographic synthesis. This is a systematic review of 15 studies representing the views and experiences of 263 family caregivers. This also contains important insights relevant to patient choice and overall management of depression. Studies about carer experiences of supporting a family member with depression have not been included in the current review and yet are equally as relevant as clinician perspectives. The joint stakeholder group specifically advised this be included in the review. McPherson & Armstrong (2012) General practitioner management of depression: a systematic review . This is a review of 13 qualitative studies representing the experiences and views of more than 200 GPs. The set of studies reviewed overlaps with a number of primary studies included in the current review. The review reveals useful insights into approaches to supporting patients in primary care to obtain the	

						right sort of treatment.National Survivor User Network (2020) Informing a Decision Guide for Psychological Treatments for Depression. This consultation report was co-produced by experts-by-experience in collaboration with the University of Essex, involved 28 people with lived experience and directly addresses issues around patient choice of psychological treatments for people with depression. In our opinion this report is of critical relevance to the 'patient choice' review and more directly addresses the review question than the vast majority of other studies included.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

119	SH	The Association of Clinical Psychologists UK	Evidence Review I	General	General	The review evidence on service user experience We argued that creating sound policy requires that we draw on a diverse range of evidence, which includes qualitative research and service-user feedback. We were particularly concerned that the previous draft did not update the service-user experience section, thereby ignoring huge amounts of published studies providing the insights and knowledge of service-users. As such, we asked for a full systematic review of primary studies of service user experience of treatments, employing formal qualitative methodology to synthesise the findings and to incorporate these into the treatment recommendations. The guideline committee decided, however, instead to focus on a systematic review of 'patient choice'. We have questioned that decision and advised that despite its merits, it would not provide the appropriate evidence needed to inform treatment recommendation. Whilst the qualitative review carried out has highlighted the need for greater choice, which was indeed incorporated into the overall tenet of this draft guideline, it has not yielded an insight into the views and experience of the specific (pharmacological, psychological, psychosocial and physical) treatments. We have previously pointed to the numerous existing studies that would not only strengthen this treatment guideline by ensuring that the views and	Thank you for your comment. As specified in the scope, the experience of care section from the 2009 guideline was not included in this update. However, a new review question on patient choice was added to this update that includes a systematic review of primary qualitative studies that focus specifically on service user and practitioner experience around choice of treatment.

						experiences of those who use the treatments recommended are properly taken account of, but would also adhere to what we believe to be the sine qua non of a publicly funded body tasked with devising clinical guidelines.We therefore recommend that this particular review is refined to focus more clearly on experiences of treatments.	

120	SH	Institute of Psychoanalysis	Evidence review I	General	General	Patient choice versus patient experience of treatment. A systematic review of qualitative studies informing questions around treatment choice is a welcome amendment. It has indeed provided important insight into service users' experience of 'patient choice' or the lack of it, and as such enriched the guideline in a meaningful way. However, this research question has not investigated the pivotal aspect of patient/service user experience of the psychological and medical treatments reviewed in this guideline. There is an important distinction to be made between making general decisions on which psychotherapeutic interventions are the most effective, and making contextually-sensitive decisions on which interventions will be effective (appropriate) for which patients/service users. We do not believe the present version, nor the suggested changes for the third revision of the guideline, adequately address these latter considerations, and thus will not provide sufficient guidance for clinicians about making contextually sensitive referrals.As such, we are concerned that the available evidence base is not being fully utilised. A full systematic review of primary studies examining experience of treatment is required, employing formal methodology for synthesis of study results, and incorporating these findings into a broader approach for the review.	Thank you for your comment. As specified in the scope, the experience of care section from the 2009 guideline was not included in this update. However, a new review question on patient choice was added to this update that includes a systematic review of primary qualitative studies that focus specifically on service user and practitioner experience around choice of treatment.

121	Individual	Individual 5	Evidence Review, B, E	General	General	Subgroup analysis should include a comparison of metacognitive therapy with CBT, two published studies are available (Jordan et al, 2014; and Callesen et al, 2020).	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. Metacognitive therapy (MCT) was included in the class of cognitive and cognitive behavioural therapies (as was CBT). Jordan 2014 was included in the NMA that informed the recommendations. However, because the study included a within-class comparison it is not included in the forest plots, and is not mentioned in the text as the within-class comparison of MCT versus CBT, was not regarded by the committee as a critical comparison.

							Callesen et al. (2020) was identified by the searches but did not meet inclusion criteria as less than 80% of participants were receiving first-line treatment (35% receiving psychiatric medication at baseline). This study is in the excluded studies list of Supplement B1.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

122	SH	EMDRIA	Evidence reviews	General	General	A number of EMDR papers were excluded because they related to trials with patients with a comorbid physical health problem – please see our comments above about the committee's decision to exclude these trials from the review (7, above). The references can be found in the Dominguez (2020) review. We think that they are potentially relevant to the patient subgroup where depression relates to adverse life events, particularly physical health problems:Behnammoghadam et al (2015): n=60 – Cardiac patients with depression Kao et al (2018): N=57 – Cardiac patients with depression symptomsRahimi et al (2018): n=90 – patients receiving haemodyalisis.Hatefi et al., (2019): n=68 – patients with Spinal cord injury	Thank you for your comment. There is separate NICE guidance on Depression in adults with a chronic physical health problem (CG91), and that is the rationale for excluding trials that specifically recruit participants with a physical health condition in addition to depression.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

123	SH	The Association of Clinical Psychologists UK	Evidence reviews B, D, E, F, G	General	General	The categorisation of depression We noted during both previous consultations that the draft guideline is out of step with US and European guideline methodologies, leading to erroneous and unhelpful classification of research studies which do not match clinical or service user experiences. In particular we expressed our concerns to (a) the dichotomisation of depression into 'less severe' and 'more severe' in the evidence review of treatment of a new episode of depression, and (b) the separation of the more complex forms of depression into distinct groups. We remain very concerned that these two key methodological issues have not been changed as advised. Given that the treatment recommendations are based on these unvalidated distinctions of depression, their generalisability and applicability to clinical practice is highly questionable/disputable. We therefore urge for these categorisations to be reconsidered. We stress again that any treatment recommendations based on methodological choices that have not been validated will need to be viewed with caution.The distinction between less severe and more severe depressionWe uphold that there is neither methodological/statistical nor clinical validity of the categorisation of first episode depression into 'less severe' and 'more severe'. Most researchers and clinicians have a common	Thank you for your comment. The committee considered the current NICE classifications of mild to moderate and moderate to severe depression, and agreed that although these classifications have been adopted quite widely there is potential uncertainty with regards to the management of moderate depression. The committee agreed that a dichotomy of less and more severe depression was clearer, and the guideline includes definitions (that less severe depression includes the traditional categories of subthreshold symptoms and mild depression, and more severe depression includes the traditional categories of moderate and severe depression) in order to improve practical utility. The committee considered the distinction between less severe (subthreshold/mild) and more severe (moderate/severe) depression to be clinically meaningful in terms of supporting effective clinical decision making and being aligned with how clinicians conceptualize depression (in particular, GPs and other primary care staff, given that the majority of people with depression and almost all first line presentations of depression are managed in primary care). The committee did not consider it problematic that the categorisations of depression used in this guideline were not in line with US and European

						understanding that depression severity levels fall into three broad categories of mild, moderate and severe (e.g., Wahl et al., 2014). Indeed, in the guideline itself these are referred to as the "traditional subcategories" (e.g., evidence review B, p.10, l.26). Having asked for it on numerous occasions, we are still short of a plausible explanation as to why the committee decided to diverge from traditional categorisations found in the majority of literature and, in so doing, adopt an unvalidated and unreliable methodology. We are particularly disappointed as in the last response that we received it stated: "these have been updated and are now based on published work". This, however, is not true. None of the studies cited (Carmody, 2006; Rush, 2003; Uher, 2008; Wahl, 2014) provide evidence of a dichotomisation of depression severity. Moreover, Wahl et al (2014) clearly advocates the three traditional severity levels and provides clear threshold values for mild, moderate and severe depression (see their Table 3, p. 81). We further are concerned about the stringent inclusion/exclusion criteria for the two treatment reviews for new depression episodes. Many bona fide RCTs were excluded as their study populations reported > 20% of patients with chronic depression (> 2 years), > 20% of patients with a personality disorder, and > 20% receiving additional treatment (e.g.,	guideline methodologies as there was no reason to believe that the different guidelines would be used in conjunction (thereby creating confusion), and the committee prioritised alignment with clinical practice in the UK. As highlighted in your comment, for the first-line treatment review, studies were not included if more than 20% of participants were already receiving treatment for depression. While in the further-line treatment review, studies were required to have at least 80% of the participants showing no or limited response to previous treatment for the current episode of depression. The guideline review questions focus on specific populations – first-line treatment, further-line treatment/TRD, and there is not a question that specifically looks at a heterogeneous population where 21-79% are already on antidepressants and then have a psychological therapy added. Although the committee were aware that this may reflect standard care settings, the aim of the first-line treatment review question (RQ 2.1-2.2) is to estimate the effect size for psychological treatments, for antidepressants, and for combined psychological and antidepressant treatment and if the psychological studies include a significant proportion of participants

						antidepressants or psychiatric care). Research has shown that 45% of patients diagnosed with depression are also suffering from a comorbid personality disorder (Friborg et al., 2014). In addition, usage of antidepressants is highly prevalent, with 17% of the adult population in the UK (7.3 million people) taking antidepressants between 2017-2018 (https://www.gov.uk/government/publications/prescribed-medicines-review-report/prescribed-medicines-review-summary). Not only is it rather uncommon for meta-analyses of psychotherapy trials for depression to exclude studies with more than 20% use of antidepressants (e.g., Cuijpers et al., 2021a, Cuijpers et al., 2020), exclusion of these and other criteria limits the representativeness and generalisability of the results. The distinction between more complex forms of depressionWe uphold that there is no evidence that warrants the distinctions between chronic depression, treatment-resistant depression, depression with personality disorder and psychotic depression. By doing so, this draft guideline provides erroneous and unhelpful classification of research studies with the consequence that treatment recommendations may also be erroneous.We notice that the review question for further-line treatment has been changed and now includes studies of psychotic depression, depression with	who are actually receiving combined treatment this has the potential to give a misleading estimate of the effect of psychological treatments, and this is particularly problematic where these might be recommended as monotherapy. The committee discussed this at length and although it was appreciated that it was unfortunate that studies would be excluded on this basis, it was agreed that the line had to be drawn somewhere based on the rationale above. The evidence from the further-line treatment/TRD depression review is applicable to the population who are already on antidepressants, and the first-line review is applicable to those who are not, or who receive combination antidepressants and psychological therapies from the outset. Whereas, looking at the evidence from a very heterogeneous population would not provide good evidence for any of these groups. This may mean that some studies are missing, because the population doesn't fit into either review, but there is evidence for psychological therapies for people who are already on antidepressants and those who aren't, and for psychological and pharmacological interventions used in combination, and this evidence has been used to

						personality disorders, chronic depression, and so-called treatment-resistant depression. However, in light of having kept the other reviews, we feel it has not really addressed the issue and may in fact lead to further confounding outcomes.In addition to being out of step with European and US guidelines, we are in particular concerned that it will be out of step with the clinical understanding of the groupings in the UK, especially with respect to chronic depression, and will thus lead to confusion instead of providing helpful guidance.Most individuals suffering from chronic depression (as defined here as lasting for at least two years) would have sought previous help; in particular when experiencing functional impairment and suicidality, as well as high rates of hospitalisation. It therefore seems contradictory and unhelpful to create such a sub-group of depressed patients. The configuration of the guideline could also lead to confusion among clinicians seeking treatment recommendations for chronic depression irrespective of whether an individual has sought previous help.As previously highlighted, the terms treatment-resistant and chronic depression are often used interchangeably and study populations often meet criteria for both (Abbass, 2006; Town & Abbass, 2017; Fonagy et al., 2015). This is also true for depression with a comorbid personality disorder (Abbass & Town,	inform recommendations. It should also be noted that there are still a significant number of psychological intervention studies, conducted in standard care settings, included. Although these studies including mixed populations may be representative of standard care, the recommendations are for the treatment of an individual and not for the whole of primary care or IAPT, and therefore it is preferable to have the cleanest evidence about what the effects of combination treatment are (if someone is already on antidepressants) or what the effects of psychological treatment alone is if they are not. The committee agreed to include a separate review question for the first-line treatment or relapse prevention for people with depression and coexisting personality disorder. This decision was based on the committee's knowledge and experience that personality disorders can complicate the treatment of depression (see for example the meta-analysis by Newton-Howes et al (2006) Personality disorder and the outcome of depression: meta-analysis of published studies. British Journal of Psychiatry, 188, 13-20)).

						2011; Friborg et al., 2014; Skodol et al., 2011).Taken together, we continue to be concerned that the categorisation and applied exclusion criteria for studies will have provided artefacts and led to treatment recommendations that cannot be easily applied to clinical practice.We therefore continue to stress the importance to address these concerns by (a) adopting the traditional classifications for the review of a new episode of depression, which may indeed include a fourth group of individuals whose depression is longer-lasting, (b) adjusting the exclusion criteria as advised above, and (c) combining the evidence review for all more complex forms of depression.	For the further-line treatment review, studies were sought that included adults with depression showing an inadequate response to at least one previous intervention for the current episode and this included the further-line treatment of psychotic depression, depression with coexisting personality disorder and chronic depression. First-line treatment or relapse prevention of chronic depression (including dysthymia), and first-line treatment or relapse prevention of depression with coexisting personality disorder were separate reviews, as the committee did not feel that it was appropriate to combine these populations for first-line treatment or relapse prevention. The committee reviewed the European Psychiatric Association classification but did not consider it appropriate to change the term to 'persistent depression' but considered that the grouping together of psychotic depression, depression with coexisting personality disorder and chronic depression for the further-line treatment review should allow the effectiveness of interventions for a more clinically complex population to be considered.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

124	SH	Coventry and Warwickshire Partnership Trust	General	General	General	It is my understanding that talking therapies will be the first offered treatment ahead of anti-depressants. My understanding was that this fits in with the original purpose of IAPT to try one treatment and not both as it is difficult to determine which of the treatments was the most effective. However, whilst many services across the country have increased waiting times due to the COVID pandemic, it is highly likely that this change would increase the burden on secondary care services. I truly believe that there is an important place in treatment for anti-depressants and this should not be ignored whilst waits are so long.	Thank you for your comment. In less severe depression, you are correct that talking therapies are suggested as a more effective alternative to antidepressant medication. In more severe depression, they are suggested as an alternative option to talking therapies. The emphasis in the guideline on assessing the person and their needs and preferences has been increased, and this includes a discussion about waiting times. It is therefore within the guideline recommendations that if a person expresses a preference for antidepressants, that is always a treatment option that is available to them. The committee do not therefore agree that the revised recommendations will place a larger burden on secondary care.

125	SH	British Association for Counselling and Psychotherapy (BACP)	General	General	General	REFERENCESAmsterdam, J. D., Lorenzo-Luaces, L., & DeRubeis, R. J. (2016). Step-wise loss of antidepressant effectiveness with repeated antidepressant trials in bipolar II depression. Bipolar disorders, 18(7), 563-570.Barkham, M., Moller, N. P., & Pybis, J. (2017). How should we evaluate research on counselling and the treatment of depression? A case study on how the National Institute for health and care excellence's draft 2018 guideline for depression considered what counts as best evidence. Counselling and Psychotherapy Research, 17(4), 253-268.Barkham, M., Saxon, D., Hardy, G. E., Bradburn, M., Galloway, D., Wickramasekera, N., ... & Brazier, J. E. (2021). Person-centred experiential therapy versus cognitive behavioural therapy delivered in the English Improving Access to Psychological Therapies service for the treatment of moderate or severe depression (PRaCTICED): a pragmatic, randomised, non-inferiority trial. The Lancet Psychiatry, 8(6), 487-499.British Association for Counselling and Psychotherapy (2022). About BACP. Retrieved from https://www.bacp.co.uk/about_bacp/Caldwell, D. M., Ades, A. E., & Higgins, J. P. T. (2005). Simultaneous comparison of multiple treatments: combining direct and indirect evidence. Bmj, 331(7521), 897-900.Chaimani A,	Thank you for providing these references. Responses to the points raised in the comments have been addressed in the corresponding comment sections.

						Caldwell DM, Li T, Higgins JPT, Salanti G. Chapter 11: Undertaking network meta-analyses. In: Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). Cochrane Handbook for Systematic Reviews of Interventions version 6.2 (updated February 2021). Cochrane, 2021. Available from www.training.cochrane.org/handbook. Churchill, R., Khaira, M., Gretton, V., Chilvers, C., Dewey, M., Duggan, C., & Lee, A. (2000). Nottingham Counselling and Antidepressants in Primary Care (CAPC) Study Group. Treating depression in general practice: factors affecting patients' treatment preferences. Br J Gen Pract, 50(460), 905-906.Cipriani, A., Higgins, J. P., Geddes, J. R., & Salanti, G. (2013). Conceptual and technical challenges in network meta-analysis. Annals of internal medicine, 159(2), 130-137.Clark, D. M. (2011). Implementing NICE guidelines for the psychological treatment of depression and anxiety disorders: the IAPT experience. International review of psychiatry, 23(4), 318-327.Clarke, J., & Barkham, M. (2009). Tribute to Phil Richardson-Evidence de rigueur: the shape of evidence in psychological therapies and the modern practitioner as teleoanalyst. Clinical Psychology Form, 202, 7-11.Cohen, Z. D., & DeRubeis, R. J. (2018). Treatment selection in depression. Annual Review	

						of Clinical Psychology, 14, 209-236.Cuijpers, P. (2016). Are all psychotherapies equally effective in the treatment of adult depression? The lack of statistical power of comparative outcome studies. Evidence-Based Mental Health, 19(2), 39-42.Cuijpers, P., Karyotaki, E., de Wit, L., & Ebert, D. D. (2020). The effects of fifteen evidence-supported therapies for adult depression: a meta-analytic review. Psychotherapy Research, 30(3), 279-293.Cuijpers, P., Pineda, B. S., Quero, S., Karyotaki, E., Struijs, S. Y., Figueroa, C. A., ... & Muñoz, R. F. (2021). Psychological interventions to prevent the onset of depressive disorders: A meta-analysis of randomized controlled trials. Clinical psychology review, 83, 101955.Dorow, M., Löbner, M., Pabst, A., Stein, J., & Riedel-Heller, S. G. (2018). Preferences for depression treatment including internet-based interventions: results from a large sample of primary care patients. Frontiers in psychiatry, 9, 181.Fonagy, P., Rost, F., Carlyle, J. A., McPherson, S., Thomas, R., Pasco Fearon, R. M., ... & Taylor, D. (2015). Pragmatic randomized controlled trial of long-term psychoanalytic psychotherapy for treatment-resistant depression: the Tavistock Adult Depression Study (TADS). World Psychiatry, 14(3), 312-321.Friborg, O., Martinsen, E. W., Martinussen, M., Kaiser, S., Øvergård, K. T., & Rosenvinge, J. H. (2014). Comorbidity of personality disorders in mood	

						disorders: a meta-analytic review of 122 studies from 1988 to 2010. Journal of affective disorders, 152, 1-11.Gyani, A., Pumphrey, N., Parker, H., Shafran, R., & Rose, S. (2012). Investigating the use of NICE guidelines and IAPT services in the treatment of depression. Mental health in family medicine, 9(3), 149.Gyani, A., Shafran, R., Layard, R., & Clark, D. M. (2013). Enhancing recovery rates: lessons from year one of IAPT. Behaviour research and therapy, 51(9), 597-606Houle, J., Villaggi, B., Beaulieu, M. D., Lespérance, F., Rondeau, G., & Lambert, J. (2013). Treatment preferences in patients with first episode depression. Journal of affective disorders, 147(1-3), 94-100.Johnston, O., Kumar, S., Kendall, K., Peveler, R., Gabbay, J., & Kendrick, T. (2007). Qualitative study of depression management in primary care: GP and patient goals, and the value of listening. British Journal of General Practice, 57(544), e1-e14.Kendrick, T., Dowrick, C., McBride, A., Howe, A., Clarke, P., Maisey, S., ... & Smith, P. W. (2009). Management of depression in UK general practice in relation to scores on depression severity questionnaires: analysis of medical record data. BMJ, 338.Kriston, L. (2013). Dealing with clinical heterogeneity in meta-analysis. Assumptions, methods, interpretation. International journal of methods in psychiatric research, 22(1), 1-15.Leonidaki, V., &	

						Constantinou, M. P. (2021). A comparison of completion and recovery rates between first-line protocol-based cognitive behavioural therapy and non-manualized relational therapies within a UK psychological service. Clinical Psychology & Psychotherapy.Leuzinger-Bohleber, M., Hautzinger, M., Fiedler, G., Keller, W., Bahrke, U., Kallenbach, L., ... & Beutel, M. (2019). Outcome of psychoanalytic and cognitive-behavioural long-term therapy with chronically depressed patients: a controlled trial with preferential and randomized allocation. The Canadian Journal of Psychiatry, 64(1), 47-58.Lindhiem, O., Bennett, C. B., Trentacosta, C. J., & McLear, C. (2014). Client preferences affect treatment satisfaction, completion, and clinical outcome: a meta-analysis. Clinical psychology review, 34(6), 506-517.Machmutow, K., Meister, R., Jansen, A., Kriston, L., Watzke, B., Härter, M. C., & Liebherz, S. (2019). Comparative effectiveness of continuation and maintenance treatments for persistent depressive disorder in adults. Cochrane Database of Systematic Reviews, (5).Mars, B., Heron, J., Kessler, D., Davies, N. M., Martin, R. M., Thomas, K. H., & Gunnell, D. (2017). Influences on antidepressant prescribing trends in the UK: 1995–2011. Social psychiatry and psychiatric epidemiology, 52(2), 193-200.McCrea, R. L., Sammon, C. J., Nazareth, I., & Petersen, I. (2016).	

						Initiation and duration of selective serotonin reuptake inhibitor prescribing over time: UK cohort study. The British Journal of Psychiatry, 209(5), 421-426.Mercier, A., Auger-Aubin, I., Lebeau, J. P., Van Royen, P., & Peremans, L. (2011). Understanding the prescription of antidepressants: a qualitative study among French GPs. BMC family practice, 12(1), 1-9.Moller, N. P., Ryan, G., Rollings, J., & Barkham, M. (2019). The 2018 UK NHS Digital annual report on the Improving Access to Psychological Therapies programme: a brief commentary. BMC psychiatry, 19(1), 1-5.Munder, T., Bruetsch, O., Leonhart, R., Gerger, H., & Barth, J. (2013). Researcher allegiance in psychotherapy outcome research: an overview of reviews. Clinical Psychology Review, 33(4), 501-511.NHS Digital (2014). Psychological therapies: Annual report on the use of IAPT services. England, 2013-2014. Retrieved from https://digital.nhs.uk/data-and-information/publications/statistical/psychological-therapies-annual-reports-on-the-use-of-iapt-services/annual-report-2013-14NHS Digital (2015). Psychological therapies: Annual report on the use of IAPT services. England, 2014-2015. Retrieved from https://digital.nhs.uk/data-and-information/publications/statistical/psychological-therapies-annual-reports-on-the-use-of-iapt-	

						services/annual-report-2014-15NHS Digital (2016). Psychological therapies: Annual report on the use of IAPT services. England, 2015-2016. Retrieved from https://digital.nhs.uk/data-and-information/publications/statistical/psychological-therapies-annual-reports-on-the-use-of-iapt-services/annual-report-2015-16 NHS Digital (2017). Psychological therapies: Annual report on the use of IAPT services. England, 2016-2017. Retrieved from https://digital.nhs.uk/data-and-information/publications/statistical/psychological-therapies-annual-reports-on-the-use-of-iapt-services/annual-report-2016-17NHS Digital (2018). Psychological therapies: Annual report on the use of IAPT services. England, 2017-2018. Retrieved from https://digital.nhs.uk/data-and-information/publications/statistical/psychological-therapies-annual-reports-on-the-use-of-iapt-services/annual-report-2017---18/content.oldNikolakopoulou, A., Higgins, J. P., Papakonstantinou, T., Chaimani, A., Del Giovane, C., Egger, M., & Salanti, G. (2020). CINeMA: an approach for assessing confidence in the results of a network meta-analysis. PLoS medicine, 17(4), e1003082.Nordmo, M., Monsen, J. T., Høglend, P. A., & Solbakken, O. A. (2021). Investigating the	

						dose–response effect in open-ended psychotherapy. Psychotherapy Research, 31(7), 859-869.Public Health England (2020) Prescribed medicines review: summary. Available at: https://www.gov.uk/government/publications/prescribed-medicines-review-report/prescribed-medicines-review-summaryPuhan, M. A., Schünemann, H. J., Murad, M. H., Li, T., Brignardello-Petersen, R., Singh, J. A., ... & Guyatt, G. H. (2014). A GRADE Working Group approach for rating the quality of treatment effect estimates from network meta-analysis. Bmj, 349.Pybis, J., Saxon, D., Hill, A., & Barkham, M. (2017). The comparative effectiveness and efficiency of cognitive behaviour therapy and generic counselling in the treatment of depression: evidence from the 2 nd UK National Audit of psychological therapies. BMC psychiatry, 17(1), 1-13.Raza, G. T., & Holohan, D. R. (2015). Clinical treatment selection for posttraumatic stress disorder: Suggestions for researchers and clinical trainers. Psychological Trauma: Theory, Research, Practice, and Policy, 7(6), 547.Salanti, G. (2012). Indirect and mixed-treatment comparison, network, or multiple-treatments meta-analysis: many names, many benefits, many concerns for the next generation evidence synthesis tool. Research synthesis methods, 3(2), 80-97.Richards, D. A., Rhodes, S., Ekers, D., McMillan,	

						D., Taylor, R. S., Byford, S., ... & Woodhouse, R. (2017). Cost and Outcome of BehaviouRal Activation (COBRA): a randomised controlled trial of behavioural activation versus cognitive-behavioural therapy for depression. Health Technology Assessment (Winchester, England), 21(46), 1-366.Robinson, L., Delgadillo, J., & Kellett, S. (2020). The dose-response effect in routinely delivered psychological therapies: A systematic review. Psychotherapy Research, 30(1), 79-96.Salanti, G., Del Giovane, C., Chaimani, A., Caldwell, D. M., & Higgins, J. P. (2014). Evaluating the quality of evidence from a network meta-analysis. PloS one, 9(7), e99682.Swift, J. K., Callahan, J. L., Cooper, M., & Parkin, S. R. (2018). The impact of accommodating client preference in psychotherapy: A meta-analysis. Journal of Clinical Psychology, 74(11), 1924-1937.Van, H. L., & Kool, M. (2018). What we do, do not, and need to know about comorbid depression and personality disorders. The Lancet Psychiatry, 5(10), 776-778Waitzfelder, B., Stewart, C., Coleman, K. J., Rossom, R., Ahmedani, B. K., Beck, A., ... & Simon, G. E. (2018). Treatment initiation for new episodes of depression in primary care settings. Journal of general internal medicine, 33(8), 1283-1291.Wakefield, S., Kellett, S., Simmonds-Buckley, M., Stockton, D., Bradbury, A., & Delgadillo, J. (2021). Improving Access to Psychological	

						Therapies (IAPT) in the United Kingdom: A systematic review and meta-analysis of 10-years of practice-based evidence. British Journal of Clinical Psychology, 60(1), 1-37.Williams, R., Farquharson, L., Palmer, L., Bassett, P., Clarke, J., Clark, D. M., & Crawford, M. J. (2016). Patient preference in psychological treatment and associations with self-reported outcome: national cross-sectional survey in England and Wales. BMC psychiatry, 16(1), 1-8.Windle, E., Tee, H., Sabitova, A., Jovanovic, N., Priebe, S., & Carr, C. (2020). Association of patient treatment preference with dropout and clinical outcomes in adult psychosocial mental health interventions: a systematic review and meta-analysis. JAMA psychiatry, 77(3), 294-302.Winter, S. E., & Barber, J. P. (2013). Should treatment for depression be based more on patient preference?. Patient preference and adherence, 7, 1047.Zimmerman, M., Posternak, M., Friedman, M., Attiullah, N., Baymiller, S., Boland, R., ... & Singer, S. (2004). Which factors influence psychiatrists' selection of antidepressants?. American Journal of Psychiatry, 161(7), 1285-1289.	

126	SH	Sport England	General	General	General	Which areas will have the biggest impact on practice and be challenging to implement? Clinicians are a trusted source of patient information, therefore offering exercise as a treatment option will help patients become more aware of the important role of exercise in the management of mental health and bring about benefits to physical health too.Given the symptoms associated with depression i.e. low motivation and fatigue, recruitment and attrition rates could be challenging if the expectation of patients is to complete 60 minutes x 3 times a week within the exercise treatment pathway.If delivered effectively, the exercise treatment pathway and broader 'move more' support (in adjunct to all treatment pathways) has potential to improve longer term self-care and relapse prevention.Would implementation of any of the draft recommendations have significant cost implications? An exercise on referral, structured exercise treatment programme will require venue and facilitator costs. The high frequency suggested (3 times a week for 60 minutes) could be financially challenging for commissionersWhat would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice).There are a number of existing physical activity programmes and activities that the guidelines could refer to that	Thank you for your comments. The committee addressed your points in turn. 1. The committee were pleased that you support the inclusion of exercise as an intervention and noted that the evidence was for a structured formal exercise programme, with exercise of moderate to high intensity, but recognise there may be challenges to implement this, including financial. The committee has now removed the suggested duration of exercise sessions and modified the recommended frequency to allow more flexibility in the delivery of exercise programmes. Implementation issues will be considered by NICE where relevant support activity is being planned. However, the committee also supported less intense 'move more' exercise for general wellbeing (although not a treatment for depression) and made a new recommendation to reflect this. 2. Thank you for telling us about the exisiting physical activity programmes and campaigns. These will be passed onto the NICE shared learning team. 3. Thank you for telling us about the impact of Covid-19 on exercise activities and how some of these have been overcome using on-line or other alternatives.

						Sport England have funded or co-developed:Resources for clinicians to support patients to be more active:Moving Medicine - a free initiative developed by The Faculty of Sport and Exercise Medicine, Sport England, Office for Health Improvement and Disparities and British Association of Sport and Exercise Medicine which supports healthcare professionals integrate physical activity conversations into routine clinical care. It includes evidence-based resources specifically for the treatment of depression. We Are Undefeatable – an inspiring, inclusive, and empathetic 'We are Undefeatable' campaign (https://weareundefeatable.co.uk/about-us) developed alongside 16 leading health and social care charities. This supports and encourages people with health conditions to find ways to be active that works with each person's conditions. This campaign runs several times a year nationally and can be activated in any healthcare care setting. Resources are free and are available via the Supporters' Hub.We welcome the opportunity to discuss further linking to these wider resources.Resources patients can access to help them become more active:Self-led activity - We Are Undefeatable, Join the Movement, Active 10, 10 Today and Couch to 5k, Couch to fitnessCommunity based provision - OurParks and Parkrun.We welcome the opportunity to discuss	

						further linking to these wider resources.Please tell us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication.The Covid-19 pandemic has caused disruption to the delivery of sport and physical activity. Whilst much provision has recovered and returned to face-to-face delivery, there is still a need for some delivery via alternative methods i.e. online/home workouts. Many people (particularly those with long term conditions and who are more likely to be classed as clinically vulnerable) have found it difficult to return to their typical pre pandemic physical activity habits. Some have found alternative online alternatives, others have de-conditioned and their activity levels have decreased as a result. This needs to be factored into delivery. Our recent IAPT physical activity investments have adapted well and have included online physical activity provision or self-led time within treatment pathways if patients feel concerned about socialising out in the community.	

127	SH	The Mindfulness Initiative	General	General	General	We are pleased to see the increased emphasis on providing an individual with choice and options over their treatment for depression within these guidelines, and thank the committee for the work that has been done on this, taking in the feedback given in previous consultations. The fact that mindfulness is used within the population at large regardless of their mental health status, makes it a popular non-stigmatising intervention with considerable benefits.Most of our comments are intended to help improve the choice aspect of the guidelines to ensure that access to evidence-based mindfulness-based approaches, in particular, is open to all, and that the options are set out clearly in a way which allows a person to make an informed choice about their treatment.	Thank you for your comment and support of the increased emphasis on choice. Mindfulness is included as a treatment option for less severe depression and so people would be able to make an informed choice for that as their treatment modality.
128	SH	The Mindfulness Initiative	General	General	General	There is very little reference throughout these guidelines to a trauma-informed approach underpinning the interventions offered. Choice is central to a trauma-informed approach, while the interventions themselves should not make assumptions about whether or not someone will or won't have experienced trauma. There is a growing consensus amongst trained mindfulness practitioners that it is good practice to ensure that mindfulness courses are trauma sensitive regardless of the context[3].Given the causal link between trauma and depression, we feel that an express recognition of the need to take a trauma-	Thank you for your comment. The guideline did not review evidence for a trauma-informed approach as an intervention or service delivery model, so the committee did not consider it appropriate to make a stand-alone recommendation. The committee were also aware of differing definitions and meanings of trauma-informed care. In response to your comment, a recommendation about initial assessment has been amended to include trauma as a factor to discuss with the person that may have affected the development, course and severity of their depression. This

						informed approach would be helpful within this set of guidelines.	recommendation is also cross-referred to in a choice of treatment recommendation, so trauma should also be considered when making a shared decision about which intervention is right for the individual.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

129	SH	The Association of Clinical Psychologists UK	General	General	General	The ACP-UK welcome updated NICE guidelines for Depression and the principles of care outlined in this draft guideline. We recognise the enormous importance of NICE guidelines in relation to psychological interventions, especially for conditions such as depression. The guidelines affect not only treatment recommendations by GPs and other healthcare professionals, but also the provision of different services and treatments, and influences the public perception of the effectiveness of different interventions. In addition NICE recommendations often set the direction for research funding and it is important that we don't end up researching an ever-decreasing range of options for intervention.We are encouraged by a number of aspects of the latest draft guideline (NICE, 2021a), when compared to both the currently approved guideline (NICE, 2009) and the previous consultation draft (NICE, 2018). In particular, we welcome:The significant efforts made to engage with the concerns we have raised with the previous drafts of this guideline – we are grateful for the meaningful stakeholder engagement process. We welcome the substantial additional work that has been carried out to address our shared concerns. We notice that as a result this third draft is much improved. The greater overall transparency and clarity provided in this draft. The inclusion of both Counselling and	Thank you for your comment and support of the updated guideline.

						Short-term psychodynamic psychotherapy (STPP) as first-line treatments for depression (NICE, 2021a, pp. 29-30, 33-35), rather than only as secondary options (NICE, 2018, pp. 23, 25) increasing choice for people experiencing depression.The new section 1.3 on choice of treatments (NICE, 2021a, pp. 10-11), emphasising shared decision-making and respect for the preferences of people with depression (in line with the new NICE guideline NG197), and the requirement for commissioners to ensure that all NICE-recommended treatments are available in practice (NICE, 2021a, p. 11).Underpinning section 1.3, the inclusion of evidence relating to service user experiences, and the use of a range of qualitative studies for this purpose (NICE, 2021c).A discussion of issues related to antidepressant withdrawal (sections 1.4.10 to 1.4.20, NICE, 2021a, pp. 15-18), especially as compared to the cursory overview in the 2009 guideline (NICE, 2009, p. 34-35, cp. NICE, 2018, pp. 14-17).	

130	SH	The Association of Clinical Psychologists UK	General	General	General	The ACP-UK remain concerned that the methodological difficulties previously outlined have not been sufficiently addressed and therefore people experiencing depression will not be offered the best and most appropriate treatments. We are also concerned that the draft guideline does not encompass the complexities of real-world practice, as it continues to focus on a narrow evidence base, narrowly-defined outcome measures, and questionable classifications of depression. This draft guideline has many sections on co-occurring conditions, a recognition of the real-life experience of people with depression, yet lots of research evidence is excluded from analysis because of co-occurring conditions. This does not make sense.Excessive weight is still given to randomised controlled trials (RCTs), and consequently other high-quality data is ignored, including the huge volume of data available from the national Improving Access to Psychological Therapies (IAPT) programme. This may be partly an issue for the consultation on NICE guideline development, but the current guideline development manual (NICE, 2014, pp. 106-110) still allows for flexibility in this area.Depression is often a long-term, re-occurring condition (cp. IAPT data in Hepgul et al., 2016), and yet the current draft guideline relies heavily on very short-term outcomes, most commonly over a 6 to 12 week period. It also adopts a simple, binary	Thank you for your comment. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context (including drawing on their knowledge of the IAPT dataset) so that the 'reality' for people experiencing depression was taken into consideration. In response to stakeholder comments, the committee have re-structured treatment recommendations in order to take into account implementation factors. In January 2020 NICE published a statement of intent signalling the ambition for the future use of wider sources of data and analytic methods (including sources commonly referred to as real-world data and evidence). To make decisions about the relative effectiveness of interventions, RCTs will continue to be prioritised in line with the NICE guidelines manual, in order to ensure that the populations treated with various interventions are equivalent. However it is possible that in the future, high-quality real-world datasets such as the IAPT dataset, could inform questions about access and engagement. The committee agree that long-term follow-up is important and share your disappointment that this is not more routinely measured and reported. The committee considered all long-term follow-up data found in making its

						model of recovery, ignoring partial recovery which in the real world may be very significant.The categories of depression in the draft guideline are significantly out-of-step with generally accepted classifications. On the one hand the guideline condenses the generally-accepted four categories of severity into just two ("less severe" and "more severe"), partly in order to simplify the application of Network Meta-Analysis (NMA, see below). On the other hand it distinguishes "depression in people with a diagnosis of personality disorder" (previously labelled "complex depression") and "psychotic depression" from "chronic depression", contrary to guidance from the European Psychiatric Association (Jobst et al., 2016, pp. 19-20).The definition of counselling in the draft guideline is also confusing and contradictory. The guideline states that Counselling "Uses an empirically validated protocol developed specifically for depression" (NICE, 2021a, pp. 28-29, 33-34). This would suggest that it refers to the Person-Centred Experiential Therapy / Counselling for Depression (PCET/CfD) protocol approved for IAPT (UCL Psychology and Language Sciences, 2021). However, the corresponding entries in the lists of assessed interventions (NICE, 2021b, pp. 291-292) refer to "non-directive/supportive/person-centred counselling [individual counselling]", and in discussing a recent	recommendations and the committee based their judgement of the importance of this data on the availability and quality of the long term data. Long-term follow-up is included in the research recommendations in the guideline. The guideline includes continuous changes in scores on depression scales as a critical outcome for every treatment question, which will show changes for people who have both fully and partially recovered. This was agreed by the committee to be a better way to capture this data than the use of a dichotomous outcome for partial recovery. The committee considered the current NICE classifications of mild to moderate and moderate to severe depression, and agreed that although these classifications have been adopted quite widely there is potential uncertainty with regards to the management of moderate depression. The committee agreed that a dichotomy of less and more severe depression was clearer, and the guideline includes definitions (that less severe depression includes the traditional categories of subthreshold symptoms and mild depression, and more severe depression includes the traditional categories of moderate and severe depression) in order to

						study that looked at PCET/CfD, the guideline documents state that “the PCET used in this study was not the same as non-directive counselling” (NICE 2021b, p. 146).Summary of remaining concernsHaving raised several serious concerns with the first and second version of this draft guideline as one of the partners in the stakeholder coalition, we are responding to this iteration as a group with respect to these concerns.As summarised in the coalition stakeholder position statement, and outlined and discussed during previous consultations, we have identified six key concerns regarding the methodology adopted to inform the selection, grouping and analysis of supporting evidence. We have emphasised that, if all of these are not adequately addressed, the resulting treatment recommendations cannot be relied on and may therefore impede the care of millions of people in the UK experiencing depression. While we strongly welcome that some of the methodological flaws we raised have been addressed in this iteration, we need to point out that not all of them have been adequately resolved. We therefore maintain that this draft version, although much improved, continues to be of concern. While these methodological concerns remain unaddressed, we continue to question the trustworthiness of the resulting treatment recommendations in the guideline.As such, we	improve practical utility. The committee considered the distinction between less severe (subthreshold/mild) and more severe (moderate/severe) depression to be clinically meaningful in terms of supporting effective clinical decision making and being aligned with how clinicians conceptualize depression (in particular, GPs and other primary care staff, given that the majority of people with depression and almost all first line presentations of depression are managed in primary care). For the further-line treatment review, studies were sought that included adults with depression showing an inadequate response to at least one previous intervention for the current episode and this included the further-line treatment of psychotic depression, depression with coexisting personality disorder and chronic depression. First-line treatment or relapse prevention of chronic depression (including dysthymia), and first-line treatment or relapse prevention of depression with coexisting personality disorder were separate reviews, as the committee did not feel that it was appropriate to combine these populations for first-line treatment or relapse prevention. The committee reviewed the European Psychiatric Association classification but did not consider it

						believe that a significant proportion of individuals suffering from depression could be impeded from accessing the right treatment for them. We are particularly concerned about the care of individuals who experience more complex and persistent forms of depression. Already disadvantaged in many respects, we have serious doubts that this group will receive the most appropriate treatment following the treatment recommendation in this draft. In summary we recommend the following amendments before the guideline is published:Inconsistencies regarding the utilisation of outcomes derived from long-term follow-up needs addressing.Adopting the traditional classifications for the review of a new episode of depression – mild, moderate, severe and adjust the exclusion criteria to allow for higher ecological validity.Trials where the majority of the population is clinically complex (i.e., has a comorbid psychosis or personality disorder), chronic or treatment resistant need to be combined and partial recovery needs to be included as critical outcome.Findings from indirect or mixed comparisons using Network Meta-Analysis (NMA) should only be used to supplement evidence derived from direct comparison (using the standard meta-analyses carried out)The review evidence on service user experience needs to be refined to focus more clearly on experiences of	appropriate to change the term to 'persistent depression' but considered that the grouping together of psychotic depression, depression with coexisting personality disorder and chronic depression for the further-line treatment review should allow the effectiveness of interventions for a more clinically complex population to be considered. All the evidence for counselling that was included in the review for the treatment of a new episode of depression was non-directive counselling, and the committee therefore did not consider it appropriate to recommend specific interventions (for example, Counselling for Depression/Person-Centred Experiential Therapy [PCET]) as the evidence was not reviewed for these interventions. However, based on informal consensus, the committee agreed that counselling should use an empirically validated protocol developed specifically for depression and this was included in the recommendation. NICE do not accept that the use of NMA was inappropriate and using NMAs both to assess clinical effectiveness and to inform the economic model was in accordance with the NICE guidelines manual. However, pairwise data were

						treatments.The hierarchy of treatment options for individuals with a new depression episode must be replaced with a menu (non-ranked) to accurately reflect the findings that all included interventions were clinically and cost effective.The evidence from important and well-known UK pragmatic trials needs to be considered fully, not partially.	also presented separately in the new version of the guideline to enable an easier comparison between direct and NMA results. There was also a peer review of all NMAs by a NICE Technical Support Unit contractor and the code for the NMAs was published. NICE recognises that no statistical technique will ever lead to an indisputably 'correct' answer, since they all involve assumptions and extrapolations of the available data. Both the committee and quality assurance team considered any limitations of the analysis and the confidence they had in it when making recommendations. The data from the NMA was also considered alongside the other sources of data, including the pairwise data, economic model results and newly reviewed qualitative evidence. As specified in the scope, the experience of care section from the 2009 guideline was not included in this update. However, a new review question on patient choice was added to this update that includes a systematic review of primary qualitative studies that focus specifically on service user experience around choice of treatment. Based on their overall review of the clinical evidence the committee agreed that some

							treatment classes and interventions appeared to be more effective than others, but there was otherwise little to choose between treatments. The committee therefore reviewed the results of the health economic modelling which determined which treatments were cost-effective, and used this to develop a suggested prioritisation of which treatments should be offered to people with depression, or considered for use. In response to stakeholder comments some changes have been made to the tables guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. Interventions are arranged in the tables in the suggested order in which options should be considered, based on the committee's interpretation of their clinical and cost effectiveness and consideration of implementation factors. However, this is not a rigid hierarchy, all treatments included in Tables 1 and 2 can be used as first-line treatments, and it may be appropriate to recommend an intervention from lower down in the table where this best matches the person's preferences and clinical needs. The committee were aware of the need to provide a wide range of interventions to

							take into account individual needs and allow patient choice. However, the committee did not consider it appropriate to present an entirely non-ranked list based on the evidence reviewed. The committee were aware of pragmatic RCTs that were excluded from the NMA typically because the samples in the trials were <80% first-line treatment or <80% non-chronic depression. These were stipulations of the review protocol in order to create a homogenous data set, but the committee used their knowledge of these studies in the round when interpreting the evidence from the systematic review and making recommendations. By way of illustration some of these studies were listed in Evidence report B, however, in response to stakeholder comments the committee agree that it would be more consistent to name all UK-based studies which were excluded on this basis but which the committee were aware of when making recommendations.

131	SH	The Association of Clinical Psychologists UK	General	General	General	Limiting the evidence to RCTsAs stressed during the previous stakeholder consultations, given the various limitations of RCTs specifically in the field of mental health that have been pointed out repeatedly by experts from many scientific disciplines and positions - irrespective of any modality allegiance - creating sound policy requires that we draw on a diverse range of evidence. We are disappointed that the evidence reviewed in this draft guideline continues to be limited to RCTs. We strongly uphold that this is a restrictive science and therefore leads to limiting patients' choice. We would like to signpost you to the NICE manual where it is states: "In order to formulate recommendations, the guideline Committee needs to consider a range of evidence about what works generally, why it works, and what might work (and how) in specific circumstances. The Committee needs evidence from multiple sources, extracted for different purposes and by different methods." (p.67)We would like to stress that the exclusion of available "important and well-known" UK-based pragmatic trials and real-world data collected from millions of patients treated for depression within the NHS in the very setting where the evidence from the guideline mist closely followed, is simply wrong.The guideline itself makes reference to these studies, however, only appears to consider these partially to aid interpretation of clinical and	Thank you for your comment. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context (including drawing on their knowledge of the IAPT dataset) so that the 'reality' for people experiencing depression was taken into consideration. In response to stakeholder comments, the committee have re-structured treatment recommendations in order to take into account implementation factors. In January 2020 NICE published a statement of intent signalling the ambition for the future use of wider sources of data and analytic methods (including sources commonly referred to as real-world data and evidence). To make decisions about the relative effectiveness of interventions, RCTs will continue to be prioritised in line with the NICE guidelines manual, in order to ensure that the populations treated with various interventions are equivalent. However it is possible that in the future, high-quality real-world datasets such as the IAPT dataset, could inform questions about access and engagement. The committee were aware of pragmatic RCTs that were excluded from the NMA typically because the samples in the trials were <80% first-line treatment or <80% non-chronic depression. These were stipulations of the

						cost effectiveness. We therefore ask that this draft is amended by the inclusion of such evidence from real-world data and pragmatic trials into the review. At the very least, we ask that their results are not merely used partially and selectively in order to justify the arbitrary treatment hierarchy (e.g. p. 141, l. 21f; and p.146, l.31f of the evidence review B).	review protocol in order to create a homogenous data set, but the committee used their knowledge of these studies in the round when interpreting the evidence from the systematic review and making recommendations. By way of illustration some of these studies were listed in Evidence report B, however, in response to stakeholder comments the committee agree that it would be more consistent to name all UK-based studies which were excluded on this basis but which the committee were aware of when making recommendations. Based on their overall review of the clinical evidence the committee agreed that some treatment classes and interventions appeared to be more effective than others, but there was otherwise little to choose between treatments. The committee therefore reviewed the results of the health economic modelling which determined which treatments were cost-effective, and used this to develop a suggested prioritisation of which treatments should be offered to people with depression, or considered for use. In response to stakeholder comments some changes have been made to the tables guided by the principles of offering the least intrusive

							intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. Interventions are arranged in the tables in the suggested order in which options should be considered, based on the committee's interpretation of their clinical and cost effectiveness and consideration of implementation factors. However, this is not a rigid hierarchy, all treatments included in Tables 1 and 2 can be used as first-line treatments, and it may be appropriate to recommend an intervention from lower down in the table where this best matches the person's preferences and clinical needs. The committee were aware of the need to provide a wide range of interventions to take into account individual needs and allow patient choice. However, the committee did not consider it appropriate to present an entirely non-ranked list based on the evidence reviewed.

132	SH	The Association of Clinical Psychologists UK	General	General	General	References in this document:Albornoz, Y. (2011). The effects of group improvisational music therapy on depression in adolescents and adults with substance abuse: a randomized controlled trial. Nordic Journal of Music Therapy, 20(3), 208-224.Nan, J. K. M., & Ho, R. T. H. (2017). Effects of clay art therapy on adults outpatients with major depressive disorder: A randomized controlled trial. Journal of Affective Disorders, 217, 237-245. doi:http://dx.doi.org/10.1016/j.jad.2017.04.013	Thank you for providing these references. Albornoz 2011 is included in the network meta-analysis for the treatment of a new episode of more severe depression. However, this was the only included study for music therapy, and the committee considered the evidence too limited to make a recommendation. Nan 2017 is included in the further-line treatment review. However, this was the only included study for art therapy, and the committee considered the evidence too limited to make a recommendation.
133	SH	The Association of Clinical Psychologists UK	General	General	General	Stakeholders are invited to respond thinking about the impact of the COVID-19 pandemic. There has been a depression pandemic in the UK for a long time and a history of mental health services focusing on individualised responses rather than public health and community responses to mental health. If a wider breadth of evidence was considered it is likely that NICE would be making recommendations at the Public Health and Communities level to prevent as well as work with depression, and calling for Government departments to work together to deliver them.	Thank you for your comment. The remit and scope of this guideline was the recognitions and management of depression in adults, and did not include wider public health and community issues relating to the causes and prevention of depression.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

134	SH	The Association of Clinical Psychologists UK	General	General	General	Different groups of people are prescribed medicines differently dependent on protected equality characteristics (Equality Act, 2010). It is well known that women are more likely to be prescribed 'anti-depressants' and black men likely to be prescribed 'anti-psychotic' medication. In the past the Government did recognise the disparity between minoritised groups in mental health and introduced The Delivering Race Equality in Mental Health Care (2005) programme of work. At the very least the guidelines should include mandatory standards for training clinicians in equity, equality and prescribing as well as the requirement for services to audit and review what is offered to people experiencing depression on the basis of protected characteristics.	Thank you for your comment. The committee agreed that equity and equality in delivering mental healthcare was an important principle and that all NHS healthcare professionals would be required to undertake regular mandatory equality and diversity training, and providers would undertake audits of their service broken down by demographic, so it was not necessary to specify this in the guideline. However, the committee have expanded the recommendations in the section of the guideline on principles of care to cover potential methods to overcome stigma , and added awareness and avoidance of discrimination to this section as well.
135	SH	Institute of Psychoanalysis	General	General	General	Quality of referencing - Inadequate It is clear that references are not included in all introductions resulting in the fact that it is not possible to check the accuracy of some of the statements made. This would not be acceptable in a paper that is sent for publication and the paper would consequently be rejected on the grounds of potential plagiarism or imprecision. It is hoped that they will be added in the published version thereby allowing for these to be fully checked.	Thank you for your comment. The introductions to NICE evidence reviews are written by the committee as a brief introduction to the topic, the current knowledge and the aim of the review and are not referenced. References will therefore not be added prior to publication.

136	SH	Institute of Psychoanalysis	General	General	General	Lack of evidence does not mean “no evidence”In our opinion, there is an underlying tone in this draft guideline that continues to convey two assumptions which are clearly incorrect: firstly, that the existence of more evidence equals stronger evidence and secondly that the lack of evidence (or in the case of these reviews, the omission of evidence due to their failure to make the inclusion criteria) equals no evidence. It needs to be borne in mind that absence of evidence is not evidence of ineffectiveness (Roth and Fonagy 2004). Furthermore, more studies does not simply imply higher efficacy.Following, for example, Chambless and Hollon (1998), two RCTs are sufficient for a treatment to be classified as efficacious. However, a lot of the language throughout the various documents would need to be re-phrased to make it clear that the results stated and discussed in the guideline are very much dependent on the methodology of these particular reviews.	Thank you for your comment. The committee agrees that absence of evidence is not absence of effectiveness. However in developing the guideline, recommendations can only be made for those interventions where there is evidence of their effectiveness.

137	SH	Institute of Psychoanalysis	General	General	General	The inclusion of long-term follow-up dataThe inclusion of some data on longer-term outcomes in the analyses is not only welcome but, in our opinion, vital. However, there seems to be an inconsistent approach in utilising the findings to inform treatment recommendations. This inconsistency appears to favour some treatment approaches over others without justification and we regard this as extremely problematic. NICE's recognition that long-term effectiveness is an important outcome is important. It is also of paramount importance to report and integrate evidence that demonstrates whether treatment effects can be sustained over time or appear, or indeed disappear, after treatment has ended over the long-term follow-up. This is especially important with respect to long-term conditions such as depression. We therefore welcome the amendment to include long-term follow-up data in all the treatment reviews.It is consequently very disappointing to note that very few of the included studies actually report long-term follow-up data. It is acknowledged that these outcomes cannot therefore be easily prioritised. Despite the low numbers of studies that have reported long-term follow-up data, we welcome NICE's decision to analyse the available data nonetheless and take the findings into consideration for treatment recommendation. We did, however, note	Thank you for your comment. The committee agree that long-term follow-up is important and share your disappointment that this is not more routinely measured and reported. Long-term follow-up is included in the research recommendations in the guideline. As highlighted in table 13 of Evidence report B and the corresponding 'committee discussion of the evidence' section, group CBT and group problem-solving showed benefits on depression symptoms at follow-up compared to treatment as usual, and CBT with antidepressants showed benefits compared to antidepressants alone. The committee agreed that this provided a useful indication that the results seen from the NMA for group CBT and group problem-solving may be maintained over a longer period. A 6-month follow-up of short-term psychodynamic psychotherapy (STPP) compared to non-directive counselling found a benefit for STPP for the outcomes of depression symptoms and remission at 6 months, but the committee noted that this small amount of evidence did not change their view, based on the NMA results, that these treatments had similar levels of effectiveness. In the further-line treatment evidence report

						inconsistencies in doing so which therefore need to be rectified. For example, as highlighted in Table 13 on p.39, for less severe depression, four studies showed a statistically significant effect at their respective follow-up point. Yet only the two studies on group CBT and the one study on group problem-solving were considered whereas the study in STPP was not! Another example pertains to the further-line treatment recommendations, where the statistically significant findings of LTPP at follow-up was not considered whilst for other treatments it was (p. 113).Moreover, it appears that only studies that yielded a statistically significant effect at the relevant follow-up point were considered, whilst those that did not find an effect were excluded, especially in the reviews for new episodes. Again, the findings of all of these studies would need to be taken into account as they provide important information as to whether a treatment has been found to lose its effect after treatment ended. For example, for less severe depression 55 out of 127 studies included in the NMA had follow-up data (43%). Of those four were found to show statistically significant effects at their respective follow-up point (Table 13 on p.39). This means that 51 studies did not show a statistically significant effect. Similarly, for those with more severe depression, 27 studies were identified with follow-up data, and out of those	(D), under the 'committee discussion of the evidence' section the committee highlight the sparsity of follow-up data from further-line treatment studies. The committee noted that a small number of studies could be combined in meta-analyses for outcomes up to 6 months after endpoint, however, beyond this point it was predominantly single-study analyses. The committee considered this limited evidence, and noted that a small number of studies showed evidence for sustained benefits on depression outcomes associated with augmenting antidepressants with CBT (up to 40 months), IPT (up to 12 months), short-term psychodynamic psychotherapy (up to 12 months), and long-term psychodynamic psychotherapy (up to 2 years). The committee agreed that the effects on depression outcomes at follow-up were generally in line with the effects observed at endpoint, and this strengthened their confidence in the recommendations.

						seven were found to have a statistically significant effect (Table 27, p.109). Again, this means that 19 studies showed no sustained effect. A thoughtful consideration of the lack of treatment efficacy in longer-term follow ups appeared absent let alone considered in terms of the treatment recommendations.Consequently and given the importance of this finding, we suggest that NICE comments on this important aspect of the data treatment in the guideline. Additionally, we would suggest that NICE adds to their research recommendations for all future studies to include a meaningful long-term follow-up in order to provide evidence of sustained treatment effects for depression. This is especially important given that research and clinical practice has shown that two thirds of patients relapse and appear not to have benefitted from their first-line treatment (p.7 of evidence review D). Two-thirds of the UK population with depression equates to more than 2 million individuals (from ONS and NICE data, 2021), who are estimated to be likely not to benefit from the first-line treatments recommended. As such, it is critical that studies are designed to provide the evidence of treatments that help in the long-term/show sustained effects after treatment has ended.	

138	SH	Institute of Psychoanalysis	General	General	General	The inclusion of functioning and quality of life measuresThe inclusion of functioning and quality of life measures is broadly welcomed but it is regrettable that of those studies included in the reviews, only a few had reported on these crucial outcomes.Consequently, whilst the committee decided to disregard these findings, an inconsistency in doing so was apparent. Results showing an effect on these measures were highlighted and indeed taken into consideration when interpreting results and formulating treatment recommendations for some treatment modalities (especially in favour of CBT), and not for others (for example psychodynamic psychotherapy). In addition to addressing these inconsistencies and hence taking a consistent approach to the evaluation of all treatment approaches, we would like to suggest that a sentence be added in the relevant sections in all documents referring to functioning and quality of life measures, in particular the importance of (a) future studies that report on such outcomes, and (b) for existing studies to publish these findings where the data was collected. As Paludan-Muller et al. (2021) have stressed, that many pharmacological trials collect such data but do not report it. The same can probably said about psychological treatments.	Thank you for your comment. The committee agree that quality of life and functioning outcomes are important. The committee noted the limited evidence for these outcomes, and included quality of life and functioning outcomes for the research recommendations in the guideline. The committee does not agree that the limited findings available were disregarded or considered inconsistently. The committee considered all clinically important and statistically significant effects on quality of life and functioning outcomes. However, given the sparsity of this evidence, and that it was broadly consistent with the findings observed for critical depression outcomes, the committee did not consider it necessary to make any changes to recommendations based on effects observed for quality of life and functioning outcomes.

139	SH	Institute of Psychoanalysis	General	General	General	All psychological treatments recommended are short-term. There is a need to include longer-term treatments as an optionThis point further elaborates an important issue delineated in point four above, i.e. that in the current guideline, all psychological treatments recommended are short-term, ranging between 6 – 16 sessions. As has been stressed in this guideline response at various points, non-response to treatment has usually been found to be high amongst individuals with depression, with one in three individuals estimated or found not to respond to offered treatments. Very recently, Cuijpers et al (2021a) have found that response and remission rates across different approaches of short-term psychotherapy are not satisfactory, with rates of response of 41% and remission of about 30%. This draft guideline fails to discuss this important aspect of patient response to treatment (specifically the high levels of depression remission and treatment non-response in depression). We suggest and request that this absence to be addressed. As stressed by many, more studies on the outcome of long-term treatments are needed and therefore the research recommendations should include a call for studies that investigate the effectiveness of longer-term psychotherapies and include a long-term follow-up. An additional important research recommendation, alongside that included on the	Thank you for your comment. The committee agree that long-term follow-up is important and included long-term follow-up in the research recommendations in the guideline. The number of research recommendations that the committee can develop is limited and long-term treatments or the investigation of differential effects for short-term relative to long-term treatments were not prioritised for separate and additional research recommendations. However, the research recommendation on mechanisms of action of effective psychological interventions recognises the room for improvement in terms of treatment recovery rates and recommends further research in order to isolate the most effective components in order to develop more potent, cost-effective and acceptable treatments. This research recommendation also recommends that psychological interventions are analysed in terms of therapy structure (for example session duration, frequency), in addition to generic therapeutic components (for example therapeutic relationship, rationale; remoralization), and specific ingredients. The further-line treatment recommendation that cross-refers to psychological treatment options

						mechanism of change, would be the investigation of differential effects, i.e., which individuals with depression would benefit more from short-term and which from longer-term psychotherapies. Research and clinical practice have shown that many individuals with chronic or complex forms of depression have tried the available and recommended first or second-line short-term treatments without success (e.g., Leichsenring & Rabung 2011; Maj et al. 2020). However, in the guideline the recommendation for those classified as having treatment-resistant depression, chronic depression, and depression with PD defaults back to first or further-line treatment recommendations - i.e. once again to a short-term treatment, instead of recommending a longer-term treatment. In complex mental disorders, longer-term psychotherapy proved to be superior to short-term psychotherapy (Leichsenring & Rabung, 2011, Leichsenring et al., 2013).This is particularly perplexing as there is evidence of the effectiveness of longer-term treatments, both for long-term CBT (e.g., Leuzinger-Bohleber et al., 2019) and long-term psychodynamic psychotherapy (e.g. Fonagy et al., 2015; Leuzinger-Bohleber et al., 2019) for individuals diagnosed with treatment-resistant/chronic depression. For individuals suffering from depression and comorbid personality disorder in particular, dose-effect	for more severe depression is for people whose depression has had no or a limited response to treatment with antidepressant medication alone. There was no evidence that specifically examined switching to a psychological intervention for those who have not responded to initial antidepressant treatment, however, the committee drew on the evidence for first-line treatments in more severe depression. The committee agreed that the psychological interventions that had been identified as effective and cost-effective for first-line treatment of more severe depression could be used for people who had not responded to antidepressants and wished to try a psychological therapy instead. Leuzinger-Bohleber et al 2019 was considered for the chronic depression review and was excluded. This study also did not meet eligibility criteria for the further-line treatment review as the inclusion criteria of the study was not limited to those receiving further-line treatment, participants were not randomised at the point of non-response, and it could not be regarded as an augmentation study following limited or no response to antidepressants as only 36% of participants were taking antidepressants at baseline. This study has now been added to the

						relationships suggest that long-term treatments are required to improve response and remission rates (Kopta et al., 1994). The Leuzinger-Bohlehber et al (2019) study was excluded from the chronic depression review as >20% had previous treatments, and for unexplained and inexplicable reasons it was not included under the further-line treatment review. Although the Fonagy et al., 2015 study was included, their important findings that both depression severity and functioning improved over the long-term have been ignored. Additionally, there exist numerous qualitative studies and reviews of patient experience that highlight that GPs, service providers and service-users stress that the currently available short-term treatments are inadequate, including studies that were reviewed in the 2009 update of this guideline and two studies that were reviewed in the evidence review I on patient choice (Johnston 2007; Mercier 2011, p. 52).One of the reasons for stressing the importance of focusing the evidence review on 'patient experience' of treatment rather than limiting it to 'patient choice' in this guideline, was to allow a synthesis of all these available studies. Such a synthesis may have highlighted crucial insights that could have been incorporated into and strengthened this guideline. In its current form, we consider the guideline to discriminate	excluded studies list in supplement D. There was only single-study evidence (Fonagy et al. 2015) for augmenting antidepressant treatment with long-term psychodynamic psychotherapy, and the committee considered the evidence too limited to make a recommendation for long-term psychodynamic psychotherapy specifically. However, a treatment option in the recommendation for people whose depression has had no or a limited response to treatment with antidepressant medication alone, includes changing to a combination of psychological therapy and medication, which could include long-term psychodynamic psychotherapy although it is not listed as an example due to the limited evidence. As specified in the scope, the experience of care section from the 2009 guideline was not included in this update. However, a new review question on patient choice was added to this update that includes a systematic review of primary qualitative studies that focus specifically on service user experience around choice of treatment.

						against those who want and need longer-term treatments.	

140	SH	Institute of Psychoanalysis	General	General	General	The Nature of depression The definition of depression in the guideline is descriptive and symptom based, rather than explanatory. In this, it is disorder focussed. It uses a practical severity classification which determines the step on which the person is placed at entry into the healthcare system.However, since depression is often an extension of or inextricably linked to the person's personality, assessment should take account of that aspect of a person's being.Symptom based definitions of depression are a practical way of categorising disorder with benefits in communication, research and service provision. However, symptoms have meaning and can be signposts to what is wrong in a person's life and might be open to change. Depression is not just an imposed disorder but frequently is part of that person's life narrative: the relationship with genetic and cultural inheritance, the interaction with their growing up and life, the quality and supportiveness of personal relationships, their ability to work and love and the opportunities open to them to have either or both, and the meaning they take and impose on their world. While welcome reference is made to multiple complicating problems (P 1.14.4), little reference is made across the draft as a whole to assessing the person in the context of their life, personality and situation. Where is reference to the need for	Thank you for your comment. The committee recognise the limits of the current nosolgy of depression and acknowledge that the problems of depression need to be addressed in a wider personal and social context. Throughout the guideline, and particularly in the sections on initial assessment and choice of treatments, there is a strong theme of collaborative decision making about care. Personal narratives, psychological formulation and the importance of the social context are not referred to explicitly in the recommendations but they form part of assessment. As specified in the scope, the recognition, assessment and initial management section from the 2009 guideline was not included in this update. In line with NICE processes, the 2009 content has been carried across to this updated guideline. However, the evidence on recognition, assessment and initial management has not been reviewed. As specified in the scope, the experience of care section from the 2009 guideline was not included in this update. However, a new review question on patient choice was added to this update that includes a systematic review of primary qualitative studies that focus specifically

						formulation, ideally following a psycho-social-biological approach? (see e.g., Aveline 1999). The fine details of a patient's depression can point the way to which therapy or combination or sequence of therapy are likely to be most apt. Thus, as stressed previously, that the service user experience evidence section was not updated with respect to a synthesis of the available studies on how patients experience and would define their depression, is very regrettable.	on service user experience around choice of treatment.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

141	SH	Institute of Psychoanalysis	General	General	General	The usage of the term counselling We would like to point out that how the word 'Counselling' as used in this draft is misleading and prejudicial to a particular employment group. In the UK, Counselling is a level of training, lower and different to psychoanalysts for example. It is not a modality of treatment. As such, counsellors can be from a variety of modalities. Looking at the trials included under counselling and they are almost entirely in the Humanistic camp. It appears that 'counselling' is being used as a label for humanistic therapies (including person-centred and experiential therapies) but that this is not at all clear in this draft guideline. This is an important issue of language thus that needs to be clarified. The guideline should specify the modality of counselling (i.e., humanistic, dynamic, couple, family etc.) in the same way that they refer to different families or waves of cognitive and behavioural therapy approaches.Similarly confusing is that psychodynamic counselling is classified or appears under the class of other psychodynamic/psychoanalytic treatments and not under the counselling cluster.	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. All the evidence for counselling that was included in the review for the treatment of a new episode of depression was non-directive counselling, and the committee therefore did not consider it appropriate to recommend specific interventions (for example, Counselling for Depression/Person-Centred Experiential Therapy [PCET]) as the evidence was not reviewed for these interventions. However, based on informal consensus, the committee

							agreed that counselling should use an empirically validated protocol developed specifically for depression and this was included in the recommendation. No eligible evidence was identified for psychodynamic counselling for treatment of a new episode of depression or for further-line treatment. However, the committee agreed and specified in the protocol that psychodynamic counselling should be categorised with psychodynamic psychotherapies based on the principles of grouping into classes outlined above.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

142	SH	Institute of Psychoanalysis	General	General	General	The application of the GRADE system We are very concerned about the GRADE system upon which the quality assessment of the studies as well as the statistical adjustments and penalisation of studies is based, and that it has not been adapted to studies that investigate psychological treatments. The system follows a medical paradigm that cannot be applied to psychological studies. Our view is that the draft guideline applies GRADE inappropriately. The application of the GRADE system needs to be adapted when psychological studies are investigated and the system itself was designed to be used flexibly with regard to the nature of the intervention and index problem being assessed. Applying it without modifications reinforces the false belief that the medical paradigm can easily be applied to psychological treatments.This is fundamentally incorrect and a pertinent example is the downgrading of studies that did not follow a double-blind approach, marking this as high risk. We recommend adapting the GRADE system in order to reflect the complex endeavour of comparing medical and psychological treatments. More specifically, the revision of the draft guideline should include the following relevant quality criteria:The inclusion of end of treatment long-term follow-up data. This would be in line with the draft guideline's emphasis stating the high	Thank you for your comment. In assessing risk of bias using GRADE, the non-blinding of participants and intervention administrators presents a risk of bias, although this is more of a problem for psychological than pharmacological trials, it does not negate the fact that participant and intervention administrator knowledge of the treatment being received/delivered is likely to introduce some degree of performance bias due to an individual's inherent beliefs about that intervention. However, in assessing risk of bias, blinding of outcome assessors and the comparaor (use of an attention-placebo condition) is also taken into account. The GRADE system 'quality' rating is not a value judgement on the quality of an individual study but rather an estimate of confidence that an estimate of the effect is correct and is unlikely to change with further research. It is also important to note that the GRADE rating of the evidence is just one factor that the guideline committee took into account when making recommendations. They also considered cost-effectiveness and interpreted all evidence in light of their clinical judgement. The committee agree that long-term follow-up, and quality of life and functioning outcomes, are

						likelihood of relapse/deterioration in patients with depression in several parts of the document. It is imperative for research to demonstrate that effects are long-lasting and any randomised controlled trails that aim to do so should be considered stronger and thus be up-graded. The call for the inclusion of long-term follow-ups extending the currently adopted time period of 3 – 6 months to several years after treatment termination has been stressed by many researchers and trial methodologists (e.g. Rawlins, 2008) given the episodic nature of depression.Adequate sample sizes providing sufficient power to detect true effects. Most psychotherapy studies are not powered enough to detect a true difference (Leichsenring et al., 2013) and relying on statistical significance of effects will create a paradox whereby small effects detected in well-powered studies is used to justify a recommendation, whereas a much larger effect detected in under-powered studies will be disregarded (Wampold et al., 2016).Utilization of a range of outcome measures, in particular the assessment of functioning in addition to targeted symptoms. As Dijkers (2014) has stressed, the quality for each outcome may differ between outcomes within a single study and across a body of evidence. Thus, we recommend the guideline to adapt the methodology not to penalise but to	important. The committee considered this data when making its recommendations, and based their judgement of the importance of this evidence on the availability and quality of the data. Long-term follow-up, and quality of life and functioning outcomes, are included in the research recommendations in the guideline. Therapist effects was not an area that was prioritised for inclusion in the guideline, therefore the evidence on this has not been reviewed and the committee did not consider it appropriate to make any recommendations on this issue. With regards to the imprecision ratings in the GRADE tables. The thresholds for clinically important SMD effects are -0.5 and 0.5. These thresholds are outlined in Supplement 1. In Table 72, the lower confidence bound is 0.21 and the higher is 0.33. This is therefore rated as 'no serious imprecision' as the confidence interval does not cross any threshold for a clinically important effect, and is consistent with no effect wherever the true point estimate is in this 95% confidence interval. This estimate of outcome demonstrates ineffectiveness but is not imprecise. The same is true for the example you

						acknowledge the benefits of a range of outcome measures (Wampold et al., 2016).Adequate statistical and methodological measures taken to control for error rates. The quality of assessment currently adopted does not examine whether studies have controlled for variability across therapist participants (i.e., therapist effects). A review of 71 therapist effect studies by Baldwin and Imel (2013) identified that therapist effects account for approximately 5-8% of patient outcomes: approximately 7% in naturalistic studies, and 3% in efficacy studies. Considering patient severity, Saxon and Barkham (2012) studied 10,786 patients seen by 119 therapists and identified that therapist effect sizes increased up to 10% as patient non-risk severity increased. Most patients in this sample presented with a level of depression (77.2%) and anxiety (84.6%). The extant empirical evidence points to the presence of therapist effects as an important factor to consider: its robust nature (across research designs) and its increasing contribution to the outcome of more severe patient presentations. We are concerned that the evidence identifying effective treatment does not control for variability between participating therapists within respective studies. We suggest the inclusion of a) a quality criterion to identify trials where therapist effects have been controlled for, and b) if possible, where	cite in Table 71 where confidence intervals include -0.39 to 0.04 and -0.36 to 0.07.

						therapist effects analyses have not been conducted, and data is accessible, to consider post hoc analysis to control for therapist effects. A specific question pertains to inconsistent application of the threshold criterion for clinically important benefit. It is unclear what the threshold criterion is. One assumes it is 0.5, however, it is neither stated nor justified. It furthermore appears to have been applied inconsistently between and within studies. Is the down rating on grounds of Optimal Information Size? In which case what is the OIS being applied and is it being applied consistently across studies? Furthermore, it appears to have been applied inconsistently between and within studies. Compare, for example, Table 72 in which imprecision is rated as 'no serious imprecision' with a lower confidence bound of 0.21 with Table 71, where a rating of 'no serious imprecision' is given for a lower CI bound of 0.04 and 0.07	

143	SH	Institute of Psychoanalysis	General	General	General	Limited generalisability – Exclusion criteria First-line treatment: Studies with > 20% of patients with chronic depression (> 2 years), > 20% of patients with a personality disorder, and > 20% receiving additional treatment (e.g., antidepressants or psychiatric care) were excluded from the NMA.Research has shown that 45% of patients diagnosed with depression were found to also suffer from a comorbid personality disorder (Friborg et al., 2014). In addition, usage of antidepressants is highly prevalent with 17% of the adult population in the UK (7.3 million people) taking antidepressants between 2017-2018 (https://www.gov.uk/government/publications/prescribed-medicines-review-report/prescribed-medicines-review-summary).Not only is it rather uncommon for meta-analyses of psychotherapy trials for depression to exclude studies with more than 20% use of antidepressants (e.g., Cuijpers et al., 2021a, Cuijpers et al., 2020), exclusion of these and other criteria limits the representativeness and generalisability of the results. Moreover, it is not clear whether this review double-checked whether the studies included had indeed all checked or reported whether participants had co-morbid PD or were receiving medication.Further-line and complex depression:We uphold that there is no evidence that warrants distinguishing between the more complex forms of depression (i.e. chronic	Thank you for your comment. For the first-line treatment review, studies were not included if more than 20% of participants were already receiving treatment for depression. While in the further-line treatment review, studies were required to have at least 80% of the participants showing no or limited response to previous treatment for the current episode of depression. The guideline review questions focus on specific populations – first-line treatment, further-line treatment/TRD, and there is not a question that specifically looks at a heterogeneous population where 21-79% are already on antidepressants and then have a psychological therapy added. Although the committee were aware that this may reflect standard care settings, the aim of the first-line treatment review question (RQ 2.1-2.2) is to estimate the effect size for psychological treatments, for antidepressants, and for combined psychological and antidepressant treatment and if the psychological studies include a significant proportion of participants who are actually receiving combined treatment this has the potential to give a misleading estimate of the effect of psychological treatments, and this is particularly problematic where these might be recommended as monotherapy.

						depression, treatment-resistant depression, depression with personality disorder and psychotic depression), and that by doing so this guideline provides erroneous and unhelpful classification of research studies with the consequence that treatment recommendations may also be erroneous and unhelpful. For treatment resistant depression a significant overlap with chronic depression exists (Abbass, 2006; Town & Abbass, 2017; Fonagy et al., 2015). This is true for depression with a comorbid personality disorder (Abbass & Town, 2011; Friborg et al., 2014; Skodol et al., 2011).The review question for further-line treatment now includes studies of psychotic depression, depression with personality disorders, chronic depression, and so-called treatment-resistant depression. However, in light of having kept the other reviews, we feel that this change has not really addressed the issue and may in fact have actually led to further confounding evidence. We are very concerned that it will be out of step with the clinical understanding of the groupings, especially with respect to chronic depression, and will lead to confusion instead of providing helpful guidance. Specifically, we point to the fact that:Most individuals suffering from chronic or persistent depression lasting for at least two years would have sought previous help, in particular, as highlighted on p. 7, l. 36f when individuals	The committee discussed this at length and although it was appreciated that it was unfortunate that studies would be excluded on this basis, it was agreed that the line had to be drawn somewhere based on the rationale above. The evidence from the further-line treatment/TRD depression review is applicable to the population who are already on antidepressants, and the first-line review is applicable to those who are not, or who receive combination antidepressants and psychological therapies from the outset. Whereas, looking at the evidence from a very heterogeneous population would not provide good evidence for any of these groups. This may mean that some studies are missing, because the population doesn't fit into either review, but there is evidence for psychological therapies for people who are already on antidepressants and those who aren't, and for psychological and pharmacological interventions used in combination, and this evidence has been used to inform recommendations. It should also be noted that there are still a significant number of psychological intervention studies, conducted in standard care settings, included. Although these studies including mixed

						experience functional impairment and suicidality. As such, it does not make sense to us at all, to review the evidence for first-line treatment only for this group. It seems contradictory even to your own description of this sample group which states that it includes “high rates of hospitalisation” (p.7, l.38). At the very least, individuals experiencing persistent depression would most likely have been prescribed medication at some point. The terms treatment-resistant and chronic depression are often used interchangeably and study populations often meet criteria for both. A brief look at the empirical literature on this topic identified three studies for which that is the case (Fonagy et al, 2015, Kocsis, 2009, and Leuzinger-Bohlber et al, 2018). As McPherson (2020) has pointed out, of the studies included in the 2017 guideline version, approximately half of the studies included under ‘further line treatment’ do not report the mean duration of episode, making it impossible to ascertain what percentage of participants also met the criteria for chronic depression. Of those that do report episode duration, more than half report a mean duration longer than 24 months.	populations may be representative of standard care, the recommendations are for the treatment of an individual and not for the whole of primary care or IAPT, and therefore it is preferable to have the cleanest evidence about what the effects of combination treatment are (if someone is already on antidepressants) or what the effects of psychological treatment alone is if they are not. Given the size of the evidence base it was not possible to contact all authors for missing data, and the review relied on the data reported in the papers. For the further-line treatment review, studies were sought that included adults with depression showing an inadequate response to at least one previous intervention for the current episode and this included the further-line treatment of psychotic depression, depression with coexisting personality disorder and chronic depression. First-line treatment or relapse prevention of chronic depression (including dysthymia), and first-line treatment or relapse prevention of depression with coexisting personality disorder were separate reviews, as the committee did not feel that it was appropriate to combine these populations for

							first-line treatment or relapse prevention. The committee reviewed the European Psychiatric Association classification but did not consider it appropriate to change the term to 'persistent depression' but considered that the grouping together of psychotic depression, depression with coexisting personality disorder and chronic depression for the further-line treatment review should allow the effectiveness of interventions for a more clinically complex population to be considered.

144	SH	Institute of Psychoanalysis	General	General	General	Economic analyses The committee acknowledged that the results from the economic models of treatment for a new episode were also taken into consideration in formulating treatment recommendations for these groups of depression. E.g., as stated: “The committee acknowledged that the economic evidence in this area is rather sparse and has limitations, and decided to draw additional information from the economic analysis of treatments of a new depressive episode that was undertaken for the guideline” (evidence review D, p. 180). Overall, the experts who, on behalf of our stakeholder organisation, reviewed the two cost analyses of first episode depression reported these two ambitious analyses were well conducted and that what was done is transparent. They pointed out however that the resulting findings are heavily influenced by the NMA and that the developers have duly reported that the economic analysis results need to be viewed in light of these limitations (in particular some evidence of inconsistency). The authors of the economic analysis also themselves stated that the results overall were “characterised by considerable uncertainty, as reflected in the wide 95% credible intervals around their mean rankings” (evidence review B. p. 360).Overall comment:Acknowledging the comments of the authors of economic analysis	Thank you for your comment. This first quote from evidence review D refers to the available economic evidence for interventions for further line treatment of depression. For this review question, economic evidence was derived exclusively from a systematic review of existing economic studies, as the area was not prioritised for de-novo economic modelling. When formulating recommendations the committee considered the existing clinical and economic evidence in the area of further line treatment. As the economic evidence in this area was limited and of variant quality, the committee looked at the economic evidence on treatments for a new episode of depression only to check and confirm whether it supports recommendations for further-line treatment, as an intervention that is cost-effective in treating a new episode gives more confidence that it may also be cost-effective in further-line treatment of depression. Thank you for your positive feedback on the guideline economic modelling. It is true that the economic models of treatments for a new episode of depression were informed by the guideline NMAs on discontinuation, response in completers and remission in completers, and that any limitations and uncertainties of the NMAs are reflected in the methods and results

						about how the findings should be viewed, we (too) would like to point that the models overall show high levels of uncertainty related to the relative effectiveness and cost effectiveness of all the interventions, including a very high degree of uncertainty about estimates of cost. This is expressed in the relatively modest or limited difference in overall quality of life gains, cost per QALY gains, and net monetary benefits between most interventions, and wide 95% credible intervals (CIs)around their mean rankings. For example, group CBT was identified as having the highest net monetary benefit for less severe depression. However, the CIs imply that the net monetary benefit could be anywhere between the 1st most cost effective and the 12th most cost-effective.Consequently, we do not think the economic cost analysis that was conducted warrants the suggested rankings of treatment recommendation. Given the lack of strong evidence of differences in the economic benefits of the different treatments we again would strongly suggest that the hierarchy of treatment choices needs to be changed to provide a menu (non-ranked) of treatment choices.Additionally:Overall, we feel that the models are very ambitious and, as with the NMA to assess clinical evidence, we are concerned that this developed model has not been tested before and consequently that its validity	of the economic models. Results were characterised by uncertainty, nevertheless, they did allow conclusions on cost-effectiveness to be made. For example, in less severe depression, group CBT did indeed show wide 95%CrI around its mean ranking, however it is noted that these were very skewed and that in most iterations group CBT ranked in a high place among other treatments (since its mean ranking was 2.76 in an analysis involving 16 interventions). It is noted that group CBT was found to be dominant in its comparison with group BA (which ranked 2nd most cost-effective), i.e. it was less costly and more effective, and, in their in-between comparison, group CBT had a 85% probability of being more cost-effective than group BA (data not shown in the report). Similarly, it was shown to have an ICER of £1,466/QALY versus group exercise (3rd most cost-effective option), which is well below the NICE lower cost-effectiveness threshold of £20,000/QALY, and a probability of being cost-effective of 81%. Therefore, the uncertainty expressed in the rankings reflects uncertainty in the overall results across the 16 interventions included in the analysis, but not necessarily uncertainty in the relative cost-effectiveness of each intervention and comparison within the analysis. Moreover, some interventions were found to be less cost-

						and reliability has not been made public for peer-reviewed scrutiny. This thus begs the question as to whether such an utmost important review of the evidence which is used to inform national treatment guidelines should utilise novel, and as such untested, models. The identified uncertainty in the results is a further and significant concern, which to our mind weakens the reliability of the treatment recommendations. The analysis looks at a 2-year follow-up phase. It is unclear why only two years have been chosen; the economic evaluation for PTSD, for example, chose a 3-year time horizon (see National Institute for Health and Care Excellence. Post-traumatic stress disorder. NICE; 2018. https://www.nice.org.uk/guidance/ng116). We are, furthermore, concerned that the data utilised to model these effects are based on the 6-months follow-up data derived from the NMA. As emphasised above the lack of available long-term follow-up data is crucial here, and the assumption that the effects at 6-months follow-up are sustained is highly questionable. Although the short-term follow up of the patient-level studies is a limitation that has not been acknowledged, this is important given that the impact of further-line treatment is likely to extend to the longer term, particularly cost savings.The definition or criteria for 'more severe depression' is rather confusing and needs clarifying. Looking at the evidence	effective than GP care, which was the reference treatment and was considered as a benchmark. Overall, uncertainty in relative cost-effectiveness may be higher for interventions in close places in ranking, but is lower between interventions ranked further apart, e.g. at the top and at the bottom of the ranking. After reviewing the clinical and economic evidence (including uncertainties and limitations), the committee considered it appropriate to arrange recommended treatments in the tables in the suggested order in which options should be considered, based on the committee's interpretation of their clinical and cost effectiveness and consideration of other issues such as the applicability of the evidence (e.g. for individual problem solving). However, this is not a rigid hierarchy, all treatments included in Tables 1 and 2 can be used as first-line treatments, and it may be appropriate to recommend an intervention from lower down in the table where this best matches the person's preferences and clinical needs. The committee were aware of the need to provide a wide range of interventions to take into account individual needs and allow patient choice. However, the committee did not consider it appropriate to list interventions in a non-ranked

						review B: appendix j, p. 289ff. it states on the one hand: “multiple recurrent episodes have not been incorporated” and that a separate model for relapse prevention has been developed. Yet, further down when depression is defined it is stated: “People in the economic analysis were assumed to be experiencing their first depressive episode if they had less severe depression and their third depressive episode if they had more severe depression, to cover a range of presentations of adults with a new episode of depression in routine clinical practice. The number of previous episodes determined the study population’s risk of relapse following remission of the current episode but had no impact on the effectiveness of interventions in treating their current episode.” It is not clear how these decisions about definitions were made or indeed how they are scientifically justified. It is of real concern that economic studies for those populations with chronic depression have been excluded in the other three reviews within this guideline because treatment recommendations for this group are based on the economic evidence from populations with ‘new depression episodes’. We consider it an error to assume that these study populations are similar. Even if this was the case, other aspects of difference may play an important role, including (a) that health care pathways differ,	menu, as this would not reflect the evidence base nor serve as a guide to choice for those who do not have pre-existing preferences. Regarding your additional comments: (a) The models are built following Markov modelling principles. These are not novel or untested techniques. Actually, Markov modelling techniques are routinely used in the economic evaluation of healthcare interventions for over 20 years. The complexity of the guideline economic modelling lies in the number of interventions tested for each level of depression severity, rather than in the models’ structure or underlying assumptions. (b) The 2-year follow-up phase (following treatment endpoint) was determined based on the committee’s advice. The purpose of selecting a longer time horizon (rather than a short time horizon that would end right after treatment for the new episode was completed) was in order to allow the longer-term impact of treatment success or failure as well as of potential treatment discontinuation on costs and outcomes to be captured. Moreover, a 2-year follow-up allowed modelling events such as drug continuation and tapering and/or provision of

						(b) the model chosen for new episodes may not be appropriate in terms of number of remission states, (c) the two-year time horizon considered is not sufficiently long to capture relative differences in cost and effects between interventions for chronic pression. A further concern of ours pertains to the additional scenario work that was carried out, which highlights that a stronger economic argument for all psychological interventions can be made when lower pay bands have been applied. We would urge NICE to consider the potential impact of this analysis and whether it might support further marginalisation of the psychological therapies professions within NHS services by providing an apparent rationale to reduce staff costs even more (with the consequence that services would nearly entirely need to be staffed by trainees or newly qualified therapists/psychologists). Salary costs at band 7 can already be considered rather low and mean that professionals would struggle to make a living, which has significant potential workforce implications for a healthcare sector already struggling with workforce supply issues.Lastly, we would like to point out the empirical basis for the QALYS threshold range of £20,000 to £30,000 currently adopted by NICE is limited and yet to be properly ascertained. We note that the threshold was recently lowered to £20,000, which is the	relapse preventive interventions, where relevant. It is noted that the effects and course of depression beyond end of treatment were based on synthesis of data from long-term epidemiological studies that examined the course of depression, studies on relapse prevention (where this was relevant to model), as well as a UK cohort study that reported related resource use and costs incurred by people with depression, and not on extrapolation of short-term data from the RCTs included in the NMAs. The NMAs informed only the first 3 months of the models, i.e. from treatment initiation until treatment effect was measured (either after completion or early discontinuation of treatment). Results regarding relative cost-effectiveness of interventions are not expected to be substantially different between 2 and 3 years, given that the immediate effects of the interventions assessed were applied onto the first 3 months in the model. Beyond the initial treatment period, people in the model were assumed to follow the same course of depression (same risk of relapse and future recovery) across all treatments (but with different proportions of people in remission/at risk of relapse, as different proportions of people recovered, responded or remained depressed at treatment endpoint in each arm of the model,

						threshold used in this guideline. We have not been able to find any explanation or indeed rationale as to why that was the case.	according to each treatment's relative effectiveness). (c) The text you cite around modelling recurrent episodes and the number of previous episodes are not related to the criteria for more severe depression. Definitions of less and more severe depression are provided in evidence review B, under 'Methods and Process - Summary of methods' Defining less and more severe depression' as well as in Appendix A. These definitions have been used throughout the report and across all analyses, including the economic analysis. The text you cite regarding multiple recurrent episodes describes the model structure and refers to future events, following treatment of a new episode. The text explains that the model included a two-year follow-up period, but (future) multiple recurrent episodes have not been incorporated in this model (which assesses 'acute' treatment) as they have been considered in a separate 'relapse prevention' model that was developed to support the respective review. The text has now been amended to clarify that the model has not incorporated multiple recurrent episodes that may happen in the future, following treatment of the new episode.

							Nevertheless, people in the model may have experienced depressive episodes before the treatment of their current episode. As stated, the number of previous episodes was needed in order to determine the risk of relapse following response/remission and had no impact on the effectiveness of the interventions in treating the current episode. In the base-case analysis, people with less severe depression were assumed to be experiencing their first depressive episode, while people with more severe depression were assumed to be experiencing their third depressive episode, based on the committee's advice. However, in deterministic sensitivity analysis, the number of previous episodes was increased from 0 to 2 in adults with less severe depression and was varied between 0 and 5 in adults with more severe depression (see 'Handling uncertainty' section). As seen in the results of sensitivity analysis, the impact of this change on the relative cost-effectiveness of treatments was negligible. (d) Economic studies for chronic depression have not been excluded from other reviews. Reviews of economic literature were conducted across all areas covered in the guideline. However, economic modelling was not possible to conduct across all areas due to time restrictions.

							According to NICE guideline development processes, an economic plan was prepared, which identified guideline areas prioritised for economic modelling, after consideration of expected resource implications and available clinical and economic evidence that would allow development of robust models. The areas of treatment of new episodes and relapse prevention were prioritised for de-novo modelling. In the area of chronic depression, the systematic search of the literature identified no relevant economic studies. Recommendations in chronic depression were thus primarily based on clinical evidence. As no economic evidence was identified for treatments for chronic depression, the committee looked at the economic evidence on treatments for a new episode of depression only to check and confirm whether it supports recommendations for chronic depression, as an intervention that is cost-effective in treating a new episode gives more confidence that it may also be cost-effective in chronic depression, provided that it has been shown to be effective in treating chronic depression. (e) The committee agreed that the sensitivity analysis relating to delivery of high intensity psychological interventions by therapists in lower pay bands is not relevant and it has now

							been removed from the economic analysis appendix. This scenario was only tested in sensitivity analysis and it played no role in interpretation of the economic results or when formulating recommendations. (f) The analysis was based on NICE principles and according to the NICE guidelines manual. The threshold has not been changed and is consistent with NICE guidance. According to the NICE guidelines manual (Box 7.2) "in general, interventions with an ICER of less than £20,000 per QALY gained are considered to be cost effective. […] Above a most plausible ICER of £20,000 per QALY gained, judgements about the acceptability of the intervention as an effective use of NHS resources will specifically take account of the following factors. The degree of certainty around the ICER. In particular, advisory bodies will be more cautious about recommending a technology when they are less certain about the ICERs presented in the cost-effectiveness analysis. The presence of strong reasons indicating that the assessment of the change in the quality of life has been inadequately captured, and may therefore misrepresent, the health gain. When the intervention is an innovation that adds demonstrable and distinct substantial benefits

							that may not have been adequately captured in the measurement of health gain. As the ICER of an intervention increases in the £20,000 to £30,000 range, an advisory body's judgement about its acceptability as an effective use of NHS resources should make explicit reference to the relevant factors considered above." In the case of the guideline economic modelling results, there were no strong indications of the presence of any of the conditions above (and in particular of differential presence of any of these conditions across interventions) that would dictate use of the NICE upper threshold of £30,000/QALY.

145	SH	Janssen	General	General	General	ReferencesMarshall L, Bibby J, Abbs I (2020), Emerging evidence on COVID-19's impact on mental health and health inequalities. Available here: https://www.health.org.uk/news-and-comment/blogs/emerging-evidence-on-covid-19s-impact-on-mental-health-and-health Accessed 12th January 2022.Mitchell, A., Hardy, S., & Shiers, D. (2017). Parity of esteem: Addressing the inequalities between mental and physical healthcare. BJPsych Advances, 23(3), 196-205. oi:10.1192/apt.bp.114.014266NICE ID1414: Esketamine for treatment resistant depression. Appraisal consultation document 2. Pg. 31-33. Section 3.30-3.31. Available here: https://www.nice.org.uk/guidance/gid-ta10371/documents/129-2 Accessed 10th January 2022Denee T, Kerr C, Ming T, Wood R, Tritton T, Middleton-Dalby C, Massey O, Desai M. Current treatments used in clinical practice for major depressive disorder and treatment resistant depression in England: A retrospective database study. J Psychiatr Res. 2021 Jul;139:172-178. doi: 10.1016/j.jpsychires.2021.05.026. Epub 2021 May 22. PMID: 34077893.Rush AJ, Trivedi MH, Wisniewski SR, Nierenberg AA, Stewart JW, Warden D, Niederehe G, Thase ME, Lavori PW, Lebowitz BD, McGrath PJ, Rosenbaum JF, Sackeim HA, Kupfer DJ, Luther J, Fava M. Acute and longer-term outcomes in depressed outpatients requiring	Thank you for providing these references. Responses to the points raised in the comments have been addressed in the corresponding comment sections.

						one or several treatment steps: a STAR*D report. Am J Psychiatry. 2006 Nov;163(11):1905-17. doi: 10.1176/ajp.2006.163.11.1905. PMID: 17074942.	
146	SH	Coventry and Warwickshire Partnership Trust	General	31	General	I appreciate the idea of more clients being able to access therapy as a first line treatment over medication initially for depression, but we have to make sure, as services we have the infrastructure to accommodate this rise in demand. Cutting therapy session times at step 2 would not be the way forward in my opinion or the opinion of my colleagues in services or wider Step 2 Networks, and will only further create stresses as revolving door clients are likely to place pressure on waiting lists, HI CBT and Secondary Care Services. It would be a false economical answer to the mental health crisis we are seeing in our country. Instead, what	Thank you for your comment. In response to stakeholder comments, the committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.

						Mental Health services need is more time, and more staff and investment.	
147	SH	Coventry and Warwickshire Partnership Trust	General	33	General	The work that PWP's do is already often undervalued and can be stressful and pressured enough, without making it completely unrealistic to see patients and generate positive outcomes – not only in terms of the client's recovery, but of the client's experience and perception of mental health services. Furthermore, the impact on the PWP morale, sense of purpose and role will likely be negatively impacted and thus likely lead to further depletion of an already thinning workforce.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.
148	SH	Coventry and Warwickshire Partnership Trust	General	36	General	I am unsure of 15-minute sessions and what empirical evidence they are based on. Step 2 Interventions include as essential: an agenda, safety (Risk) MDS review. These items alone would take the 15 minutes, where is the therapy? Or intervention? It also suggests having 8 of these 15-minute sessions over a period of 16 weeks. This WILL have a massive impact on recovery rates, revolving door patient culture and waiting lists which are already stretched to capacity. Not to mention impact on the wider	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.

						impact on training programmes for PWP's. It would appear this is quantity of quality of care, it also shows a lack of total disregard for the step 2 workforce and what we do as a profession.	
149	SH	Coventry and Warwickshire Partnership Trust	General	36	General	Looking at where the evidence for 15-minute appointments comes from - the only reference I can see is in Evidence Review B to 15 minutes is in regard to computerised CBT. I think that the draft guidance may have conflated cCBT with broader spectrum of the Supported Self Help that PWP's can and do deliver both face to face or via telephone / video link. This in itself is confusing, as if the proposed changes are to offer shorter appointments and review for the mild cases of depression, we already have a treatment and therapy platform set up for that, (SilverCloud) although it is not accessible for everyone, therefore where do these new guidelines fit in? Or are they a repeat of what we already have in services. Again, apparently showing a lack of understanding of front-line work and what IAPT services already are providing.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

150	SH	Coventry and Warwickshire Partnership Trust	General	36	General	One of the main concerns that came from PWP's in Coventry and Warwickshire NW team, was time and feeling undermined in their roles as clinicians. IAPT service in theory were set up to work with mild to moderate cases of depression and anxiety, however I feel it is fair to say personally working within IAPT service for 9 years now the complexity of clients is ever increasing across all the interventions not just at step 2. Therefore, the proposal of reducing any treatment time across any interventions but particularly at step 2 where it is already limited with complexity of client increasing is worrying and doesn't appear to be based on any IAPT recorded evidence, or clinical evidence?	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.
151	Individual	Individual 15	Guidance	General	General	Qualitative data extrapolated from service user experience by means of a systemic review employing formal methodology for qualitative synthesis should be used to inform the guidance. This would ensure comprehensive recommendations based on both quantitative and qualitative data from patients who have actually experienced treatment for depression.	Thank you for your comment. The committee agreed that a qualitative evidence review identifying the factors that can promote choice and act as barriers to choice, would enable recommendations to be made that improved the implementation of shared decision-making and ensured the people's preferences were taken into consideration, better than qualitative review looking at people's experiences of individual treatments.

152	Individual	Individual 15	Guidance	General	General	The guideline review should not recommend treatments based solely on clients who recover from depression by end of treatment, but should incorporate the amount of clinical effect (ie partial recovery) achieved from a severe baseline point. IAPT outcome measures already provide data on reliable change and reliable recovery. In addition, categorisations of depression severity must be based on validated tools, not un-validated non-transparent functions of them.	Thank you for your comment. The guideline includes continuous changes in scores on depression scales as a critical outcome for every treatment question, which will show changes for people who have both fully and partially recovered. This was agreed by the committee to be a better way to capture this data than the use of a dichotomous outcome for partial recovery. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context (including drawing on their knowledge of the IAPT dataset) so that the 'reality' for people experiencing depression was taken into consideration. In response to stakeholder comments, the committee have re-structured treatment recommendations in order to take into account implementation factors. In January 2020 NICE published a statement of intent signalling the ambition for the future use of wider sources of data and analytic methods (including sources commonly referred to as real-world data and evidence). To make decisions about the relative effectiveness of interventions, RCTs will continue to be prioritised in line with the NICE guidelines manual, in order to ensure that the populations treated with various interventions are equivalent. However it is possible that in the

							future, high-quality real-world datasets such as the IAPT dataset, could inform questions about access and engagement. The committee considered the distinction between less severe (subthreshold/mild) and more severe (moderate/severe) depression to be clinically meaningful in terms of supporting effective clinical decision making and being aligned with how clinicians conceptualize depression (in particular, GPs and other primary care staff, given that the majority of people with depression and almost all first line presentations of depression are managed in primary care). Based on this distinction, an anchor point of 16 on the PHQ-9 was selected as the cut-off between less severe and more severe depression, on the basis of alignment with the clinical judgement of the committee and eligibility criteria in the included studies. Published standardization of depression measurement crosswalk tables (Carmody 2006; Rush 2003; Uher 2008; Wahl 2014) were used in order to 'read-across' different symptom severity scales that were used in different studies.

153	Individual	Individual 15	Guidance	General	General	NICE must run a re-analysis of studies using quality of life and/or functions outcomes, where these are available, and prioritise recommendations based on these measures, given that these are the measures of greatest priority to service users.	Thank you for your comment. The committee agree that quality of life and functioning outcomes are important, and these outcomes were included in the treatment reviews. The committee noted the limited evidence for these outcomes, and included quality of life and functioning outcomes for the research recommendations in the guideline. The committee agreed that the results for these outcomes in the limited evidence base confirmed that there may be additional benefits on quality of life and functioning with some of the interventions for depression that had shown benefit for the critical (depression) outcomes. This provided reassurance, but there was not enough evidence on these important outcomes to alter their recommendations.
154	Individual	Individual 15	Guidance	General	General	The guideline should emphasise the need for shared decision-making and for clinicians to listen to and respect patient preferences. Recommendations should not be listed on a hierarchical basis but should include both quantitative and qualitative data, short and long-term effectiveness and cost, ensuring informed and fair decision-making by commissioners, clinicians and patients.	Thank you for your comment. The guideline recommendations on choice (and in the sections on treatment options) are very clear that a shared decision should be made and patient preferences taken into consideration. The NICE guidelines are evidence-based and so the interventions for first-line treatment are listed in order of clinical effectiveness and cost-effectiveness to aid clinicians and people with depression to choose the most effective treatment that is right for them, and to guide choice when there is no preference.

155	Individual	Individual 15	Guidance	General	General	While acknowledging the extension by five days of the original deadline, given the importance of this unprecedented third consultation, a closing date not so close to the Christmas and New Year holidays would perhaps have provided an opportunity for greater collaboration and a richer response from stakeholders.	Thank you for your comment. The time period for consultation was extended but needs to achieve a balance between time for stakeholders to respond, and ensuring the guideline is published in a timely fashion.
156	Individual	Individual 15	Guidance	General	General	Findings from indirect or mixed comparisons using Network Meta-Analysis (NMA) should only be used to supplement evidence derived from direct comparisons. NICE must re-analyse the data using standard meta-analyses and should NMA be used to supplement the findings, a validated and reliable model for doing so should be employed.	Thank you for your comment. NICE do not accept that the use of NMA was inappropriate and using NMAs both to assess clinical effectiveness and to inform the economic model was in accordance with the NICE guidelines manual. Pairwise data were also presented separately in the new version of the guideline to enable an easier comparison between direct and NMA results. Further sensitivity analyses were also conducted to test the robustness of the NMAs. In addition, there was a peer review of all NMAs by a NICE Technical Support Unit contractor and the code and data for the NMAs were made publicly available to enable further scrutiny. NICE recognises that no statistical technique will ever lead to an indisputably 'correct' answer, since they all involve assumptions and extrapolations of the available data. Both the committee and the quality assurance team considered any limitations of the analysis and the confidence they had in it when making recommendations. The data from the

							NMA were also considered alongside the other sources of data, including the pairwise meta-analysis data, economic model results, results of pragmatic trials and newly reviewed qualitative evidence, when forming recommendations.

157	Individual	Individual 15	Guidance	General	General	Trial where the majority of the population is clinically complex, chronic or treatment-resistant need to be grouped together as persistent depression for the purposes of review, following the European Psychiatric Association.	Thank you for your comment. For the further-line treatment review, studies were sought that included adults with depression showing an inadequate response to at least one previous intervention for the current episode and this included the further-line treatment of psychotic depression, depression with coexisting personality disorder and chronic depression. First-line treatment or relapse prevention of chronic depression (including dysthymia), and first-line treatment or relapse prevention of depression with coexisting personality disorder were separate reviews, as the committee did not feel that it was appropriate to combine these populations for first-line treatment or relapse prevention. The committee reviewed the European Psychiatric Association classification but did not consider it appropriate to change the term to 'persistent depression' but considered that the grouping together of psychotic depression, depression with coexisting personality disorder and chronic depression for the further-line treatment review should allow the effectiveness of interventions for a more clinically complex population to be considered.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

158	SH	Sport England	Guidance	General	General	Key points summaryWe support the inclusion of exercise as an optional first line treatment for people experiencing mild depression. However, feel there is significant opportunity for clinicians to promote a broader 'move more' message and integrate physical activity in adjunct to all treatment pathways for patients experiencing mild or severe depression.We support the inclusion of peer support in exercise treatment pathways for mild and severe depression.We would welcome the consideration within the methodology of the inclusion of broader research (including real-life setting research, physical activity non-randomised trials and physical inactivity research) to enrich the guideline development. Whilst structured, group exercise may be appropriate for some individuals, broader options that are person-centred and individualised should be considered due to their proven effectiveness such as social prescribing, community provision and self-led activity.We feel the high level of frequency and duration information included within the exercise treatment pathway delivery information could be too ambitious and unrealistic for many people experiencing mild or severe depression.We feel a ranking approach of intervention options on the treatment wheel undermines true patient choice. We are concerned how in practice a patient will be informed of the exercise treatment option,	Thank you for your comment. The committee agreed that, although the evidence for exercise had indicated that a certain level of exercise (in terms of duration and intensity) was most effective for the treatment of depression, based on their knowledge and experience it would be useful to include advice that any level of exercise may be beneficial and so have added a recommendation stating this. In response to stakeholder comments, the recommendations on structured exercise for depression have however, now been changed and the committee has now removed the suggested duration of exercise sessions and modified the recommended frequency to allow more flexibility in the delivery of exercise programmes. Due to the very large quantity of evidence available on the treatment of depression, the committee prioritised randomised controlled trials for their evidence reviews on effectiveness, and so non-randomised trials and real-life research were not included. The NICE guidelines are evidence-based and so the interventions for first-line treatment are listed in order of clinical effectiveness and cost-effectiveness. Cost-effectiveness is an important NICE criterion that underpins recommendations, as it ensures efficient use of resources. When

						particularly if they have no preference and limited understanding of what could be available to them.We feel the starting point for treatment options should not be the most cost-effective interventions. We suggest a method that starts with understanding patient needs through appropriate questioning and responding with the most relevant treatment option/s.The barriers to being active for those living with mental health conditions should be addressed in any exercise treatment pathway created. This will support recruitment and patient attrition rates.	formulating recommendations, the committee considers the available clinical and cost-effectiveness evidence, as well as the quality, applicability and uncertainty around this evidence. They also make further considerations including equity, individual needs, patient choice, legal and regulatory constraints, implementation issues and practicalities of use. The hierarchy of recommendations therefore aids clinicians and people with depression to choose the most effective treatment that is right for them, and to guide choice when there is no preference. We have already addressed in the table of options that any barriers to being physical activity should be considered and addressed.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

159	SH	Turning Point	Guidance	General	General	The use of the generic term 'counselling' is not specific enough and fails to adequately illustrate the specific form of talking therapy that is being recommended.There is no reference to Person Centred Experiential Counselling (previously CfD). This is an (up to) 16 session High Intensity model used within IAPT services in the treatment of depression. We employ a large PCEC team within our IAPT services who work with an emotion focussed form of counselling and have well over 50% recovery rates consistently for some of our most complex cases and clients, where a cognitive or behavioural approach is inappropriate /ineffective. Generic term for “counselling used” does not specify the model that should be used or differentiate from and identify the strong evidence for PCE counselling.	Thank you for your comment. All the evidence for counselling that was included in the review for the treatment of a new episode of depression was non-directive counselling, and the committee therefore did not consider it appropriate to recommend specific interventions (for example, Counselling for Depression/Person-Centred Experiential Therapy [PCET]) as the evidence was not reviewed for these interventions. However, based on informal consensus, the committee agreed that counselling should use an empirically validated protocol developed specifically for depression and this was included in the recommendation.

160	SH	Turning Point	Guidance	General	General	‘Guided self-help’ and lack of alignment with Low Intensity Step 2 therapy delivered in IAPTMention of “problem solving” and “guided self-help” (no mention of step 2, PWP or low intensity) as interventions. No mention of other PWP interventions commonly successfully delivered by PWPs such as step 2 behavioural activation or cognitive restructuring, or sleep hygiene. In the new guidelines BA is completed at step 3 over 8 x 60 min sessions according to the new guidelines so this would appear to correspond with step 3 CBT. Guided self self help for Depressions states:Usually consists of 8 structured sessions with an initial session of up to 30 minutes and further sessions of up to 15 minutes • Usually takes place over 16 weeksThis significantly impacts the IAPT service delivery model and does not fit with IAPT interventions or trainingIn step 2 IAPT sessions it is a requirement to review Minimum Data set scores which are completed every week, review and set homework and complete an intervention - 15 minutes is not enough to complete the MDS review and risk assess and effectively review and set between session work, never mind provide psychoeducation and/or interventionStep 2 problem solving – Guidance states - Usually first session is 1 hour and then 8 weekly sessions of 30 minutes each – this does not fit with IAPT curriculum or experience and would impact waiting	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The self-help with support section has been relabelled as guided self-help and the description of guided self-help has been amended to recommend that printed or digital materials that follow the principles of guided self-help are used including structured CBT, structured BA, problem solving or psychoeducation materials, delivered face-to-face or by telephone or online. In response to stakeholder comments, the committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.

						times and service delivery. Step 2 problem solving is delivered in up to 6 half an hour sessions.	
161	SH	Turning Point	Guidance	General	General	There's a reliance on research methodology that fails to appreciate the necessarily complex process of treatment decision making and identifying a therapy that is likely to alleviate distress. The hierarchical suggestions for treatment offer fail to incorporate psychological processes that lead to depression, e.g., complex grief, poor self-efficacy.	Thank you for your comment. The consideration of the processes that lead to depression and on treatment decision-making are considered in the section of the guideline on principles of care, and in the recommendations on choice of treatments. The suggestions for interventions to treat depression are based on clinical and cost-effectiveness evidence, but due to the very large quantity of evidence available on the treatment of depression, the committee prioritised randomised controlled trials for their evidence

							reviews on effectiveness. However, patient preference and shared decision-making is still a key component of these recommendations.

162	SH	Turning Point	Guidance	General	General	The differentiation between less and more severe depression should be clearer, to inform decision making within a stepped-care model. How is this measured? Within IAPT we see clients with 'severe' depression (as ascertained by PHQ-9 scores) who recover very well through step 2 BA or cognitive restructuring. Is severity referring to mood scores, complexity, longevity, treatment resistance, impact on function etc. These needs defining.	Thank you for your comment. The committee were aware that a proper assessment of severity cannot be based solely on a symptom scale and the guideline includes a recommendation to conduct a comprehensive assessment that does not rely simply on a symptom count but also takes into account both the degree of functional impairment and/or disability associated with the possible depression and the length of the episode. The committee considered the studies identified by the review and agreed that although baseline symptom scores have limitations as an indicator of severity, this information was available for the majority of studies, whereas other factors such as duration of disorder or functional impairment were not reported in a sufficiently consistent manner for them to be of use in determining severity. The committee considered the current NICE classifications of mild to moderate and moderate to severe depression, and agreed that although these classifications have been adopted quite widely there is potential uncertainty with regards to the management of moderate depression. The committee agreed that a dichotomy of less and more severe depression was clearer, and the guideline includes definitions (that less severe depression includes

							the traditional categories of subthreshold symptoms and mild depression, and more severe depression includes the traditional categories of moderate and severe depression) in order to improve practical utility. The committee considered the distinction between less severe (subthreshold/mild) and more severe (moderate/severe) depression to be clinically meaningful in terms of supporting effective clinical decision making and being aligned with how clinicians conceptualize depression (in particular, GPs and other primary care staff, given that the majority of people with depression and almost all first line presentations of depression are managed in primary care). Based on this distinction, an anchor point of 16 on the PHQ-9 was selected as the cut-off between less severe and more severe depression, on the basis of alignment with the clinical judgement of the committee and eligibility criteria in the included studies. Published standardization of depression measurement crosswalk tables (Carmody 2006; Rush 2003; Uher 2008; Wahl 2014) were used in order to 'read-across' different symptom severity scales that were used in different studies.

163	SH	Turning Point	Guidance	General	General	Quality of life, partial-recovery and patient experience is under-represented in the guidance.	Thank you for your comment. The committee agree that quality of life is important, and this outcome was included in the treatment reviews. The committee noted the limited evidence for quality of life, and included this outcome for the research recommendations in the guideline. The committee agreed that the results for this outcome in the limited evidence base confirmed that there may be additional benefits on quality of life with some of the interventions for depression that had shown benefit for the critical (depression) outcomes. This provided reassurance, but there was not enough evidence on this important outcome to alter their recommendations. The guideline includes continuous changes in scores on depression scales as a critical outcome for every treatment question, which will show changes for people who have both fully and partially recovered. This was agreed by the committee to be a better way to capture this data than the use of a dichotomous outcome for partial recovery. As specified in the scope, the experience of care section from the 2009 guideline was not included in this update. However, a new review

							question on patient choice was added to this update that includes a systematic review of primary qualitative studies that focus specifically on service user experience around choice of treatment.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

164	SH	Turning Point	Guidance	General	General	Whilst evidence is currently low, more guidance on remote therapy delivery would be helpful (i.e. can face to face mean video therapy, how are telephone or type talk therapies perceived)	Thank you for your comment. Some of the evidence reviews did include delivery of interventions by a remote method (for example videoconferencing), and the review on access looked at interventions specifically for groups who may not access treatment for depression, which included remote delivery methods. Based on this, and on their own experience, the committee recommended remote consultations be considered for use at several places in the guideline, and be used as an alternative for people who wish to and are able to access services in this way to increase uptake. However, the committee did not carry out a specific review to identify which remote methods are effective or perceived well by the general population of people with depression.

165	SH	Turning Point	Guidance	021-037	General	The guidance does not align with the IAPT manual, and therefore does not align with IAPT staffing, model, funding arrangements, contracts, HEE teaching curriculum or experience/evidence. There is a lack of alignment with step 2 interventions or delivery and excludes Person Centred Experiential Counselling (previously CfD).Guidelines fail to reflect 'real-world' routine practice by neglecting retrospective IAPT data collection and evidence; as such, local data supporting the efficacy of HI-CBT, IPT, PCEC and LI-CBT isn't represented. Locally in our IAPT services for example we have large active IPT and PCE counselling teams with recovery rates well over 65%.	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. All the evidence for counselling that was included in the review for the treatment of a new episode of depression was non-directive counselling, and the committee therefore did not consider it appropriate to recommend specific interventions (for example, Counselling for Depression/Person-Centred Experiential Therapy [PCET]) as the evidence was not reviewed for these interventions. However, based on informal consensus, the committee agreed that counselling should use an empirically validated protocol developed specifically for depression and this was included in the recommendation. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context (including drawing on their knowledge of the IAPT dataset)

							so that the 'reality' for people experiencing depression was taken into consideration. . In January 2020 NICE published a statement of intent signalling the ambition for the future use of wider sources of data and analytic methods (including sources commonly referred to as real-world data and evidence). To make decisions about the relative effectiveness of interventions, RCTs will continue to be prioritised in line with the NICE guidelines manual, in order to ensure that the populations treated with various interventions are equivalent. However it is possible that in the future, high-quality real-world datasets such as the IAPT dataset, could inform questions about access and engagement.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

166	SH	Turning Point	Guidance	19	General	Should incorporate that antidepressant use should be used for a limited amount of time and should be reviewed regularly by a health practitioner	Thank you for your comment. The over-arching information on starting antidepressant medication already includes advice about the recommended duration of antidepressant medication and that people taking antidepressants should be reviewed regularly, so this information has not been repeated again in this later section of the guideline.

167	SH	Turning Point	Guidance	23	25	Recommendation for 2 people per group, with attendance of 8, whilst a gold standard, is not cost effective or possible within IAPT services due to funding and capacity issues. 2 facilitators would result in half as much of an impact on waiting lists, and as the guidance points out, longer waits lead to poorer recovery rates. It feels this could be an unnecessary detail in the guidance that could cause problems for service delivery	Thank you for your comment. The recommended resource use was based on relevant information reported in the RCTs that were considered in the guideline NMA and economic analysis of treatments for a new episode of depression, supplemented by the committee's clinical experience of optimal delivery of interventions within the NHS. This information has now been added in evidence review B, under Appendix N. Few studies reported the number of participants in group interventions and even fewer made specific reference to the number of therapists per group. For group behavioural therapy in less severe depression, only one study reported the number of participants per group. The reported number was 7-8 per group. For group CBT in less severe depression, 4 studies reported the number of participants per group, and this ranged from 4 to 6. For group MBCT in less severe depression, only one study reported the number of participants per group. The reported number was 8-15 per group. Regarding the number of therapists, the committee expressed the view that group interventions should be optimally delivered by two therapists, one leading the delivery of the intervention and another one observing. The information and committee's considerations on optimal delivery of group interventions have been reflected in the

							economic modelling and the respective recommendations. It is noted that the guideline economic modelling, which assumed delivery of group interventions by 2 therapists to groups of 8, suggests that group interventions are cost-effective. The recommendation on the number of therapists has now been modified, to clarify that at least one of the therapists (rather than both) needs to have therapy-specific training and competence. The recommendations suggest the number of participants that groups should 'usually' have, to allow flexibility around the number of participants per group. The suggested number of participants for MBCT groups has now been modified according to available evidence.

168	SH	Turning Point	Guidance	33	General	The list of what is supported via counselling does not feel extensive enough. In addition, PCE counsellors work with psychosocial, relationship, coming to terms with change, grief and loss, self-esteem/work, recovery from adverse childhood experiences etcWhilst patient choice is incredibly important, it could be clearer that this is only where there is a clinical indication of need/appropriateness. For example, a client with significant substance misuse issues may undergo CBT for depression, but clinically they need specialist services to reduce their usage in the first instance, and NICE should be clearer in helping services manage this challenge.	Thank you for your comment. All the evidence for counselling that was included in the review for the treatment of a new episode of depression was non-directive counselling, and the committee therefore did not consider it appropriate to recommend specific interventions (for example, Counselling for Depression/Person-Centred Experiential Therapy [PCET]) as the evidence was not reviewed for these interventions. However, based on informal consensus, the committee agreed that counselling should use an empirically validated protocol developed specifically for depression and this was included in the recommendation. The committee acknowledge that the problems of depression need to be addressed in a wider personal and social context. Throughout the guideline, and particularly in the sections on initial assessment and choice of treatments, there is a strong theme of collaborative decision making about care. The recommendations in the choice of treatment section include a recommendation that discussions are had with the person with depression that explore what, if anything, they think might be contributing to the development of their depression (including living conditions, drug and alcohol use, debt, employment situation and social isolation, and in

							response to stakeholder comments trauma has also been added as a factor to consider). In the further-line treatment section of the guideline, there is also a recommendation that if a person's depression has not responded to treatment, discussion should be had about whether there are any personal or social factors or physical or other mental health conditions that might explain why the treatment isn't working.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

169	SH	Turning Point	Guidance and visual summaries	021 - 033	18	The guidance document sounds like all options are on equal footing and people can jump straight through to most appropriate option, however the visual summary 'wheel of choice' very much sounds like a stepped approach where you can only get to options like IPT by exhausting the other options. Wording "recommended order" should be removed so that clients and therapists are able to consider the appropriateness of the full range of options and ensuring the right treatment first. The wheel implies that CBT options are better/try first options. It also neglects stepped care and 'least intrusive option first'. Trying the wrong treatment first, can cause disengagement and hopelessness in clients, and burnout and disillusionment in therapists. It is also costly to the NHS for clients to 'try' multiple forms of therapy. Would support wording in the guidelines but the 'wheel of choice is confusing'. There is a feeling that the visual summary suggests that IPT and counselling are last options behind CBT where actually in deprived areas such as Wakefield, psychosocial and relationship difficulties are highly prevalent due to social factors and in this instance IPT and counselling are clinically warranted.	Thank you for your comment. The guideline recommendations on choice (and in the sections on treatment options) are very clear that a shared decision should be made and patient preferences taken into consideration. The NICE guidelines are evidence-based and so the interventions for first-line treatment are listed in order of clinical effectiveness and cost-effectiveness to aid clinicians and people with depression to choose the most effective treatment that is right for them, and to guide choice when there is no preference. However, it is made clear that people can start at any point in the list (or the wheel) and there is no requirement for people to fail one treatment in order to access another one. However, based on stakeholder feedback, the use of stepped care, as you suggest, and early consideration of guided self-help, has been added into the recommendations.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

170	SH	Association for Dance Movement Psychotherapy UK, British Association of Art Therapists, British Association of Music Therapists and the British Association of Dramatherapists	Guideline	010-011	012-023003-018	Under Choice of treatments (1.3) the guideline suggests on page 10 the following:1.3.1 Discuss with people with depression: • what, if anything, they think might be contributing to the development of their depression• whether they have ideas or preferences about starting treatment, and what treatment options they might prefer• the person's experience of any prior episodes of depression or treatments for depression • what they would expect to gain from treatment.1.3.2 Allow adequate time for the initial discussion about treatment options, and involve family members, carers or other supporters if requested by the person with depression.And later on (page 11):1.3.4 Discuss with people with depression their preferences for treatments (including declining an offer of treatment) by providing: • information on what treatments are available, their potential benefits and harms, any waiting times for treatments, and the expected outcomes • a choice of: − the treatments recommended in this guideline − how they will be delivered (for example individual or group, face-to-face or remotely) and where they will be delivered • the option to express a preference for the gender of the healthcare professional, to see a professional they already have a good relationship with, or to change professional if the relationship is not working.1.3.5 Make a shared decision with the	Thank you for your comment. As specified in the scope, the experience of care section from the 2009 guideline was not included in this update. However, a new review question on patient choice was added to this update that includes a systematic review of primary qualitative studies that focus specifically on service user experience around choice of treatment. Thank you for drawing our attention to Millard et al. (2021), however, this was not included in the patient choice review as it is a cross-sectional survey rather than primary qualitative study design. Windle et al. (2020), Blomdahl et al. (2018), and Zubala et al. (2015) were not identified by our searches. However, they do not meet eligibility criteria for the patient choice review as the outcomes are not relevant (no experiences relevant to the choice of treatment). These studies have now been added to the excluded studies list of Supplement I. Sajnani et al. (2018) was not eligible for inclusion as it is a book section (as outlined in the review protocol). Art therapy and music therapy were listed as interventions of interest for the treatment reviews. However, only one study of music therapy (Albornoz 2011) is included in the network meta-analysis for the treatment of a

						person about their treatment.However, we would like the draft guideline to acknowledge evidence on client preferences for arts therapies. For example, the following are missing:Millard, E., Medlicott, E., Cardona, J., Priebe, S., & Carr, C. (2021). Preferences for group arts therapies: a cross-sectional survey of mental health patients and the general population. BMJ Open 2021;11: e051173. doi: 10.1136/bmjopen-2021-051173.In the study of people's preferences by Millard et al (2021), approximately 60% of participants were interested in taking part in group arts therapies. Music therapy was the most frequent choice among mental health patients (41%) and art therapy was the most frequent choice in the general population (43%). Past experience of arts therapies was the most important predictor of preference for that same modality. Expectations of enjoyment, helpfulness, feeling capable, impact on mood and social interaction were most often reported as reasons for preferring one form of arts therapy. The authors concluded that large proportions of the participants expressed an interest in group arts therapies. This may justify the need for a wide provision of arts therapies and the offer of more than one modality to interested patients. It also highlights key considerations for assessment of preferences in the arts therapies as part of shared decision-making.Windle, E., Hickling,	new episode of more severe depression. There was also only one eligible study for art therapy (Nan 2017), in the further-line treatment review. The committee considered the evidence too limited to make a recommendation for art therapy or music therapy.

						L. M., Jayacodi, S., & Carr, C. (2020). The experiences of patients in the synchrony group music therapy trial for long-term depression. The Arts in Psychotherapy, 67, 101580. doi:10.1016/j.aip.2019.101580The client reports on their experiences of these groups are also important to note and currently missing from this guideline. For example, Windle et al (2020) explored the lived experiences of the participants in music therapy groups. Ten individuals participated in semi-structured interviews. These were analysed by a music therapist, research psychologist and lived experience researcher, using interpretative phenomenological analysis (IPA). Three superordinate themes were identified: „the group as a happy and safe place", „music stimulates new feelings and songwriting aids expression into words" and „uncertainty, unmet needs and the ending were challenging". Findings underscore the importance of early group cohesion and the role of music and song-writing in promoting enjoyment, exploration and a sense of achievement.Blomdahl et al. (2017). Meeting oneself in inner dialogue: A manual-based phenomenological art therapy as experienced by patients diagnosed with moderate to severe depression. The Arts in Psychotherapy, 59, 17-24.Blomdahl et al. (2017) reported on the experience of patients diagnosed with moderate to	

						severe depression participating in art psychotherapy in Sweden and highlighted that they become more aware of inner dialogues through the art, with support of the therapist. Sajnani, N., Cho, A., Landis, H., Raucher, G. and Trytan, N., 2018. Collaborative discourse analysis on the use of drama therapy to treat depression in adults. In Zubala A and Karkou V (eds) Arts Therapies in the Treatment of Depression (pp. 87-101). London: RoutledgeIn drama therapy in the USA, Sajnani et al (2018) presents a collaborative discourse analysis of four accounts of using drama therapy in the treatment of depression in adults with value placed on the embodied, imaginative, externalizing, expressive, relational, and integrative functions of drama therapy with this population. Zubala, A., & Karkou, V. (2015). Dance movement psychotherapy practice in the UK: Findings from the Arts Therapies Survey 2011. Body, Movement and Dance in Psychotherapy, 10(1), 21-38In dance movement psychotherapy, Zubala et al (2015) report of the prevalence of working with depressive symptoms with people with mixed diagnosis, highlighting the positive impact of the psychotherapeutic use of movement and dance on mood.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

171	Individual	Individual 1	Guideline	General	General	Frankly, these suggestions are abhorrent and clear violation of patient care and evidence-based practice in favour of saving money which will backfire as in the long-run more money will be spent managing step-ups and re-referrals. The recent changes in funding by HEE will see a reduction in those applying for IAPT training programmes and these measures will reduce that further making it impossible to fill the ever-growing demand in services. I suggest a complete overhaul of the IAPT programme. Target caps at 20 clinical contacts for every service, sticking to the evidence in terms of offering up to 20 sessions within individual CBT.	Thank you for your comment. The treatment suggestions in the revised guideline are based on evidence for effectiveness and cost-effectiveness. Cost-effectiveness is important to maximise the use of limited NHS resources. However, the recommendations also allow for patient choice, preference and shared decision-making and so it is hoped the guideline will enable people with depression to be offered a treatment that is both effective and acceptable to them, to maximise treatment outcomes.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

172	SH	Viatris	Guideline	General	General	1. We recognise the importance of correct early identification and management of depression in adult patients and welcome the NICE update to this guideline. We wish to draw the guideline committee's attention to the occurrence of low mood amongst menopausal women. The low mood associated with the menopause differs from that of major clinical depression. However, symptoms of the menopause may overlap with depression and can lead to women being mis-diagnosed as depression. Low mood is a prevalent symptom amongst women going through the menopausal transition. A survey conducted by the British Menopause Society found that low mood affected up to 52% of women surveyed, between the age of 45-65.1With women spending up to a third of their life post-menopause, it is important to ensure that they are properly identified, and their treatment optimised. In order to appropriately treat this cohort of patients, the two conditions should be carefully differentiated. National and international menopause guidelines are aligned in their recommendation for the use of HRT (hormone replacement therapy) and CBT (cognitive behavioural therapy) to alleviate menopause associated low mood and are against the use of SSRIs, SNRIs within this context.2,3,4 We would therefore call for inclusion into the Depression in Adults guideline: 1) a reminder to clinicians to be	Thank you for your comment. A link to the NICE guideline on menopause has been added to the recommendations as you suggest, to remind healthcare professionals to consider the care of these women separately.

						alert to menopausal symptoms when treating women in that typical age group, 2) the provision of information on differentiating depression from menopausal symptoms, and 3) a link to the NG 23 menopause guidelines for further information on appropriate treatment.ReferencesThe British Menopause Society Are women suffering in silence? 2016. Available at: https://thebms.org.uk/2016/05/women-suffering-silence-new-bms-survey-putsspotlight-significant-impact-menopause/.NICE. Menopause: diagnosis and management. NICE Guideline 23. NICE, 2015 (last updated December 2019). Available at: www.nice.org.uk/guidance/ng23 Hamoda H et al. The British Menopause Society & Women's Health Concern 2020 recommendations on hormone replacement therapy in menopausal women. Post Reproductive Health. October 2020Baber R et al. IMS Writing Group. 2016 IMS Recommendations on women's midlife health and menopause hormone therapy. Climacteric. 2016; 19(2): 109–50.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

173	SH	NHS Nottingham and Nottinghamshire CCG	Guideline	General	General	Concerned that the terms antidepressant withdrawal and withdrawal effects, that are used throughout the guideline, may imply that antidepressants are addictive. The terms antidepressant discontinuation and discontinuation effects would be more accurate.	Thank you for your comment. The committee agreed to use the terminology 'stopping antidepressant medication' as the most unambiguous and clear terminology, but have referred to withdrawal symptoms, as these are known to occur when antidepressants are stopped. There is no suggestion in the guideline that antidepressants are addictive, as tolerance or cravings do not occur.
174	SH	NHS Nottingham and Nottinghamshire CCG	Guideline	General	General	Concerned that there is a lot more detail in the guideline about stopping antidepressants than there is about starting antidepressants. There is no level of detail about how to start SSRIs or how to choose between them.	Thank you for your comment. The committee were aware that the safe and successful stopping of antidepressants requires care and that tapering is not always carried out appropriately so were keen to make detailed recommendations about this. They did not think the same level of detail was required about starting antidepressants, but did include detailed information about the factors to take into consideration and to discuss with the person with depression. The committee discussed whether to make more detailed recommendations about the choice of antidepressants but agreed that there was a lack of head-to-head comparisons, that choice should be individualised , and that naming specific drugs might affect the longevity of the guideline as the choice of available antidepressants may change.

175	Individual	Individual 5	Guideline	General	General	The guideline does not include evidence on the effectiveness of metacognitive therapy (MCT). There are 15 published studies on the effects of MCT across mild, moderate and treatment resistant depression. Three studies are randomised trials in depression with follow-up (and should meet inclusion criteria for this guideline), with two of these being comparisons of MCT against CBT. These studies are: Hagen et al 2017; Jordan et al, 2014; and Callesen et al 2020, and should be reviewed. The guideline does not include two eligible published systematic reviews and meta-analyses of MCT in anxiety or depression (Normann et al, 2014; Normann & Morina, 2018). A greater volume of evidence is available for assessing MCT in depression than is available for several of the other treatments that are included in the guideline. I am concerned that the general guideline and evidence review will therefore be seen as suffering from an important omission.	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. Metacognitive therapy (MCT) was included in the class of cognitive and cognitive behavioural therapies (as was CBT). Jordan 2014 was included in the NMA that informed the recommendations. However, because the study included a within-class comparison it is not included in the forest plots, and is not mentioned in the text as the within-class comparison of MCT versus CBT, was not regarded by the committee as a critical comparison.

							Callesen et al. (2020) was identified by the searches but did not meet inclusion criteria as less than 80% of participants were receiving first-line treatment (35% receiving psychiatric medication at baseline). This study is in the excluded studies list of Supplement B1. Hagen et al. (2017) was not identified by the searches. However, it does not meet inclusion criteria as more than 20% of participants have a coexisting personality disorder (33% have an Axis II disorder). This study has now been added to the excluded studies list of Supplement B1. Normann et al. (2014) and Normann and Morina (2018) were not identified by the searches. However, they have been checked for relevant references and no additional eligible studies were identified. These studies have now been added to the excluded studies list of Supplement B1.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

176	SH	UK ECT Improving Standards campaign group	Guideline	General	General	NICE 2003 stated that 'Further research is urgently required to examine the long-term efficacy and safety of ECT'.In relation to safety, we note:There is no statement about safe dosage, frequency or duration of treatment and there are no standardised dosing protocols, although NICE 2003 noted that '…. stimulus parameters impact on the safety and efficacy of the technique, and recent research needs to be augmented.' This is highly problematic because ECT devices were never subjected to pre-market safety and effectiveness testing to establish dosing limits or protocols typically required by the MRHA for modern medical devices. MECTA ECT machine manufacturer recently filed for bankruptcy because it could not maintain product liability insurance due to the number of pending lawsuits regarding ECT's long-term consequences of having marketed ECT devices without first completing safety testing to establish dosing limits and protocols. (https://reorg.com/mecta-corp-first-day-declaration/)Research in 2021 on ECT's electrical dosing states: 'Dose optimization has followed heuristic approaches, and controversies remain unreconciled despite decades of research'(A); 'there is still no scientific rationale and for variables involved in present dosing practices' (B). There can never be a predictable, safe way of delivering ECT using the existing	Thank you for your comment. The committee discussed the fact that people need to be fully informed about the risks and benefits of ECT prior to its administration, and need to make an informed decision to have ECT. For this reason the committee stregthened the recommendations from the previous version of the guideline and added the requirement for clinics providing ECT to be ECTAS-accredited, with board level accountability for compliance with ECTAS standards. The committee did not review the evidence for ECT dosage and titration, and this was outside the scope of this update. The committee were aware that the ECTAS standards were developed with a wider range of ECT experts than were available on the guideline committee, and were updated on a regular basis, and therefore agreed that it was more appropriate to refer to these standards than create new recommendations. The committee have reiterated their call for more research into the place in therapy of ECT, and will also recommend to NICE that it explore doing future work on neuromodulatory techniques (and/or rapidly acting treatments) including ECT.

						titration method of dosing. This is explained by the fact that there are over 12 variations of settings on ECT machines plus an infinite combination of conduction properties of tissues within an individual's brain. This means ECT is not consistently applied; the same dose may alleviate depression in some, have no effect on depression in another whilst causing serious brain damage in others.The other danger posed by the ECTAS dosing scheme is the 1.5 multiplication factor which leads to the largest incremental changes at the highest and most dangerous doses. E.g.90mc x1.5 = 135mc an increase of just 45 mc whereas 450mc x1.5 = the next dose is 675mc an increase of 275mc. No other medical treatment recommends less caution at higher doses. This undoubtedly increases the risk of irreversible damage in an inherently unpredictable dosing scheme.However, over the last decade research into electric field density (v/m) generated by ECT within the brain has not only demonstrated the unpredictable nature of the titration method, but also suggested a way forward that could make ECT much safer.(A,B,C,D,E,F)Deng et al (B) suggest that if the electric field dose is restricted to below 112v/m in the hippocampus then cognition could be spared. They state: 'Our results have implications for ECT dosing. With a fixed extracranial current amplitude, the ECT "dose" as	

						represented by the intracranial E-field is highly variable due to anatomic differences in skin, skull, fluid, and brain tissue [29]. This anatomic variability is prominent in older (age 50+ years) adults with MDD and can compromise both antidepressant efficacy (insufficient stimulation of mood-related circuitry) and safety (inducing cognitive impairment due to excessive stimulation of cognitive related circuitry……. To improve the accuracy and precision of ECT dosing, we propose a solution towards individualized amplitude "E-fieldinformed-ECT.'Some authors state that the time and cost could make E-field informed ECT impractical and expensive. Our experience is that the injuries caused by ECT are life changing, incurring heavy costs in unemployment and loss of independence, with huge financial implications for both the individual and society. ESA and PIP benefits alone add up to over £10,000 per year. Any QUALI calculations must include the cost of a lifelong disability.In view of the above research, we ask NICE to:1. Perform a review of the electric field research including, but not restricted to, A-F. This must be carried out by an expert with proven experience with the effects of electric fields on human tissues.2. Consider whether NICE can justify continuing using the dosing titration method. Can they reassure patients that this is a sensible, scientific and safe policy to	

						adopt?3. Consider whether NICE can justify supporting the method of increasing the dose by the 1.5 multiplication factor. Can they reassure patients that this is not an inherently risky policy?4. NICE should develop a scientifically proven and predictable dosing regime.5. NICE must offer reassurances that safety is paramount and the cost or practical hurdles will not get in the way of patient safety.6. NICE must require patients and hospitals to be informed that dosing is unpredictable and can cause serious injuries7. Consent must be given every time there is an increase in dosing as the risk benefit profile changes with increasing dose. A procedure with a dose of 90MC is very different than a dose of 700mc.A) Unal G, Swami JK, Canela C, et al. Adaptive current-flow models of ECT: Explaining individual static impedance, dynamic impedance, and brain current density. Brain Stimul. 2021;14(5):1154-1168.(B) Deng Z-D, Argyelan M, Miller J, et al. Electroconvulsive therapy, electric field, neuroplasticity, and clinical outcomes. Mol Psychiatry. 2021;(October):1-7. doi:10.1038/s41380-021-01380-y(C) Deng Z De, Lisanby SH, Peterchev A V. Controlling stimulation strength and focality in electroconvulsive therapy via current amplitude and electrode size and spacing: Comparison with magnetic seizure therapy. J ECT. 2013;29(4):325-335. D) Won Hee	

						Lee1, Sarah H. Lisanb, Andrew F. Laine, and Angel V. Peterchev. Comparison of electric field strength and spatial distribution of electroconvulsive therapy and magnetic seizure therapy in a realistic human head model. Eur Psychiatry. August 2016 ; 36: 55–64E) Behailu Kibret , Malin Premaratne , Caley Sullivan, Richard H. Thomson & Paul B. Fitzgerald. Electroconvulsive therapy (ECT) during pregnancy: quantifying and assessing the electric field strength inside the foetal brain. Nature 7th march 2018 F) Miklos Argyelan , Leif Oltedal, Zhi-De Deng, Benjamin Wade, Marom Bikson, Andrea Joanlanne, Sohag Sanghani, Hauke Bartsch, Marta Cano. Electric field causes volumetric changes in the human brain. Neuroscience 23rd October 2019.We note that ECT as currently practised raises the ethical issue of a doctor providing a treatment for which they have not studied the neuropathology or pathophysiology, including the bioscience of electrical dosing and the neuropathophysiology of electrical doses. Doctors encountering recipients post-ECT are unaware they may be treating a patient with a history of electrical injury causing repeated mild to moderate traumatic brain injury, repeat anoxic/hypoxic events, and possible neuronal loss/dysfunction, and are unqualified to provide long-term follow-up in such a situation. We believe it is essential that psychiatrists and neurologists are required to	

						include ECT's neuropathology, biophysics of electrical dosing and the study of electrical injury's neurological sequelae as part of their training.Given the information above, we feel it is appropriate for NICE to remove ECT from the 'static' list and place it into a special arrangements/research group until the parameters of safe practice are established and the necessary training and follow-up for safe administration are available.	

177	SH	UK ECT Improving Standards campaign group	Guideline	General	General	NICE 2003 noted that '….outcome measures should include user perspectives on the impact of ECT, the incidence and impact of important side effects such as cognitive functioning.'' In relation to the impact of cognitive functioning and other possible dysfunctions, we note:In 2022, ECTAS began requiring follow-up data about adverse events, with the additional standard of assessing memory and cognitive effects two months after treatment. Until then, monitoring for cognitive impairment was only an ECTAS Type 2 standard, not required for accreditation. Notably according to ECTAS newletters, monitoring for cognitive side-effects was the most frequently missed standard. After Dr Cunliffe met former RCP President, Dr Wendy Burn, the provision of rehabilitation for those impaired was added as a Type 3, non-essential ECTAS standard ('Patients who experience memory problems have access to a specialist assessment by a neuropsychologist or memory assessment service if clinically indicated'). Thus, although manufacturers warn long-term cognitive impairment is inevitable for a proportion of ECT recipients, there are no mandatory requirement for direct referral to appropriate rehabilitative interventions.ECTAS 2009 study of UK's ECT clinicians identified that 'The most common [outcome assessment] method used was the MMSE (which a number of respondents said	Thank you for your comment. The committee were aware of the negative experiences of some people with depression who had been treated with ECT, and also aware that it was beneficial for some people and that removing it as an option would be detrimental to some people with depression. The committee have reiterated their call for more research into the place in therapy of ECT and the administration of ECT. The committee discussed the fact that people need to be fully informed about the risks and benefits of ECT prior to its administration, and need to make an informed decision to have ECT. For these reasons, the committee stregthened the recommendations from the previous version of the guideline and added the requirement for clinics providing ECT to be ECTAS-accredited, with board level accountability for compliance with ECTAS standards. The committee were aware that ECTAS standards include detailed advice on monitoring and assessing cognitive impairment, and therefore chose to recommend adherence to these rather than create new recommendations.

						was inadequate for this purpose) and clinical interview' (Hanna D, Kershaw K, Chaplin R. How specialist ECT consultants inform patients about memory loss. Psychiatr Bull. 2009;33(11):412-415. doi:10.1192/pb.bp.108.023739). However, this caveat should be borne in mind: 'Even people with severe brain injury or lobotomy can perform well on simple tests of overlearned verbal material that require culturally common information … Highly motivated and concerned ECT patients are even more likely to do well on these tests. However, clinicians who conclude from this that there is 'no memory loss' have not measured memory loss at all, and certainly not the type of memory and cognitive disability that people can experience after ECT' (1. Robertson H, Pryor R. Memory and cognitive effects of ECT: informing and assessing patients. Adv Psychiatr Treat. 2006;12:228-238. https://www.cambridge.org/core/journals/advances-in-psychiatric-treatment/article/memory-and-cognitive-effects-of-ect-informing-and-assessing-patients/DD5C63934357779765BA7ADF308275AE and NICE 2003).Though assessment deficits were acknowledged by NICE in 2003, present NICE guidelines provide no guidance on appropriate standardized comprehensive assessments for routine use to identify ECT recipients experiencing serious adverse effects including but not limited to cognitive impairment (such as the motor	

						dysfunction, changes in vision/auditory, cardiac, pulmonary, brain activity, etc listed on medical device user manuals.) Further, if/when patients experience cognitive deficits after ECT, researchers argue that 'cognitive rehabilitative techniques that are used with brain-injured patients should also be considered for use with patients experiencing memory and/or other cognitive disability following ECT' (Mangaoang MA, Lucey J V. Cognitive rehabilitation: assessment and treatment of persistent memory impairments following ECT. Adv Psychiatr Treat. 2007;13(2):90-100. doi:10.1192/apt.bp.106.002899)Many patients share accounts of ECT's impacts on all aspects of their lives, encompassing loss of previous memories of family/friends/significant personal events; permanent difficulties with executive functioning, planning, attentional and organisational abilities; deficits in higher level cognitive processes (see http://ectjustice.com). NICE 2003 noted that ECT can also have a severe psychological impact on some people, such that they '…reported feelings of terror, shame and distress, and found it positively harmful and an abusive invasion of personal autonomy, especially when it was administered without their consent' (4.3.2). Qualitative research illustrates that for some people ECT can be re-traumatising, triggering earlier memories of violence and abuse and	

						creating lifelong distrust of psychiatric services (Johnstone L. Adverse psychological effects of ECT. J Ment Heal. 1999;8(1):69-85. doi:10.1080/09638239917652) NICE 2003 also recognised 'the nature of cognitive impairment experienced by users was variable and often long lasting to such a degree that it outweighed their perception of any benefit from ECT treatment.'In the most recent ECT handbook ETCAS appears to be waiting for NICE committee to develop appropriate testing for ECT recipients. We ask NICE Committee to clarify who is responsible for identifying appropriate comprehensive testing in order that damage, in some cases irreversible, does not occur. We also ask NICE to clarify what measures will be put into place to ensure early brain injury rehabilitation interventions are immediately accessible to injured patients. We recommend consulting with the ABIF and Headways foundation in order to develop rehabilitation intervention pathways where needed. We also urge a continuing commitment to acknowledging the full range of patient experiences. Many of our members do not feel that the impact on their lives is represented in this Guideline.	

178	Individual	Individual 7	Guideline	General	General	The guideline is lacking in emphasis on the key challenge when treating depression with antidepressants in primary care settings: the fact that the vast majority of patients stop treatment prematurely. There is copious evidence of this phenomenon, observed in very large populations. Premature drop-out can lead to relapse and the development of chronic and treatment-resistant depression. Although evidence is lacking on interventions to address this problem, it is nonetheless essential to make it clear to practitioners that premature treatment discontinuation is extremely common. It is safer to presume that a patient has stopped their antidepressant unless there is clear evidence to the contrary. Patients require more and better information and education, support and regular follow-up with the specific aim of improving treatment continuation. It would be useful to add this information as an introduction to Section 1.8 of the Guideline.	Thank you for your comment. The committee recognised that people may stop antidepressants early and addressed this issue in the beginning of section 1.9 of the guideline (Further-line treatment).

179	Individual	Individual 7	Guideline	General	General	In addition to the point made above about premature treatment discontinuation, better guidance is needed about treatment options if first-line treatment with an SSRI is unsuccessful. The STAR*D study found that if second-line treatment was also unsuccessful, a good outcome was much more difficult to achieve, with response and remission rates at third-line of only 17% and 14% respectively. Choosing an acceptable antidepressant at the earliest opportunity is crucial. The draft guideline as it stands does not make this clear and recommendations regarding second-line treatments seem unnecessarily limited to the point of being unhelpful when antidepressants with low acceptability such as TCAs are suggested as options.Since antidepressants have similar efficacy, the most important consideration when selecting one is acceptability, especially as a second-line treatment when a first-line SSRI has failed. The network meta-analysis by Cipriani & colleagues brought together data on both efficacy and acceptability. When both efficacy and tolerability are considered together three antidepressants were found to be superior: agomelatine, escitalopram and vortioxetine. In accordance with the recommendation in this guideline, an SSRI should be used first. It should be escitalopram unless there are compelling reasons not to. If this treatment fails, it makes no sense to	Thank you for your comment. The committee discussed whether to make more detailed recommendations about the choice of antidepressants but agreed that there was a lack of head-to-head comparisons, that choice should be individualised , and that naming specific drugs might affect the longevity of the guideline as the choice of available antidepressants may change. Of the 3 drugs you mention escitalopram may not be appropriate in people due to its effects on QT prolongation; vortioxetine is recommended when there has been no or limited response to at least 2 previous antidepressants (as described in the NICE technology appraisal TA367) and NICE is unable to make recommendations about agomelatine as it has been the subject of a terminated appraisal (TA231).

						switch to second-line treatment with another SSRI which is inferior to the first. In addition to escitalopram the Cipriani study identified two additional better-tolerated antidepressants: agomelatine and vortioxetine. These antidepressants should therefore be considered as better second-line treatment options than less acceptable antidepressants like SNRIs or TCAs. Rush JA, Trivedi MH, Wisniewski SR, Nierenberg AA, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report.Am J Psychiatry 2006; 163: 1905–1917Cipriani A, Furukawa TA, Salanti G, Chaimani A, et al. Comparative efficacy and acceptability of 21 antidepressant drugs for the acute treatment of adults with major depressive disorder: a systematic review and network meta-analysis. Lancet 2018; 391: 1357-1366	
180	Individual	Individual 7	Guideline	General	General	There is no mention in the guideline of esketamine nasal spray for the treatment of resistant depression. This omission should be rectified.	Thank you for your comment. Esketamine nasal spray is undergoing evaluation by NICE for treatment resistant depression (GID-TA10371) and for depression in adults at imminent risk of suicide (GID-TA10518) so its use will follow the recommendations in these documents, when published.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

181	SH	The Minded Institute	Guideline	General	General	OverviewCurrent NICE guidelines provide guidance on pharmacological, psychological, mind-body and self-help interventions to inform a shared decision making model of care. Evidence-based recommendations include group mindfulness for less severe depression and group exercise for both less severe and more severe depression. Yoga is a multicomponent mind-body practice that typically incorporates both exercise (physical postures and movement) and mindfulness/meditation, alongside breathing and relaxation practices. Given the evidence for the effectiveness of exercise and mindfulness in reducing depressive symptoms, yoga may have similar or additional benefits for depression given its multiple components, each with individual and potentially additive effects. Indeed, yoga is a popular practice in both the general population (1,2) and amongst people with mental health disorders to self-manage depression and anxiety (3). Additionally, it may be more acceptable for those with mental health conditions who do not wish to engage in other forms of exercise or lack confidence and self-efficacy (4).Current evidenceThe use of yoga as both a method of self-care and an adjunct to standard treatment for depression is reflected in the increasing number of studies evaluating the effectiveness of yoga as a treatment for depressive symptoms and depressive disorders. This is	Thank you for your comment. As outlined in the review protocols, yoga was included as an intervention for all treatment reviews, with studies sought by the searches, and eligible evidence included in the reviews. However, the committee considered this evidence too limited to make a recommendation for yoga.

						captured in several systematic reviews and meta-analyses published since 2005. An early review identified five clinical randomized controlled trials (RCTs) suggesting some benefit of yoga (5). A later systematic review and meta-analysis (6) included 12 RCTs and 619 participants, finding reductions in severity of depression compared to receiving usual/standard care (moderate evidence), and somewhat better than relaxation or aerobic exercise (limited evidence). Benefits were shown for both patients with depressive disorders and in individuals with elevated levels of depression. A subsequent systematic review focused specifically on efficacy of yoga for major depressive disorder, including seven RCTs with 240 patients (7). They reported comparable effects for yoga compared to both exercise and medication, however, the methodological limitations of the studies included in the review precluded specific recommendations regarding the use of yoga in the treatment of major depressive disorders.Two reviews have found greater effectiveness of more mindfulness-focused forms of yoga compared with physically active yoga styles, consistent with broader research (6,8). Interestingly, a recent systematic review and meta-analysis by Brinsley et al (2021) focused specifically on the effectiveness of physically active yoga interventions for treating depressive symptoms in people with diagnosed	

						mental health disorders (9). In an analysis of 19 studies and 1080 participants, they found a moderate positive effect of yoga on depressive symptoms across all control groups combined, with greatest effects when compared with waiting list control. Additionally, they found evidence of a dose-dependent effect, with higher frequency of weekly sessions associated with greater reduction of depressive symptoms (range 1-3 sessions per week). Given the challenges of motivation in people suffering from depression and mental disorders (4), it is notable that attendance and drop-out did not differ significantly from control groups suggesting the feasibility of yoga in this population.Whilst the body of research exploring the effectiveness of yoga for depression is increasing and suggests comparable effects of yoga with other evidence-based interventions, there are several limitations in the quality of existing research and therefore of what can be claimed. Sample sizes are small in many studies, suggesting they may not be sufficiently powered to detect significant effects (7,9). The majority of studies only assess short-term effects of yoga interventions, further follow-up is required to ascertain the duration of any effects beyond the intervention. Adverse effects are not consistently reported in all studies; whilst few studies included in the earlier reviews reported on adverse events,	

						encouragingly it was included in 7/19 studies in the most recent review, with no adverse events reported (9). A key challenge in yoga research is the variability in yoga intervention content/styles and lack of standardised reporting of intervention content, making it difficult to make comparisons between interventions and evaluate the relative impact of different components (physical activity, mindfulness, relaxation etc). However, both mindfulness-focused and physically active styles appear to have positive effects on depressive symptoms (6,9). More broadly, there are inconsistencies in whether yoga is included in systematic reviews assessing effectiveness of exercise for depression and other health-related outcomes, as highlighted in a recent scoping review (10). Notwithstanding research limitations in this relatively new field, a 2019 narrative research review providing guidelines for clinicians recommended that "yoga can be suggested as a monotherapy for depression, but it is preferred as an adjunctive treatment for depression and anxiety" (11). Treatment considerationsHow yoga is delivered for depression: typically group classes led by an experienced certified teacher. Whilst the optimal frequency and duration are not established, median duration of yoga programmes in the research reviews were eight weeks, with a frequency of two times per week. Whilst yoga	

						participation frequency is associated with greater symptom reduction, effects have been found with a once weekly yoga class with homework (12).Key features: biopsychosocial treatment mechanisms Other considerations: Yoga may be more accessible and acceptable than other physical exercise programmes in this population. Motivation and time commitment may prove significant barriers in depressed individuals, although adherence does not differ from control conditions (9). Evidence suggests that group yoga classes may provide peer support from others with similar experiences, with positive benefits on mood, social connectedness and self-confidence (13). SummarySystematic reviews evaluating the effectiveness of yoga consistently demonstrate positive effects on depressive symptoms. As Brinsley et al. (2021) conclude in their recent meta-analysis "consideration of yoga as an evidence based exercise modality alongside conventional forms of exercise is warranted." Indeed, many individuals are choosing to use yoga as part of their self-management of depression. Thus, the practice of yoga warrants serious consideration as a potentially efficacious strategy to enable individuals to cope with depressive symptoms and their consequences. Further rigorous research is warranted to determine the best practices and optimal dosage of yoga that yield optimum benefit.	

						References1. Birdee GS, Legedza AT, Saper RB, Bertisch SM, Eisenberg DM, Phillips RS. Characteristics of yoga users: results of a national survey. J Gen Intern Med. 2008;23. Available from: https://doi.org/10.1007/s11606-008-0735-52. Cartwright T, Mason H, Porter A, Pilkington K. Yoga practice in the UK: a cross-sectional survey of motivation, health benefits and behaviours. BMJ Open. 2020;10:e031848. 3. Pilkington K, Wieland LS. Self-care for anxiety and depression: a comparison of evidence from Cochrane reviews and practice to inform decision-making and priority-setting. [cited 2022 Jan 4]; Available from: https://doi.org/10.1186/s12906-020-03038-84. Ussher M, Stanbury L, Cheeseman V, Faulkner G. Physical activity preferences and perceived barriers to activity among persons with severe mental illness in the United Kingdom. Psychiatr Serv. 2007;58(3):405–8. 5. Pilkington K, Kirkwood G, Rampes H, Richardson J. Yoga for depression: the research evidence. J Affect Disord. 2005;89(1–3):13–24. 6. Cramer H, Lauche R, Langhorst J, Dobos G. Yoga for Depression: A systematic review and meta-analysis. Depress Anxiety. 2013;30(11):1068–83. 7. Cramer H, Anheyer D, Lauche R, Dobos G. A systematic review of yoga for major depressive disorder. J Affect Disord. 2017;213:70–7. 8. Gong H, Ni C, Shen X, Wu T, Jiang C. Yoga for prenatal depression: A systematic	Thank you for drawing our attention to these references. Birdee et al. (2003), Cartwright et al. (2020), Pilkington and Wieland (2020), Ussher et al. (2007), Brinsley et al. (2021b), and Atezaz et al. (2019) provide useful background information but would not be eligible for inclusion in the treatment reviews as study design eligibility criteria are not met (as outlined in the review protocol). The Pilkington et al. (2005) and Cramer et al. (2013) systematic reviews that you cite had not been identified by the searches but in response to your comment, these reviews have been checked for additional relevant primary studies, and listed under excluded studies in Supplement B1 (as they were not appropriate to include in their entirety). Cramer et al. (2017) and Brinsley et al. (2021) had been identified by the searches and already been checked for any eligible studies and are listed in the excluded studies list of Supplement B1. Gong et al. (2015) does not meet eligibility criteria as the population includes those with

						review and meta-analysis. BMC Psychiatry. 2015;15(1):1–8. 9. Brinsley J, Schuch F, Lederman O, Girard D, Smout M, Immink MA, et al. Effects of yoga on depressive symptoms in people with mental disorders: a systematic review and meta-analysis. Br J Sports Med. 2021;55(17):992–1000. 10. Brinsley J, Girard D, Smout M, Davison K. Is yoga considered exercise within systematic reviews of exercise interventions? A scoping review. Complement Ther Med. 2021 Jan 1;56:102618. 11. Atezaz Saeed S, Cunningham K, Bloch RM. Depression and Anxiety Disorders: Benefits of Exercise, Yoga, and Meditation. Am Fam Physician. 2019;99(10). 12. Uebelacker LA, Tremont G, Gillette LT, Epstein-Lubow G, Strong DR, Abrantes AM, et al. Adjunctive yoga v. health education for persistent major depression: a randomized controlled trial. Psychol Med. 2017;47(12):2130–42. 13. Kinser PA, Bourguignon C, Taylor AG, Steeves R. "A Feeling of Connectedness": Perspectives on a Gentle Yoga Intervention for Women with Major Depression. Issues Ment Health Nurs. 2013;34(6):402–11. doi.org/10.3109/01612840.2012.762959	prenatal depression, and as outlined in the review protocol, trials of women with antenatal or postnatal depression are excluded from the evidence reviews for this guideline. There is a separate NICE guideline, Antenatal and postnatal mental health (CG192). Uebelacker et al. (2017) is included in the further-line treatment evidence review. However, there were only two included studies for yoga as a further-line treatment for depression and results were equivocal for the outcomes of remission and response. On this basis, the committee did not consider it appropriate to make a recommendation for yoga as a further-line treatment. Kinser et al. (2013) does not meet inclusion criteria as the experience of care section from the 2009 guideline was not included in this update (as outlined in the scope).

182	Individual	Individual 8	Guideline	General	General	The new draft guidelines published last autumn after considerable delay, leave me, someone who has experienced depression, as a recurrent, sometimes disabling, often lifelong illness, curiously disappointed. Yes, the options for treatment, based on the best evidence are all there (though not quite all – I'll come back to that later), but something else is missing. The sense that, for many people, those who aren't among the 50% who do recover after brief treatment, that depression is a journey, and to help you on that you need a guide, who can help you to make the choices and decisions about which treatment you want to try from the wheel of options at a time in your life when you may be less able to make a decision than ever before. For most people that guide will be their GP. But what if he or she isn't interested in mental health and doesn't know much about the options? Some doctors sadly are not. What if you haven't established a trusting relationship with them? its harder than ever now with the pressure on primary care to have that kind of continuous relationship I had with my old GP over many years – the person who was the 'keeper of my story.' The short paragraph on 'principles of care' on the first page of the guidelines doesn't acknowledge that. Without a guide, we fall back on 'self-management' but It's extremely difficult to self-manage your own care	Thank you for your comment. The guideline does take into consideration that a number of people will need longer-term psychological treatment for depression - either to prevent relapse or for chronic depression. The guideline also emphasises that personal, social and environmental factors that cause or contribute to depression should be identified, and help from other agencies sought where necessary. Finally, as you have identified, collaborative care is recommended for people with significant other problems or more chronic depression.

						when you are significantly depressed. You can easily get lost or even harmed by wrong choices that you make.In my academic research and clinical work with an Improving Access to Psychological Therapies (IAPT) service in Salford over many years we showed how psychological well-being practitioners could act not only as therapists but also as guides, working closely with the GP, supervised by experienced mental health staff. We tried to help people get access to what might really be needed from the whole biopsychosocial spectrum of care, not simply psychological therapy because many of them had a wide range of life difficulties, physical illnesses and problems – not only 'depression'. 'Collaborative care' as it's known, has the best evidence base for treating depression in primary care, because it recognises that even if you know what helps people to recover from depression (the first 50 pages of the NICE guidance) they often don't get it because when you are depressed you may not think you deserve treatment and you can easily disappear. Collaborative care has been adopted across the world, but not in the UK where (in England at least) the standalone IAPT model of providing mostly brief CBT, largely disengaged from primary care and the rest of the mental health service, has prevailed. Collaborative care gets a brief mention on page 51 yet collaborative	

						care workers don't just help you to navigate the system they help you to get the best out of it. A significant number of us spend many years on this journey, struggling to come to terms with the life events that predisposed, triggered or maintain our difficult moods. What happens when we run out of options? When our own inner compass refuses to start working again or has been seriously damaged by our early life experiences. When the brief therapies described here are exhausted and we 'fall off the map'. Working in a IAPT service you soon become familiar with the scenario of having nowhere suitable to refer a person with symptoms of chronic depression who requires referral for individual therapy to begin to resolve early trauma or psychological conflicts. Those for whom brief therapies, and those based on CBT, are not sufficient. I suspect that the NICE guidance considers these under the rubric of 'depression in people with a diagnosis of personality disorder' but why should people who fail to recover from depression have to accept that label, with its associated stigma, to receive care – even if it's available? There is growing evidence for the effectiveness of longer term psychodynamic psychotherapy for chronic depression, however services that in the past could provide this have been eviscerated in the push for only brief	

						interventions to meet IAPT targets. Both are needed. Some of us (myself amongst them) needed a skilled psychodynamic therapist over a much longer period to guide our way forwards again out of the morass, back into life and help re-set our inner compass. Acknowledgement of this is missing in the draft NICE guidelines for depression even though so many of us recognise it is true. Longer-term psychodynamic therapy is now almost impossible to obtain on the NHS and, if missed out again from the guidelines will continue to be so.So, in my view, the map, as drawn, is incomplete and the journey through depression, whatever it is, is difficult to make for many of us without the help of a guide that we can trust. That is what my lived and professional experience tells me.This response has also been published on my personal website at www.lindagask.com	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

183	SH	NICE quality standards & indicators team	Guideline	General	General	CG90 Depression in adults: recognition and management is an evidence source in 3 quality standards (QS8 Depression in adults, QS23 Drug use disorders and QS95 Bipolar disorder in adults) and 5 indicators on the NICE menu (NM10, NM11, NM49, NM50, and NM123). These will all need to be reviewed and amended following the changes to the guideline. We have agreed to fully update the Depression in adults quality standard (QS8) as soon as possible. We will suspend the current quality standard when the updated guideline publishes as several of the statements are inconsistent with the updated recommendations.	Thank you for your comment and for advising which quality standards will need updating on publication of this guideline.
184	SH	NICE quality standards & indicators team	Guideline	General	General	The depression in adults quality standard (QS8) currently includes statements for people with depression and a chronic physical health problem based on CG91 Depression in adults with a chronic physical health problem: recognition and management. We note that draft recommendations 1.2.1 and 1.8.3 include people with a chronic physical health problem but that there are no cross references to CG91 from the updated guideline. The recommendations in CG91 were similar to those in CG90 but are now inconsistent with the recommendations in the updated guideline. Can you clarify if the recommendations in CG91 will be updated?	Thank you for your comment. Based on other stakeholder comments a cross-reference to CG91 has been included in section 1.2 and 1.4. The NICE editorial team will determine if any recommendations in CG91 need to be updated, based on the changes made in the depression guideline.

185	SH	Institute of Health Visiting	Guideline	General	General	Treatment for people with a new episode of less severe depression(See comments in visual summary)Should include as options: peer support, social contact/groups and benefits of healthy lifestyles and physical activity (remove the term exercise) and psychosocial education.	Thank you for your comment. Peer support was listed as an intervention of interest in the review protocol and evidence for peer support interventions was searched for and included where eligible. No eligible evidence was identified for peer support interventions for less severe depression (and only a single study for more severe depression). On the basis of the limited evidence for the effectiveness of peer support the committee made a research recommendation. The committee noted that the evidence reviewed for exercise was for a structured formal exercise programme, and so agreed to retain the term exercise. However, in response to stakeholder comments, the committee also supported less intense 'move more' exercise for general wellbeing (although not as a treatment for depression) and made a new recommendation to reflect this. The committee also recognised that people with depression, like everyone, might benefit from a healthy lifestyle but recognised that people with depression might find this harder to achieve. On this basis, a new recommendation was added to advise people with depression that maintaining a

							healthy lifestyle may help improve their sense of wellbeing. A link to the NHS advice on mental wellbeing was also added, which lists 5 steps to mental wellbeing: connect with other people; be physically active; learn new skills; give to others; pay attention to the present moment (mindfulness).

186	SH	Institute of Health Visiting	Guideline	General	General	The guidance should take into consideration the treatment and management of people with depression during emergency situations including pandemics. Learning from the current Covid-19 pandemic has identified that the prevalence of perinatal mental illness has increased due to a range of factors including socioeconomic disadvantage, social isolation and reduced access to treatment alongside the reorganisation of maternity departments which reduced access for partners. Whilst many studies on the prevalence of perinatal mental illness during COVID-19 are currently in progress, the global evidence published to date suggests that the rates of depression and anxiety in pregnant women have more than doubled compared to studies prior to the pandemic. In the first reported national UK study, prevalence rates of clinically relevant maternal depression and anxiety were extremely high. Rates of clinically relevant depression and anxiety were 27% and 47% higher when compared to studies of prevalence rates using the same measures in pre-pandemic post-partum women.References:Motrico, E., Bina, R., Domínguez-Salas, S. et al. (2021) Impact of the Covid-19 pandemic on perinatal mental health (Riseup-PPD-COVID-19): protocol for an international prospective cohort study. BMC Public Health 21, 368. https://doi.org/10.1186/s12889-	Thank you for your comment, and for providing this information on the increase in perinatal depression during the Covid-19 pandemic. Perinatal mental health was not included in the scope of this guideline as this is covered in the NICE guideline on Antenatal and postnatal mental health (CG192) and a link to this guideline has now been included.

						021-10330-w Fallon V, Davies SM, Silverio SA, Jackson L, De Pascalis L, Harrold JA. (2021) Psychosocial experiences of postnatal women during the COVID-19 pandemic. A UK-wide study of prevalence rates and risk factors for clinically relevant depression and anxiety. J Psychiatr Res. 2021 Feb 2;136:157-166. doi: 10.1016/j.jpsychires.2021.01.048. Epub ahead of print. PMID: 33596462. https://www.nct.org.uk/get-involved/campaigns/hidden-half-campaign	
187	SH	Institute of Health Visiting	Guideline	General	General	To include:If depression puts themselves or others at risk of harm.The reduced threshold for women to access specialist services in the perinatal period should be noted- as women are at risk of rapid deterioration in mental state and sharp escalation of risk,To consider thresholds for specialist perinatal mental health services as these differ from generic mental health services. https://www.england.nhs.uk/north-west/wp-content/uploads/sites/48/2021/05/GM-Antenatal-Postnatal-MH-Guide-Document-final-14.05.21-.pdf	Thank you for your comment. A link to the NICE guideline on antenatal and postnatal mental health has been included in the section of the guideline on the delivery of treatments, to remind healthcare professionals to consider the care of these women separately.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

188	Individual	Individual 9	Guideline	General	General	Your information is presented in a non-user-friendly way I found it difficult to engage with and some of the statistical information was beyond my understanding, is this the way to really engage people in a consultation process?	Thank you for your comment. The guideline recommendations are presented in the most user-friendly language possible, while conveying the actions required, and are backed up by short, clear rationale and inpact sections, with further detail on the decision-making process contained in the Committee's discussion of the evidence which are also written in a narrative style. The supporting evidence reviews are, in some cases, complex systematic reviews with supporting statistics and models undertaken by the technical team of the developer.
189	SH	NHS Sheffield CCG	Guideline	General	General	Choice of treatment: Antidepressants in women who may be pregnant/ antenatal and postnatal periods Please make reference to NICE guideline on Antenatal and Postnatal mental health.Could this also cross-reference children in the introduction?https://www.nice.org.uk/guidance/ng134https://www.nice.org.uk/guidance/cg192	Thank you for your comment. A link to the NICE guideline on antenatal and postnatal mental health has been included in the section of the guideline on the delivery of treatments, to remind healthcare professionals to consider the care of these women separately.

190	SH	Greater Manchester Mental Health Services	Guideline	General	General	The guideline does not include evidence on the effectiveness of metacognitive therapy (MCT). There are 15 published studies on the effects of MCT across mild, moderate and treatment resistant depression. Three studies are randomised trials in depression with follow-up (and should meet inclusion criteria for this guideline), with two of these being comparisons of MCT against CBT. These studies are: Hagen et al 2017; Jordan et al, 2014; and Callesen et al 2020, and should be reviewed. The guideline does not include two eligible published systematic reviews and meta-analyses of MCT in anxiety or depression (Normann et al, 2014; Normann & Morina, 2018). A greater volume of evidence is available for assessing MCT in depression than is available for several of the other treatments that are included in the guideline. I am concerned that the general guideline and evidence review will therefore be seen as suffering from an important omission.	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. Metacognitive therapy (MCT) was included in the class of cognitive and cognitive behavioural therapies (as was CBT). Jordan 2014 was included in the NMA that informed the recommendations. However, because the study included a within-class comparison it is not included in the forest plots, and is not mentioned in the text as the within-class comparison of MCT versus CBT, was not regarded by the committee as a critical comparison.

							Callesen et al. (2020) was identified by the searches but did not meet inclusion criteria as less than 80% of participants were receiving first-line treatment (35% receiving psychiatric medication at baseline). This study is in the excluded studies list of Supplement B1. Hagen et al. (2017) was not identified by the searches. However, it does not meet inclusion criteria as more than 20% of participants have a coexisting personality disorder (33% have an Axis II disorder). This study has now been added to the excluded studies list of Supplement B1. Normann et al. (2014) and Normann and Morina (2018) were not identified by the searches. However, they have been checked for relevant references and no additional eligible studies were identified. These studies have now been added to the excluded studies list of Supplement B1.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

191	SH	Royal College of Occupational Therapists	Guideline	General	General	The Royal College of Occupational Therapists supports the NICE 'Depression in adults: treatment and management' guideline. However, the vital importance of having occupational therapists working in mental health services, must not be overlooked. Supporting people experiencing mental health problems, including those with a diagnosis of depression, is a fundamental part of occupational therapy interventions. Occupational therapists help people to develop a personal routine of everyday activities that creates a sense of purpose and enhances the person's recovery journey. They will:Help people improve their self-care;Help people manage their money by learning budgeting skills;Support people to live independently;Work with people to identify and improve work skills, apply for jobs and stay in employment;Help people to access and use mainstream leisure activities;Provide advice on how much assistance a person may need to live independently in the long-term.Therefore, occupational therapists focus on helping people achieve their life ambitions and chosen occupations, such as looking after a home, having a good education and good employment. The Getting-my-life-back_England.pdf (rcot.co.uk) report states:Occupational therapists can work with people in a more streamlined way because they are uniquely trained to address both mental	Thank you for your comment. The committee appreciates the role of occupational therapists in the treatment of mental health conditions and recognises that there are many facets of their recommendations which may be delivered by occupational therapists. However, it is not usual practice in NICE guidelines to specify the practitioners required to deliver treatments as this may vary between settings and organisations.

						health and physical health at the same time. They work across all ages and at all stages of a person's mental health recovery. It is recognised, for example, that inpatient units with higher occupational therapy input have the shortest lengths of stay by up to 20%.Occupational therapists are already established in many statutory mental health services and are recognised as key members of the multidisciplinary team. In addition, as demonstrated by the examples in this report, occupational therapists are moving out of traditional services and offering occupational therapy in new, innovative and cost-effective ways, such as in universities and football clubs. Initiatives such as these can reduce mental health stigma and give people speedier access to services.Meeting the current and future mental health needs of the population requires the full expertise of the workforce. Enabling occupational therapists to lead innovation in primary care can ensure that people transition well through education and employment, staying both mentally and physically well. Health Education England states that occupational therapists have a 'fundamental role to play in the delivery of the Five Year Forward View for Mental Health', particularly in tackling education, employment, housing, social connection and physical health Education England (2017) Stepping forward to 2020/21: the mental	

						health workforce plan for England. London: HEE. Page 17. Available at: https://www.rcpsych.ac.uk/pdf/FYFV%20Mental%20health%20workforce%20plan%20for%20England%20FINAL.pdfOccupational therapists, as the experts in 'occupation', help people with mental health problems achieve their full potential. They offer a cost-effective and efficient way to improve mental health and wellbeing. By engaging in healthy occupations at the right time, people get their lives back on track.The 'Depression in adults: treatment and management' guideline, covers many important issues wherein occupational therapists are already providing vital support. Occupational therapists work in a person-centred way which reflects and enforces the recommendations in this guideline such as dealing with stigma, exploring risks relating to suicidal ideations and self harm, managing anxiety, working with carers, vocational rehabilitation and rehabilitation - RCOT	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

192	SH	EMDRIA	Guideline	General	General	Thank you for asking us to contribute to the NICE depression guideline consultation. We congratulate the guideline committee and recognise all the hard work that has gone into producing such a comprehensive and scholarly review of a substantial evidence base. In general, we found the guidelines concrete, sensible and easy to follow.	Thank you for your comment and support for the guideline.
193	SH	EMDRIA	Guideline	General	General	In major depressive disorder (MDD) patients, life stress events represent a risk factor for a severe, early-onset, treatment-resistant and chronic endophenotype. Given the very substantial causal relationship between stressful, adverse and traumatic life events, and the development of MDD (e.g Kenlder et al, 1999; Stegenga et al, 2012; Kinderman et al, 2013), we felt the committee missed an opportunity to draw attention to this important relationship, both in the assessment and treatment considerations. We suggest drawing this causal link out more explicitly in the text.	Thank you for your comment. In response to your comment, a recommendation about initial assessment has been amended to include trauma as a factor to discuss with the person that may have affected the development, course and severity of their depression. This recommendation is also cross-referred to in a choice of treatment recommendation, so trauma should also be considered when making a shared decision about which intervention is right for the individual.
194	SH	Oxford Health NHS Foundation Trust	Guideline	General	General	This response has been prepared collaboratively between Oxford Health NHS Foundation Trust (OHFT) and Oxford University Dept of Psychiatry. OHFT provides a range of mental health and community health services. This includes 2 IAPT services and a range of services including mental health services for adults and older adults experiencing depression across the range of severity, complexity, and comorbidity.	Thank you for your comment and providing background information on your organisation. Each of your individual comments has been responded to separately.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

195	SH	Oxford Health NHS Foundation Trust	Guideline	General	General	Key Concerns:The guidance has ignored the substantial evidence base from IAPT indicating the effectiveness of the stepped care model (as recommended in the previous NICE guidance). As such the proposal in the guidance is not based on a comprehensive review of the available literature.There is no differentiation between low intensity and high intensity interventions when considering the evidence base and delivery of these.The guidance has overlooked the implications of delivery at the provider and national level. The cost of delivery has not been fully considered, as what is proposed is likely to lead to an increase in required funding with no evidence of improved clinical outcomes or access to services: a significant reduction in clinical cost effectiveness. Secondly, given the need for NICE guidance to be implemented, there is a need to consider the existence and availability of an appropriately trained and accredited workforce to implement the guidance. Should the proposal go ahead as it is stands there is already a national recruitment and retention issue of band 5 Psychological Wellbeing Practitioners.There appears to have been a significant deficit in expertise in the committee membership in relation to services for people experiencing mild and sub-threshold depression, and especially in terms of expertise in IAPT service delivery.	Thank you for your comment. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context (including drawing on their knowledge of the IAPT dataset) so that the 'reality' for people experiencing depression was taken into account. In response to stakeholder comments, the committee have re-structured treatment recommendations in order to take into account implementation factors. Some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The self-help with support section has been relabelled as guided self-help, moved to the beginning of Table 1, and the description of guided self-help has been amended. Recommendations relating to the stepped care model have also been updated. To make decisions about the relative effectiveness of interventions, which informed the cost-effectiveness analysis, RCTs were prioritised in line with the NICE guidelines manual. For the guideline economic analysis, other epidemiological data were obtained from published longitudinal studies. Intervention

							resource use was obtained by the RCTs that informed the guideline NMA and the economic analysis, supplemented by the committee's expert opinion. Other healthcare resource use associated with the management of depression was derived from a large cohort UK study. National UK unit costs were used. Therefore, the committee were confident that the guideline economic analysis used best quality data for every model input parameter. It needs to be noted that in January 2020 NICE published a statement of intent signalling the ambition for the future use of wider sources of data and analytic methods (including sources commonly referred to as real-world data and evidence). To make decisions about the relative effectiveness of interventions, RCTs will continue to be prioritised in line with the NICE guidelines manual, in order to ensure that the populations treated with various interventions are equivalent. However it is possible that in the future, high-quality real-world datasets such as the IAPT dataset, could inform questions about access and engagement.
196	SH	Oxford Health NHS Foundation Trust	Guideline	General	General	There is no mention of PTSD as a comorbidity. The NICE PTSD guidelines make reference to treating depression. At the very least these should be cross-referenced.	Thank you for your comment. A link has been added to the PTSD guideline from the section of the guideline on initial assessment.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

197	SH	Oxford Health NHS Foundation Trust	Guideline	General	General	There is no mention of substance misuse as comorbidity.	Thank you for your comment. The use of drugs (prescribed or illicit) and alcohol are included in the recommendations on the initial assessment of depression.
198	Individual	Individual 13	Guideline	General	General	The Negative impact these guidelines will have on the Step 2 Workforce as well as clients, especially if they are designed to replace the current step 2 guidelines of 6 – 8 x 30 – 40 minutes Sessions that are adhered to in most IAPT services. The ambiguity of whether these guidelines are in addition to the current stepped care model, or as a replacement certainly is not clear from the draft proposal, so this in itself would need further clarification.	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The self-help with support section has been relabelled as guided self-help, moved to the beginning of Table 1, and the description of guided self-help has been amended. In response to stakeholder comments, the committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.

199	Individual	Individual 13	Guideline	General	General	Confusion over what is classed as step 2 and step 3 work, stating treatment for less severe depression would require individual intervention delivered by a practitioner with therapy specific training (again unclear about what qualification this would be?) and would consist of 8 weekly sessions of 60 minutes. This session length is not in line with current Step 2 interventions and appears to fit more with High Intensity Practices. So again, clarity is really needed here.	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. Frequency and duration have now been removed from the recommendation to allow flexibility in the delivery of interventions.
200	Individual	Individual 13	Guideline	General	General	IAPT work within the Stepped Care Model with Guided self-help falling under remit of Step 2 within that model and the work is carried out and managed by the step 2 workforce of SPWP's and PWP's. At present, clients have a total of 3 – 4 hours of therapy offered in total at step 2, however under the new proposals this would be cut to a total of 2 Hours and 15 minutes, 30 minutes of which is a triage, so therapy sessions would be only 1 hour 45 minutes in total. I am unsure as to how they came up with 15-minute sessions and what empirical evidence they are basing this on. Step 2 Interventions include as essential: an agenda, safety (Risk) MDS review. These items alone would take the 15 minutes, where is the therapy? Or intervention? It also suggests having 8 of these 15-minute sessions over	Thank you for your comment. The committee agreed that PWPs need more time and flexibility to fulfil their role and responsibilities. Therefore, the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions. For the same reason, the frequency of delivery has also been removed, with the recommendation now placing importance on the sessions being delivered on a regular basis.

						a period of 16 weeks. This WILL have a massive impact on recovery rates, revolving door patient culture and waiting lists which are already stretched to capacity. Not to mention impact on the wider impact on training programmes for PWP's. It would appear this is quantity of quality of care, it also shows a lack of total disregard for the step 2 workforce and what we do as a profession.	
201	Individual	Individual 13	Guideline	General	General	Looking at where the evidence for 15-minute appointments comes from - the only reference I can see is in Evidence Review B to 15 minutes is in regard to computerised CBT. I think that the draft guidance may have conflated cCBT with broader spectrum of the Supported Self Help that PWP's can and do deliver both face to face or via telephone / video link. This in itself is confusing, as if the proposed changes are to offer shorter appointments and review for the mild cases of depression, we already have a treatment and therapy platform set up for that, (SilverCloud) although it is not accessible for everyone, therefore where do these new guidelines fit in? Or are they a repeat of what we already have in services.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.

202	Individual	Individual 13	Guideline	General	General	One of the main concerns that came from PWP's, was time and feeling undermined in their roles as clinicians. IAPT service in theory were set up to work with mild to moderate cases of depression and anxiety, however I feel it is fair to say personally working within IAPT service for 9 years now the complexity of clients is ever increasing across all the interventions not just at step 2. Therefore, the proposal of reducing any treatment time across any interventions but particularly at step 2 where it is already limited with complexity of client increasing is worrying and doesn't appear to be based on any IAPT recorded evidence, or clinical evidence?The work that PWP's do is already often undervalued and can be stressful and pressured enough, without making it completely unrealistic to see patients and generate positive outcomes – not only in terms of the client's recovery, but of the client's experience and perception of mental health services. Furthermore, the impact on the PWP morale, sense of purpose and role will likely be negatively impacted and thus likely lead to further depletion of an already thinning workforce.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.
203	SH	UK Mindfulness Centres Collaboration	Guideline	General	General	The increased emphasis on involving patients in choices about treatment options is welcome.	Thank you for your comment and support of these recommendations

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

204	SH	Insight Healthcare	Guideline	General	General	Whilst the update may be informed by the evidence base for IAPT services to date (e.g. reducing the number of treatment sessions to 8 in most cases to reflect the minimum effective 'dose') this will only reproduce current levels of outcomes i.e. 50% recovery rates. We should be investing in more sessions effectively target the range of patients who are actually treated in our IAPT services.	Thank you for your comment. The recommended resource use for all interventions was based on relevant information reported in the RCTs that informed the guideline NMA and economic analysis of treatments for a new episode of depression, supplemented by the committee's clinical experience on optimal delivery of interventions within the NHS. This information has now been added in evidence review B, under Appendix N. 'Usually' 8 sessions are recommended for group interventions, individual CBT, individual BA and counselling, for the population with less severe depression. This recommended resource use was based on the resource use reported in the RCTs of these interventions, supported by the committee's opinion that 8 sessions of a high intensity psychological intervention are usually adequate for a population with less severe depression. The recommended 'usual' number of sessions serves only as guidance and can be modified depending on individual needs. This has now been clarified in the recommendations.

205	SH	Insight Healthcare	Guideline	General	General	Given the IAPT funding for CfD courses which are based on models of 10-20 sessions, how does this 8 session recommendation fit? Why do the DIT and IPT session numbers remain true to the training models of 16 sessions?	Thank you for your comment. It needs to be clarified that all the evidence for counselling that was included in the review for the treatment of a new episode of depression was on non-directive counselling, and the committee therefore did not recommend a specific intervention (for example, Counselling for Depression/Person-Centred Experiential Therapy [PCET]) as the evidence was not reviewed for these interventions. However, based on informal consensus, the committee agreed that counselling should use an empirically validated protocol developed specifically for depression and this was included in the recommendation. The recommended resource use for all interventions was based on relevant information reported in the RCTs that informed the guideline NMA and economic analysis of treatments for a new episode of depression, supplemented by the committee's clinical expertise on the optimal delivery of interventions within the NHS. This information has now been added in evidence review B, under Appendix N. For counselling in less severe depression, 'usually' 8 sessions were recommended based on the resource use reported in the respective 2 RCTs included in the NMA (the largest of which reported 6-12 sessions), supported by the committee's opinion that 8 sessions of a high intensity intervention

							are usually adequate for a population with less severe depression. For IPT and short-term psychodynamic psychotherapy in less severe depression, ‘usually’ 8-16 sessions were recommended because most or all respective RCTs reviewed for this population reported this number of sessions. Similarly, the 'usually' 12-16 sessions for counselling and 16 sessions for IPT and short-term psychodynamic psychotherapy in more severe depression were based on the reported resource use in RCTs, supplemented by the committee's expert opinion. The recommended number of 'usual' sessions serves only as guidance and can be modified depending on individual needs. This has now been clarified in the recommendation.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

206	SH	Insight Healthcare	Guideline	General	General	There is no indication of involvement of service users in this design/ review. How can this be an appropriate recommendation/guideline when it misses potential service users input? The designers of services are constantly urged to consult and this has a profound impact on provision. If potential patients were presented with these guidelines it would be a reality check as to what is feasible and would be a reasonable 'sense-check'.	Thank you for your comment. There are 3 service users/lay members on the committee who provided input throughout the development of the guideline. In addition, the consultation process provides a mechanism for organisations and individuals to review and comment on the draft recommendations, and all these comments are considered by the committee and used to refine the recommendations.
207	SH	Insight Healthcare	Guideline	General	General	Query around the evidence base for 15-minute fortnightly GSH offering and how this has been tested as limitations of IAPT and MDS collection would mean there is no meaningful interaction at step 2 at all. This does not feel like a realistic working model in IAPT and does not fit a client centred ethos	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.
208	SH	Insight Healthcare	Guideline	General	General	Concerns raised by step 2 leads around staff wellbeing and burn out at step 2 with reduced appropriate and meaningful clinical contact time and higher caseloads due to fortnightly sessions	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.

209	SH	EFT International	Guideline	General	General	The effectiveness of EFT as a treatment for Depression has not been acknowledged in this Guideline. Although there is evidence, at the level of RCTs and meta-analysis, of EFT efficacy, cost-effectiveness and lasting effectiveness, this evidence has not been accessed within the literature search and evidence reviews and therefore not given consideration by the Guideline Development Committee. There is evidence that Emotional Freedom Technique (EFT) is a simple non-invasive tool which helps to reduce the depression symptom levels. Krishnamurthy D., Sharma A. (2019). Effectiveness of Emotional Freedom Techniques: A pilot study. Indian Journal of Public Health Research & Development, 10(10). doi:10.5958/0976- 5506.2019.02836.5 There is evidence that EFT is effective in reducing depression in a variety of population and settings. Nelms, J. & Castel, D. (2016). A systematic review and meta-analysis of randomized and nonrandomized trials of Emotional Freedom Techniques (EFT) for the treatment of depression. Explore: The Journal of Science and Healing, 12(6), 416- 26. http://dx.DOI.org/10.1016/j.explore.2016.08.001There is evidence to support the potential of EFT as a cost effective treatment to reduce the burden of a range of physical and psychological disorders on the service providers. Stewart, A., Boath, E.,	Thank you for your comment. The committee did not consider emotional freedom technique (EFT) to be an intervention that was in regular clinical use for the treatment of depression. Therefore these interventions were not specified in any of the review protocols and consequently the studies that you cite (Krishnamurthy & Sharma, 2019; Nelms & Castel, 2016; Stewart et al. 2013; Church et al. 2012; Chatwin et al. 2016) would not have met the inclusion criteria for the reviews. As such the evidence on emotional freedom technique (EFT) has not been appraised and the committee were not able to make any recommendations for the use of EFT. However, the committee will pass this to the NICE surveillance team who are responsible for ensuring guidelines are up to date to consider this for inclusion in a future update.

						Carryer, A., Walton, I., Hill, L. (2013) Can Emotional Freedom Techniques (EFT) be effective in the treatment of emotional conditions? Results of a service evaluation in Sandwell. Journal of Psychological Therapies in Primary Care, 2, 71-84.The recommendations focus on listing the treatments that are cost-effective. There is a good evidence that supports clinical usefulness of EFT as a brief, cost-effective and efficacious treatment for depression, particularly as EFT can be applied to a group. Church, D., De Asis, M., & Brooks, A. J. (2012). Brief group intervention using EFT (Emotional Freedom Techniques) for depression in college students: A randomized controlled trial. Depression Research & Treatment, 2012. DOI:10.1155/2012/257172.The recommendations focus on CBT as a cost-effective treatment for less severe depression (Guideline, page 23, line 23). There is evidence suggesting that EFT and CBT both are an effective treatment strategy in reducing depression symptoms. While we agree with the recommendation of CBT as treatment we are also concerned that EFT is not included in the recommendation either as treatment or for further research for less severe depression. There is evidence supporting the efficacy, cost-effectiveness and sustainability of its effect. Chatwin, H., Stapleton, P., Porter, B., Devine, S., Sheldon, T. (2016). The effectiveness of Cognitive	

						Behavioral Therapy and Emotional Freedom Techniques in reducing depression and anxiety among adults: A pilot study. Integrative Medicine, 15(2), 27-34.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

210	SH	LivaNova	Guideline	General	General	It is important that all relevant up-to-date information be included in this Clinical Guideline and we would request that this is extended to incorporate further stepped treatments, which include Vagus Nerve Stimulation (VNS), to reflect current NICE pathways1Rationale: NICE pathways will no longer be updated and will be removed in "spring 2022"2, despite being referred to in this consultation form, as highlighted above. Reference: Step 4: Complex and severe depression in adults - NICE PathwaysWe are withdrawing our NICE Pathways service | NICE Pathways | Our programmes | What we do | About | NICE	Thank you for your comment. A link to the NICE interventional procedure guidance on VNS has now been included in the guideline as you suggest.
211	SH	IPT-UK	Guideline	General	General	We would like to thank to committee for the huge amount of work that has been invested in the development of these guidelines. We would particularly like to note significant improvements in an underpinning ethos of patient choice and shared decision making in relation to guiding treatment, which IPT-UK welcome. We would encourage the committee to take this even further. For example for Table 1 and 2 to be expanded, specifically in patient versions of the guideline, to not only include efficacy, but also include data on acceptability, time taken to recover and relapse rates so that individuals can make a more informed choice of their treatment options.	Thank you for your comment and support of the guideline. Table 1 and Table 2 contain practical information to support shared decision-making (which includes some general comments on acceptability and time taken to see an improvement) and are ranked in order of effectiveness and cost-effectiveness. However, the committee discussed the level of detail that could be included in these tables, based on the information obtained from the evidence reviews, and that which could be discussed with people in a standard consultation, and agreed it was not possible to include relapse rates as these would vary between individual depending on a number of other individual factors, and this

							is described in more detail in the section of the guideline on relapse prevention.

212	SH	IPT-UK	Guideline	General	General	We continue to have significant concerns about the distinction the proposed guidelines make between “less severe” and “more severe”. While we understand the rationale underpinning this e.g. the need to support primary care with clear guidelines to support streamlining into treatment options, the continued use of this distinction is concerning due to the unreliability in the application of cut off metrics of self-report scales on an individual patient level and omission of key clinical factors that guide clinical decision making, such as context, complexity and behavioural indicators, to name but a few. However, our main concern within these guidelines is that this arbitrary cut off has led to overly restrictive inclusion/exclusion criteria as part of the NMA of trials, and has led to unnecessary exclusion of robust RCTs. For example 5 RCTs examining IPT were excluded from analysis for Questions 2.1 and 2.2 due to inability to categorise the baseline severity, and a further 13 IPT RCTs were excluded because the required data could not be extracted. In addition, a further 7 RCTs involving IPT were excluded due to <80% of the sample having non-chronic depression. Removing over 50 RCTs on IPT due to the less severe/more severe distinction or population restrictions (see comment 4), which comprises more than the entire corpus of most of the other therapies under consideration,	Thank you for your comment. The committee agrees that a proper assessment of severity cannot be based solely on a symptom scale and the guideline includes a recommendation to conduct a comprehensive assessment that does not rely simply on a symptom count but also takes into account both the degree of functional impairment and/or disability associated with the possible depression and the length of the episode. The committee considered the studies identified by the review and agreed that although baseline symptom scores have limitations as an indicator of severity, this information was available for the majority of studies, whereas other factors such as duration of disorder or functional impairment were not reported in a sufficiently consistent manner for them to be of use in determining severity. The committee considered the distinction between less severe (subthreshold/mild) and more severe (moderate/severe) depression to be clinically meaningful in terms of supporting effective clinical decision making and being aligned with how clinicians conceptualize depression (in particular, GPs and other primary care staff, given that the majority of people with depression and almost all first line presentations of depression are managed in primary care).

						significantly biases the overall picture. This also results in the bias for inclusion of interventions such as guided self-help, which are clinically more likely to be trialled with such specific clinical cut offs (e.g., chronic cases or more severe cases are more likely to be screened for and excluded within these trials as self help is less likely to be acceptable to more severe depression presentations). As a result of overly restrictive inclusion/exclusion criteria, despite the huge body of research on IPT for depression, only 4 IPT trials met criteria for Question 2.1 and 6 trials for Questions 2.2. This has drastically skewed the results and proposed conclusions of the guidelines. For example they are incompatible with robust recent network analysis (Cuijpers et al, 2021), where similar outcomes were explored without arbitrary cut offs of severity of depression at baseline. This NMA of trials compared CBT, IPT psychodynamic, problem solving, life review, third wave therapies and non-directive counselling with each other and TAU, WL and pill placebo. Individual psychotherapies did not differ significantly from each other, with the only exception of non-directive supportive counselling, which was less efficacious than all other therapies. No consistent differences in acceptability were found. This is clearly at odds with the current NICE recommendations, or at least the hierarchy of	Based on this distinction, an anchor point of 16 on the PHQ-9 was selected as the cut-off between less severe and more severe depression, on the basis of alignment with the clinical judgement of the committee and eligibility criteria in the included studies. Published standardization of depression measurement crosswalk tables (Carmody 2006; Rush 2003; Uher 2008; Wahl 2014) were used in order to 'read-across' different symptom severity scales that were used in different studies. The inability to categorise baseline severity was a reason for exclusion that stemmed from the decision to conduct different analyses based on baseline severity. The committee were aware of the need to have a relatively homogenous population to support a network meta-analysis and were of the view that although the network was restricted to the treatment of a new depressive episode, to include depression of all levels of severity would result in too heterogeneous a population. The committee also excluded participants with comorbid physical health problems, chronic and complex depression, perinatal depression and psychotic depression from the NMAs of treatment of a new depressive episode. This contrasts with a

						choice, and at odds with clinical common understanding.In relation to Questions 2.1 specifically, 5 RCTs on Interpersonal Counselling (IPC) were not identified or excluded (Mossey, 1996, Oranta, 2010; Neugebauer, 2006; Matzumzaka, 2017, Kontunen, 2016). IPC , based on IPT, was developed primarily for use in non-mental health settings for individuals experiencing distress and low level depression symptoms. IPC is a manualised approach for up to 6 sessions and is commonly used by community health workers. Since its conception, IPC has been used in many different setting including hospital, colleges, GP settings, community centres and with more severe presentations. The IPC model has been found to be easily implemented, with relatively short-term training, which has the potential for easier access to therapy. Inclusion of these trials representing the most appropriate IPT based treatment aligned with Question 2.1, would have would have had a significant impact on the health economics assessment of IPT due to a reduction in clinical sessions within this model and it's common implementation by non-mental health specialists. Similarly the restrictive inclusion/exclusion criteria has resulted in a number of RCTs exploring efficacy in IPT delivered in a group setting to be excluded from the final analysis, again having a significant impact on the health economic assessment of IPT	number of other NMAs which were more inclusive in terms of different levels of severity and types of depression. The committee were aware of the Cuijpers et al. (2021) NMA paper that you cite. The committee considered that this study also supported their recommendations made based on their systematic review of the evidence, that all psychological treatments will provide some benefit, so offering a wide choice of treatments is appropriate, but that counselling may not provide the same level of treatment response. Based on their overall review of the clinical evidence the committee agreed that some treatment classes and interventions appeared to be more effective than others, but there was otherwise little to choose between treatments. The committee therefore reviewed the results of the health economic modelling which determined which treatments were cost-effective, and used this to develop a suggested prioritisation of which treatments should be offered to people with depression, or considered for use. In response to stakeholder comments some changes have been made to the tables guided by

						despite increasing evidence of no difference in outcomes between group and individual IPT (e.g. Duffy et al., 2019)Furthermore, given the high rate of exclusion for IPT RCTs because of NMA inability to extract data (13 RCTs) or infer baseline severity (5 RCTs), we are interested in the efforts made to engage relevant authors to extract relevant data for studies that could not be included.	the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. Interventions are arranged in the tables in the suggested order in which options should be considered, based on the committee's interpretation of their clinical and cost effectiveness and consideration of implementation factors. However, this is not a rigid hierarchy, all treatments included in Tables 1 and 2 can be used as first-line treatments, and it may be appropriate to recommend an intervention from lower down in the table where this best matches the person's preferences and clinical needs. The committee were aware of the need to provide a wide range of interventions to take into account individual needs and allow patient choice. The exclusion criteria due to <80% having non-chronic depression was not related to the less/more severe distinction but the committee were aware that looking at the evidence from a very heterogeneous population would not provide good evidence for any groups. There is a separate review for the first-line treatment or relapse prevention of chronic depression, and the further-line treatment review includes those

							with chronic depression. However, the committee did not consider it appropriate to combine data across all groups given that different treatments may be more or less appropriate for different subgroups of people with depression. Although studies including mixed populations may be representative of standard care, the recommendations are for the treatment of an individual and not for the whole of primary care or IAPT, and therefore it is preferable to have the cleanest evidence about what the effects of an intervention is for the most relevant population. Given the size of the evidence base it was not possible to contact all authors for missing data. Interpersonal counselling was included as an intervention of interest. However, the studies you cite were excluded for the following reasons: Mossey 1996, Oranta 2010 as the trials specifically recruited participants with physical health conditions in addition to depression; Neugebauer 2006 had a sample size of less than 10 participants per arm; Matsuzaka 2017 was excluded on the basis that no endpoint data was reported (first assessment at 1-month follow-up); Kontunen 2016 was excluded on the basis that less than 80% of participants were receiving

							first-line treatment (58% on antidepressant medication at baseline). These exclusions are in line with eligibility criteria as outlined in the review protocol, and all studies (with the exception of Oranta 2010) had been identified and listed under excluded studies in Supplement B1 (Oranta 2010 has now also been added to this list). The Duffy et al. (2019) systematic review cited in your comment would not meet criteria for inclusion given that it is an adolescent population.

213	SH	IPT-UK	Guideline	General	General	Hierarchy of use (Tables 1 and 2). We have significant concerns that following all the interventions listed as recommended first line interventions, an unnecessary extra layer of hierarchy of recommendations appears based on clinical evidence and cost effectiveness and associated judgements by the committee. This unnecessary added layer of complication does not exist in any other NICE guidelines where interventions are robustly identified as first or second line interventions. The added list would needlessly confuse patients, commissioners, and clinicians. Moreover, the majority of these hierarchical decisions are based on minimal differences. We contest the disproportionate weighting given to cost in making clinical health decisions. For example, in question 2.1 IPT was ranked significantly higher in depression change scores (primary outcome of concern) than self help with support, and yet it is ranked lower within the proposed hierarchy of interventions, which we assume is a result of cost effectiveness.At the very least, the data used to form this table should be transparent e.g. listing efficacy rankings and cost effectiveness rankings separately (alongside data that is essential to patients e.g. acceptability) so that the economic influence on this grading is transparent to clinicians, patients and service users.	Thank you for your comment. There is a wide range of treatment options for depression and evidence that a number of these are effective, and as NICE guidelines are evidence-based, these interventions for first-line treatment for both less severe and more severe depression are therefore listed in order of clinical effectiveness and cost-effectiveness. This is to aid clinicians and people with depression to choose the most effective treatment that is right for them, and to guide choice when there is no preference. Cost-effectiveness is an important NICE criterion that underpins recommendations, as it ensures efficient use of resources. All the data on which the order is based are contained in Evidence review B: efficacy rankings are listed separately for clinical and cost-effectiveness. Acceptability was considered using discontinuation due to any reason as a proxy (again results reported separately) and also discontinuation due to any reason was taken into account in economic analysis. Other factors such as implementation issues (step 2 and current structure of IAPT services), side effects (drugs), size of the evidence (CBT had the largest evidence base), applicability of the evidence in the UK context (problem solving, acupuncture and antidepressant combination) were also taken

							into consideration and are also described in Evidence review B.

214	SH	IPT-UK	Guideline	General	General	Generalizability of guidelines (Review Questions 2.1 and 2.2). NICE guidelines are intended to support clinicians, commissioners, and services users in treatment choice within NHS health services. The extreme inclusion/exclusion criteria used in this literature review, omitting robust RCTs due to the inclusion of common comorbidities e.g. personality disorder, physical health difficulties, prenatal and antenatal populations and those involved in the criminal justice system, distorts the generalizability of the guidelines to the clinical population for whom we are providing services. Furthermore, such extreme inclusion criteria and have significantly reduced the number of robust RCTs on which conclusions can be based. We calculated that for Questions 2.1 and 2.2, nine IPT RCTs were excluded on these grounds with a further three RCTs excluded because <80% were not receiving first line treatment. This again significantly skews results and presents findings for a select population no longer representative of the range of patients seen within NHS mental health services and primary care. It is crucial that our clinical guidelines reflect the population they are intended to serve and provide clinical utility for, for example primary care clinicians, in supporting treatment decisions based on real life care and presentations. It is also worthwhile noting that the NICE guidelines for Depression in adults with a	Thank you for your comment. There is separate NICE guidance on Depression in adults with a chronic physical health problem (CG91), and that is the rationale for excluding trials that specifically recruit participants with a physical health condition in addition to depression. The committee are aware that this guideline was published in 2009, and will bring this to the attention of the NICE surveillance team to consider whether this guideline needs updating. There is also separate NICE guidance on Antenatal and postnatal mental health (CG192) which is now cross-referenced from the depression guideline, and Mental health of adults in contact with the criminal justice system (NG66), and this is the rationale for excluding women with antenatal or postnatal depression, and adults in contact with the criminal justice system (not solely as a result of being a witness or victim) respectively. For the first-line treatment review, studies were not included if more than 20% of participants were already receiving treatment for depression. While in the further-line treatment review, studies were required to have at least 80% of the participants showing no or limited response to previous treatment for the current episode of

						Chronic Physical Health Problem (2009) is now dated at 13 years old and only refers to CBT as an intervention, therefore the inclusion of physical health population in this guideline would be helpful interim support to clinicians and patients making decision prior to this clinical guideline being updated.	depression. The guideline review questions focus on specific populations – first-line treatment, further-line treatment/TRD, and there is not a question that specifically looks at a heterogeneous population where 21-79% are already on antidepressants and then have a psychological therapy added. Although the committee were aware that this may reflect standard care settings, the aim of the first-line treatment review question (RQ 2.1-2.2) is to estimate the effect size for psychological treatments, for antidepressants, and for combined psychological and antidepressant treatment and if the psychological studies include a significant proportion of participants who are actually receiving combined treatment this has the potential to give a misleading estimate of the effect of psychological treatments, and this is particularly problematic where these might be recommended as monotherapy. The committee discussed this at length and although it was appreciated that it was unfortunate that studies would be excluded on this basis, it was agreed that the line had to be drawn somewhere based on the rationale above. The evidence from the further-line

							treatment/TRD depression review is applicable to the population who are already on antidepressants, and the first-line review is applicable to those who are not, or who receive combination antidepressants and psychological therapies from the outset. Whereas, looking at the evidence from a very heterogeneous population would not provide good evidence for any of these groups. This may mean that some studies are missing, because the population doesn't fit into either review, but there is evidence for psychological therapies for people who are already on antidepressants and those who aren't, and for psychological and pharmacological interventions used in combination, and this evidence has been used to inform recommendations. It should also be noted that there are still a significant number of psychological intervention studies, conducted in standard care settings, included. Although these studies including mixed populations may be representative of standard care, the recommendations are for the treatment of an individual and not for the whole of primary care or NHA mental health services, and therefore it is preferable to have the cleanest evidence about what the effects of combination treatment are (if someone is

							already on antidepressants) or what the effects of psychological treatment alone is if they are not.

215	SH	IPT-UK	Guideline	General	General	The description of IPT does not accurately reflect the full range of clinical presentations this approach addresses, namely relational transitions and disputes, loss following bereavement and interpersonal isolation and recurring sensitivity. IPT-UK would welcome working with the committee in developing a more accurate description of IPT within the guidelines.	Thank you for your comment. The descriptions of IPT includes difficulties and transitions in relationships, changing interpersonal roles and loss so the committee agreed this was an accurate description.
216	Individual	Individual 15	Guideline	General	General	NICE should move from an over-reliance on data collected through randomised controlled trials (RCTs) and ensure that other types of evidence, including data from real-world practice, are recognised and valued in the production of its guidance.	Thank you for your comment. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context (including drawing on their knowledge of the IAPT dataset) so that the 'reality' for people experiencing depression was taken into consideration. In response to stakeholder comments, the committee have re-structured treatment recommendations in order to take into account implementation factors. In January 2020 NICE published a statement of intent signalling the ambition for the future use of wider sources of data and analytic methods (including sources commonly referred to as real-world data and evidence). To make decisions about the relative effectiveness of interventions, RCTs will continue to be prioritised in line with the NICE guidelines manual, in order to ensure that the populations treated with various interventions are equivalent. However it is possible that in the future, high-quality real-

							world datasets such as the IAPT dataset, could inform questions about access and engagement.
217	Individual	Individual 15	Guideline	General	General	By not using the extensive data collected by IAPT services nationally, and funded by the taxpayer, to inform its recommendations, NICE is not only failing to provide service-users with guidance based on up-to-date real-world data collected within the UK, it is also undermining the professionalism and conscientiousness of the thousands of clinicians who, for more than ten years now have been collecting this data, and the experience of the hundreds of thousands of patients, who have provided it.	Thank you for your comment. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context (including drawing on their knowledge of the IAPT dataset) so that the 'reality' for people experiencing depression was taken into consideration. In response to stakeholder comments, the committee have re-structured treatment recommendations in order to take into account implementation factors. In January 2020 NICE published a statement of intent signalling the ambition for the future use of wider sources of data and analytic methods (including sources commonly referred to as real-world data and evidence). To make decisions about the relative effectiveness of interventions, RCTs will continue to be prioritised in line with the NICE guidelines manual, in order to ensure

							that the populations treated with various interventions are equivalent. However it is possible that in the future, high-quality real-world datasets such as the IAPT dataset, could inform questions about access and engagement.
218	Individual	Individual 15	Guideline	General	General	NICE should petition NHS England to provide Step 3 outcome data that differentiates between the different treatment modalities and, particularly, in establishing the efficacy of generic counselling in comparison to other interventions. This would be particularly relevant to IAPT services, such as Steps 2 Wellbeing in Dorset HCT, where there has been a full cohort of counsellors working within IAPT since its inception, and would provide a means of ascertaining the cost-effectiveness of each intervention when set against the training cost to the NHS of practitioners, pay bandings and number of sessions offered to patients.	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context (including drawing on their knowledge of the IAPT dataset) so that the 'reality' for people experiencing depression was taken into consideration. In January 2020 NICE published a statement of intent signalling the ambition for the future use

							of wider sources of data and analytic methods (including sources commonly referred to as real-world data and evidence). To make decisions about the relative effectiveness of interventions, RCTs will continue to be prioritised in line with the NICE guidelines manual, in order to ensure that the populations treated with various interventions are equivalent. However it is possible that in the future, high-quality real-world datasets such as the IAPT dataset, could inform questions about access and engagement.

219	Individual	Individual 15	Guideline	General	General	The NICE guidance and treatment recommendations should be informed by a proper analysis of one and two-year follow-up data from any trials, prioritising treatment recommendations on this, rather than short-term outcomes (less than one year) from limited RCTs. Real-world data provided by IAPT services, which is not only already available, but is routinely collected on an ongoing daily basis, could potentially be used to carry out such longitudinal analysis.	Thank you for your comment. The committee agree that long-term follow-up is important and were disappointed that this is not more routinely measured and reported. The committee considered all long-term follow-up data found in making its recommendations and the committee based their judgement of the importance of this data on the availability and quality of the long term data. Long-term follow-up is included in the research recommendations in the guideline. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context (including drawing on their knowledge of the IAPT dataset) so that the 'reality' for people experiencing depression was taken into consideration. In response to stakeholder comments, the committee have re-structured treatment recommendations in order to take into account implementation factors. In January 2020 NICE published a statement of intent signalling the ambition for the future use of wider sources of data and analytic methods (including sources commonly referred to as real-world data and evidence). To make decisions about the relative effectiveness of interventions, RCTs will continue to be prioritised in line with the NICE guidelines manual, in order to ensure that the populations

							treated with various interventions are equivalent. However it is possible that in the future, high-quality real-world datasets such as the IAPT dataset, could inform questions about access and engagement.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

220	SH	Association for Dance Movement Psychotherapy UK, British Association of Art Therapists, British Association of Music Therapists and the British Association of Dramatherapists	Guideline	General	General	Summary of acknowledgments and remaining concerns Having raised several serious concerns with the first and second version of this draft guideline as a member of the stakeholder coalition, we are responding to this iteration as part of the coalition with respect to these concerns. We would like to begin by acknowledging the significant efforts made to engage with the concerns we have raised with the previous drafts of this guideline – we are grateful for the meaningful stakeholder engagement process. We welcome the substantial additional work that has been carried out to address our shared concerns. We notice that as a result this third draft is much improved. We are particularly pleased about the stronger focus on individualised care and the significant emphasis on the importance of service user choice and shared decision-making throughout this third iteration of the treatment guideline. We also would like to acknowledge the greater overall transparency and clarity provided in this draft. As summarised in our position statement, and outlined and discussed during previous consultations, we have identified six key concerns regarding the methodology adopted to inform the selection, grouping and analysis of supporting evidence. We have emphasised that, if all of these are not adequately addressed, the resulting treatment	Thank you for your comment. The committee agree that long-term follow-up is important and are disappointed that this is not more routinely measured and reported. The committee considered all long-term follow-up data found in making its recommendations and the committee based their judgement of the importance of this data on the availability and quality of the long term data. Long-term follow-up is included in the research recommendations in the guideline. The committee considered the current NICE classifications of mild to moderate and moderate to severe depression, and agreed that although these classifications have been adopted quite widely there is potential uncertainty with regards to the management of moderate depression. The committee agreed that a dichotomy of less and more severe depression was clearer, and the guideline includes definitions (that less severe depression includes the traditional categories of subthreshold symptoms and mild depression, and more severe depression includes the traditional categories of moderate and severe depression) in order to improve practical utility. The committee considered the distinction between less severe (subthreshold/mild) and more severe (moderate/severe) depression to be clinically

						recommendations cannot be relied on and may therefore impede the care of millions of people in the UK experiencing depression. While we strongly welcome that some of the methodological flaws we raised have been addressed in this iteration, we need to point out that not all of them have been adequately resolved. We therefore maintain that this draft version, although much improved, continues to be of concern. While these methodological concerns remain unaddressed, we continue to question the trustworthiness of the resulting treatment recommendations in the guideline.As such, we believe that a significant proportion of individuals suffering from depression could be impeded from accessing the right treatment for them. We are particularly concerned about the care of individuals who experience more complex and persistent forms of depression. Already disadvantaged in many respects, we have serious doubts that this group will receive the most appropriate treatment following the treatment recommendation in this draft. In summary we recommend the following amendments before the guideline is published:Inconsistencies regarding the utilisation of outcomes derived from long-term follow-up needs addressing.Adopting the traditional classifications for the review of a new episode of depression – mild, moderate, severe and adjust the exclusion criteria to allow for higher	meaningful in terms of supporting effective clinical decision making and being aligned with how clinicians conceptualize depression (in particular, GPs and other primary care staff, given that the majority of people with depression and almost all first line presentations of depression are managed in primary care). For the further-line treatment review, studies were sought that included adults with depression showing an inadequate response to at least one previous intervention for the current episode and this included the further-line treatment of psychotic depression, depression with coexisting personality disorder and chronic depression. First-line treatment or relapse prevention of chronic depression (including dysthymia), and first-line treatment or relapse prevention of depression with coexisting personality disorder were separate reviews, as the committee did not feel that it was appropriate to combine these populations for first-line treatment or relapse prevention. The committee considered that the grouping together of psychotic depression, depression with coexisting personality disorder and chronic depression for the further-line treatment review should allow the effectiveness of interventions for a more clinically complex population to be

						ecological validity.Trials where the majority of the population is clinically complex (i.e., has a comorbid psychosis or personality disorder), chronic or treatment resistant need to be combined and partial recovery needs to be included as critical outcome.Findings from indirect or mixed comparisons using Network Meta-Analysis (NMA) should only be used to supplement evidence derived from direct comparison (using the standard meta-analyses carried out)The review evidence on service user experience needs to be refined to focus more clearly on experiences of treatments.The hierarchy of treatment options for individuals with a new depression episode must be replaced with a menu (non-ranked) to accurately reflect the findings that all included interventions were clinically and cost effective.The evidence from important and well-known UK pragmatic trials needs to be considered fully, not partially.	considered. The guideline includes continuous changes in scores on depression scales as a critical outcome for every treatment question, which will show changes for people who have both fully and partially recovered. This was agreed by the committee to be a better way to capture this data than the use of a dichotomous outcome for partial recovery. NICE do not accept that the use of NMA was inappropriate and using NMAs both to assess clinical effectiveness and to inform the economic model was in accordance with the NICE guidelines manual. However, pairwise data were also presented separately in the new version of the guideline to enable an easier comparison between direct and NMA results. There was also a peer review of all NMAs by a NICE Technical Support Unit contractor and the code for the NMAs was published. NICE recognises that no statistical technique will ever lead to an indisputably 'correct' answer, since they all involve assumptions and extrapolations of the available data. Both the committee and quality assurance team considered any limitations of the analysis and the confidence they had in it when making recommendations. The data from the

							NMA was also considered alongside the other sources of data, including the pairwise data, economic model results and newly reviewed qualitative evidence. As specified in the scope, the experience of care section from the 2009 guideline was not included in this update. However, a new review question on patient choice was added to this update that includes a systematic review of primary qualitative studies that focus specifically on service user experience around choice of treatment. Based on their overall review of the clinical evidence the committee agreed that some treatment classes and interventions appeared to be more effective than others, but there was otherwise little to choose between treatments. The committee therefore reviewed the results of the health economic modelling which determined which treatments were cost-effective, and used this to develop a suggested prioritisation of which treatments should be offered to people with depression, or considered for use. In response to stakeholder comments some changes have been made to the tables guided by

							the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. Interventions are arranged in the tables in the suggested order in which options should be considered, based on the committee's interpretation of their clinical and cost effectiveness and consideration of implementation factors. However, this is not a rigid hierarchy, all treatments included in Tables 1 and 2 can be used as first-line treatments, and it may be appropriate to recommend an intervention from lower down in the table where this best matches the person's preferences and clinical needs. The committee were aware of the need to provide a wide range of interventions to take into account individual needs and allow patient choice. However, the committee did not consider it appropriate to present an entirely non-ranked list based on the evidence reviewed. The committee were aware of pragmatic RCTs that were excluded from the NMA typically because the samples in the trials were <80% first-line treatment or <80% non-chronic depression. These were stipulations of the review protocol in order to create a homogenous data set, but the committee used their

							knowledge of these studies in the round when interpreting the evidence from the systematic review and making recommendations. By way of illustration some of these studies were listed in Evidence report B, however, in response to stakeholder comments the committee agree that it would be more consistent to name all UK-based studies which were excluded on this basis but which the committee were aware of when making recommendations.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

221	SH	Mind	Guideline	General	General	Mind welcomes this guideline. The number of people who have experienced depressive symptoms has increased during the coronavirus pandemic (with a peak of 21% in early 2021) and so it is vital that we are providing people with a range of effective treatments and support to meet their individual needs. We welcome the guidelines emphasis on patient choice and an underscoring that anti-depressants should not be the 'default' treatment option. We do however recognise that these guidelines will be published in an environment of increasing need and strains on mental health services. Previously practitioners may not have been prescribing anti-depressants as a 'default' but because they felt this necessary to 'bridge the gap' while people have long waiting times for talking therapies or other treatment options.	Thank you for your comment and your support of this guideline. The committee are aware of the impact of Covid-19 on mental health, and the importance this places on this guideline. In less severe depression, it is correct that talking therapies are suggested as a more effective alternative to antidepressant medication. In more severe depression, they are suggested as an alternative option to talking therapies. However, the emphasis in the guideline on choice has been increased, and this includes a discussion about waiting times. It is therefore true that people with depression may choose to have an anti-depressant if waiting times for other treatments are too long.
222	SH	Mind	Guideline	General	General	Within the draft guidelines for Medicines associated with dependence or withdrawal symptoms: safe prescribing and withdrawal management for adults (rec 1.3.3) it recommends that an agreed management plan is made and shared with individuals who have been prescribed anti-depressants. We recommend that agreed management plans being made and shared with individuals who have been prescribed anti-depressants are replicated in these guidelines.	Thank you for your comment. The recommendations on starting antidepressants have been updated to include the advice to provide a management plan. There is also already a cross-reference to the NICE guideline on Safe prescribing to ensure consistency between the recommendations in the 2 guidelines.

223	SH	Mind	Guideline	General	General	Mind welcomes the inclusion of group exercise as a treatment option for both less and more severe depression. It is essential that physical activity is offered alongside medication and talking therapies as opposed to a sole intervention particularly for people with more severe depression.We also feel there is more opportunity for clinicians to frame treatment around ways to 'move more' rather than just a focus on group exercise. A more individualised and person-centred approach would be beneficial given that there are many ways to be more physically active which can be positive for people's mental health, however people also face many barriers to doing so. A more inclusive approach to physical activity may therefore be beneficial to many. Recent polling commissioned by Mind, found:65 per cent felt that physical activity should be offered alongside medication and talking therapy28 per cent said they would be interested in accessing a physical activity programme to support their mental health while waiting for further mental health treatment.6 per cent had been offered exercise on prescription or social prescribing to support their mental health.(Yonder were commissioned by Mind to conduct an online sample of 2089 UK adults 18+ between 26th and 27th April 2021. Data is weighted to be representative of the population of Great Britain. Targets for quotas and weights are	Thank you for your comment. The 'more severe' categorisation encompasses moderate and severe depression. The committee noted that there was some evidence that group exercise was both effective and cost-effective for more severe depression. However, the committee were uneasy about recommending group exercise for more severe depression, based on their knowledge and experience, and concerns that it may not be suitable for people with more severe depression as this intervention does not require the development of a therapeutic relationship in the same way that the more intensive psychological therapies do, or that would occur when people are monitored regularly if on antidepressants. However, the committee agreed that, as the evidence had shown benefit and cost-effectiveness, group exercise could be considered for use in people with more severe depression who wished to try it, or who did not want to consider any other treatment options. Group exercise is listed last in the table of treatment options for more severe depression and therefore should only be considered after other treatment options have been explored. The committee noted that the evidence was for a structured formal exercise programme, with

						taken from the PAMCO survey, a random probability face to face survey conducted annually with 35,000 adults.) We recommend that wider physical activity options (outside of group exercise) are included in the guidelines to better meet individual needs.	exercise of moderate to high intensity. However, the committee also supported less intense 'move more' exercise for general wellbeing (although not a treatment for depression) and made a new recommendation to reflect this.

224	SH	British Association for Counselling and Psychotherapy (BACP)	Guideline	General	General	Context and preparation of response:BACP has prepared this response to the exceptional 2021 third consultation on the revised Guideline for Depression in Adults: Treatment and Management in our role as a professional body for UK counsellors, psychotherapists and coaches. As the largest British professional body for those providing psychological therapies and as laid out in our mission statement (British Association for Counselling and Psychotherapy, 2022), we aim to campaign for the highest standards of care for those experiencing any form of psychological distress, including depression. Moreover, our responsibility to both the British public and our members means that we campaign for a range of treatments to be available through the NHS for those with depression. This commitment reflects the considerable range of evidence of broad equivalence between therapies for depression from trials (for example, Barkham et al., 2021; Richards et al., 2017), meta-analyses (Cuijpers et al., 2020; Cuijpers et al., 2021; Wakefield et al., 2021), as well as from observational data taken from standardised routine datasets (Gyani et al., 2013; Leonidaki & Constantinou, 2021; Pybis et al., 2017). However, the evidence also shows that it is important to give clients choice about treatment options because doing so improves outcomes, the quality of the therapeutic alliance, engagement in	Thank you for your comment, and for providing this background information. Responses to methodological concerns are addressed in response to the specific comments.

						treatment and also reduces drop-out from treatment (Lindhiem et al., 2014; Swift et al., 2018; Williams et al., 2016; Windle et al., 2020).This response has been prepared by members of the BACP Research and Policy Departments and draws on feedback from senior counselling and psychotherapy academic researchers in the UK. Our comments are also informed by reviews specifically commissioned by BACP to assess the revised network meta-analysis (NMA) and economic analysis used in the development of the revised draft guideline.Broadly, we welcome and support the focus on 'client choice' throughout the guideline, as well as the recommendation that all psychological therapies should be considered as first line treatments for depression. However, we are concerned that there are some serious methodological limitations that have not been duly acknowledged or considered.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

225	SH	British Association for Counselling and Psychotherapy (BACP)	Guideline	General	General	Length of consultation period:We welcome the provision of an exceptional third consultation period and the extension to the consultation of four days in acknowledgement of the festive period public holidays. However, we once again wish to state our view that the time provided for making a response is insufficient to allow proper scrutiny of the documents given their length (over 2500 pages in total) and the great complexity of the analyses conducted.While we acknowledge that the duration of the consultation is, as you have highlighted in your response to our comments to the previous consultation, set out in Developing NICE guidelines: the manual, we wish to reiterate that the limited time for document review undercuts the very purpose of the consultation, which is to allow NICE to benefit from robust stakeholder feedback. As before, we strongly recommend that the length of a consultation period should not be standardised but flexible to accommodate for documents of great length/analytic complexity as well as in contexts where the outcomes have huge importance for the population, as in the case of this guideline on depression. We will continue to push for this whenever Developing NICE guidelines: the manual is next updated and consulted upon.	Thank you for your comment and for reiterating your request for a longer consultation time for larger or more complex guidelines. This has been passed to the NICE team responsible for reviewing the NICE manual for consideration.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

226	SH	British Association for Counselling and Psychotherapy (BACP)	Guideline	General	General	Use of the term 'counselling':As with previous versions of the guideline, the use of the term 'counselling' in the guidelines is inconsistent and unclear which is highly problematic. Within the profession itself the term counselling refers to a bona fide evidence based activity which requires professional training in a model-based approach from a range of traditions (e.g. person-centred, CBT, psychodynamic and pluralistic). However, within the draft guideline counselling is used to refer variously to the empirically validated protocol developed specifically for depression (PCET or PCE-CfD - Person-Centred Experiential Counselling for Depression); sometimes to any non-directive but bona fide counselling approach; and sometimes to non-directive generic counselling skills used by non-counselling professionals categorised as a non-active treatment – often as a control for another intervention. This confusion and lack of clarity around the use of the term 'counselling' has profound implications for how decisions about recommendations have been made within these guidelines. For example, the committee's comments in Evidence review B in relation to the PRaCTICED trial (Barkham et al, 2021) state that "The committee discussed that the PCET used in this study was not the same as non-directive counselling and therefore this study does not provide evidence for the effectiveness of non-	Thank you for your comment. All the evidence for counselling that was included in the review for the treatment of a new episode of depression was non-directive counselling, and the committee therefore did not consider it appropriate to recommend specific interventions (for example, Counselling for Depression/Person-Centred Experiential Therapy [PCET]) as the evidence was not reviewed for these interventions. However, based on informal consensus, the committee agreed that counselling should use an empirically validated protocol developed specifically for depression and this was included in the recommendation. In response to committee and stakeholder concerns that non-directive counselling when used as a control intervention may be less likely to be manual-based, and to be delivered in a comparable number of sessions by an equivalent healthcare professional as when non-directive counselling is included as an active intervention in trials, the committee considered bias-adjusted NMA models, where bias against non-directive counselling was assumed when non-directive counselling was the control intervention.

						directive counselling" (Evidence review B, p146, lines 39-42).As argued in Barkham et al. (2017), it is our view that the committee should include clear and specific definitions of counselling that recognise that counselling includes a wide range of bona fide active and effective counselling treatments covering a range of theoretical modalities - including but not restricted to those such as CBT, STPP and others recommended within the guideline - which are distinct from both a specific counselling protocol (e.g. PCET, CfD) or from a generic intervention seen as a non-active treatment.	

227	SH	British Association for Counselling and Psychotherapy (BACP)	Guideline	General	General	Failure to include large standardised routine datasets:As we previously commented, the analysis within this revised draft guideline once again privileges RCT evidence and fails to consider evidence arising from the IAPT dataset, a routine outcomes dataset which shows how those with depression fare in response to NHS primary care treatment. The response to our previous comments (p.418 of consultation comments and responses document) states that the committee has not relied solely on RCT evidence but has taken into account “a range of different information, including health economic evidence and contextual information”. It also states that RCT evidence supporting the use of a range of psychological therapies and different pharmacological treatments have been included and that the guideline has therefore made recommendations for a range of treatments. The response to our previous comments (same document, p.418) also states that the committee has not included the IAPT data as “they did not consider routine datasets to be better or equivalent to RCT data as one cannot be sure that the populations treated with the different interventions are the same […] For example, examination of IAPT data sets shows that those who received CBT were more likely to have received a previous intervention (typically guided self-help) than those who received other	Thank you for your comment. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context (including drawing on their knowledge of the IAPT dataset) so that the 'reality' for people experiencing depression was taken into consideration. In response to stakeholder comments, the committee have re-structured treatment recommendations in order to take into account implementation factors. In January 2020 NICE published a statement of intent signalling the ambition for the future use of wider sources of data and analytic methods (including sources commonly referred to as real-world data and evidence). To make decisions about the relative effectiveness of interventions, RCTs will continue to be prioritised in line with the NICE guidelines manual, in order to ensure that the populations treated with various interventions are equivalent. However it is possible that in the future, high-quality real-world datasets such as the IAPT dataset, could inform questions about access and engagement.

						psychological interventions." Discarding data for this reason and considering only data that rigidly meet conditions that fit the committee's methodological design rather than seeking to respond to real world and naturally occurring phenomena by generating designs that fit the real-world data is a strategic failure to grasp the potential provided by the range of research paradigms and by considering both trials methodology and large-scale observational and standardised datasets.The IAPT database, comprising over half a million patients per year, provides substantial and key evidence of how NICE recommendations relating to psychological therapies work in clinical reality. Existing evidence from IAPT annual reports (NHS Digital, 2014, 2015, 2016, 2017, 2018) demonstrates that patient recovery rates have been virtually equivalent between CBT and counselling. Research on different portions of the IAPT dataset in relation to the treatment of depression have also reported comparable outcomes between CBT and counselling (Gyani et al., 2013; Pybis et al., 2017). In addition, evidence from the PRaCTICED trial (Barkham et al., 2021) shows virtually equivalent outcomes. The PRaCTICED trial randomised IAPT patients to PCET or CBT, removing the confounding factors that usually make IAPT data inadmissible for inclusion in the development of NICE	

						guidelines, which counters the committee's objections to using the routinely collected IAPT dataset.While we recognise that the inclusion of observational evidence in network meta-analysis (NMA) and combining randomised and non-randomised evidence can be challenging due to high levels of heterogeneity (potentially violating the assumption of transitivity), it is our understanding that in the current analysis the selection of studies has not included careful consideration of the risk of increased heterogeneity and intransitivity. It is therefore possible that including observational evidence would not be more problematic in terms of heterogeneity than data already included for consideration. When including observational data, a sensitivity analysis can be undertaken and more details can (and should) be given about any specific characteristics that raise concerns, allowing for transparency and greater scrutiny of the analyses. This would allow for a systematic and rigorous inclusion of real-world, practice-based data.Given all these points, it is our view that IAPT data should be considered alongside RCT data, particularly in order to ensure that sufficient consideration is given to high-quality real-world evidence that reflects the variety and complexity of patients seeking help for depression and to form a more complete, inclusive, and accurate assessment of	

						the comparative effectiveness and cost-effectiveness of psychological therapies. As in our previous response, this is not an argument to abandon RCT/NMA analyses, but rather to examine the 'weight of evidence' as a whole (Barkham et al., 2017) and to consider their results alongside those from relevant routine outcome datasets. In our view, inclusion of IAPT data is crucial when the aim of the NICE guideline is to improve treatment of depression in NHS primary care.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

228	SH	British Association for Counselling and Psychotherapy (BACP)	Guideline	General	General	Supporting patient choice of treatment: We welcome the new recommendations in this draft of the guideline that patients' ideas and preferences about treatments should be explored (1.3.1). We also welcome the recommendation for clinicians to make a shared decision with the person about their treatment (1.3.5), taking into account that all treatments in Table 1 (1.5.2) or Table 2 (1.6.1) can be used as first line treatments for the relevant severity of depression, and the recommendation that antidepressant medication should not routinely be offered as a first-line treatment for less severe depression unless that is the person's preference (1.5.3). Similarly, we are supportive of the recommendations that commissioners and services should ensure that treatments are made available and that patients can express a preference (1.3.6), as well as the comment on p.67 that "Commissioners and services will need to ensure that a meaningful choice of all NHS-recommended therapies is available". Overall, we are encouraged that these additions to the guideline are broadly supportive of patient choice and we welcome this shift in emphasis.Additionally, we welcome the presentation of information regarding delivery, key information and other aspects of treatments for consideration as presented in Table 1 (pp23-30) for less severe depression and Table 2 (pp31-37) for	Thank you for your comment and support of the choice and shared decision-making aspects of the guideline. The results of the economic modelling carried out for this guideline, although characterised by uncertainty, suggested differences in the relative cost-effectiveness between treatments. Whilst the choice of treatments by individuals may not be influenced by cost-effectiveness, cost-effectiveness is a concern of health services as resources need to be directed to treatments that are value for money. Recommending and providing cost-effective treatments ensures efficient use of resources and maximum health gains for the whole population. If patients have a specific preference, then they can choose their preferred treatment from Tables 1 and 2, but if there is no specific preference (and the committee agreed that many patients would prefer a 'talking therapy' but not have any more specific preferences beyond that), then it is reasonable to prioritise and offer treatments that appear to rank more highly in clinical and cost-effectiveness. This prioritisation benefits not only the patient receiving the selected treatment but other patients whose needs must be covered by existing NHS resources. As you point out, your concerns about the NMA methodology and models have been raised in

						more severe depression as ways of seeking to ensure that relevant information can be discussed between patients and clinicians when considering possible treatments. Similarly, we welcome the attempt at simplification of presentation of treatment options within the visual summaries for less severe depression and more severe depression.However, it is our view that listing the contents of the tables in order of recommended use, based on the committee's interpretations of their clinical and cost-effectiveness, undermines the guideline's recommendation to support the collaborative process of shared decision-making which seeks to empower people "to make decisions about the care that is right for them" (NICE guideline on shared decision making), and that offering visual summaries which present treatment options in the same order as the tables also undermines this process. First, while there is some evidence that effectiveness of proposed treatments is a consideration for patients, there is limited evidence that patients' preferences for treatment within primary care NHS services are influenced by cost-effectiveness (Churchill et al., 2000; Dorow et al., 2018; Houle et al., 2013; Winter & Barber, 2013). Indeed, research suggests that a number of other potentially contributing factors, including demographic variables such as age, race and sex, as well as aetiological beliefs	other comments and so the responses to those specific comments have not been repeated here. However, relative effects between all pairs of treatments are provided, for each outcome, in the excel files in Supplement B6 (treatment direct effects and class direct effects tabs). It was not feasible to present these outcomes in the main document, as multiple comparisons were made. You are correct that a review of patients' experiences of individual treatments was not carried out, as this was not prioritised for inclusion in the scope of this update, and instead a qualitative review of barriers and facilitators to patient choice was conducted, as this was agreed by the committee to be likely to enhance the patient choice and shared decision-making aspect of the guideline better. Your final comment about the ranking of treatments has already been addressed above and relates to the cost-effectiveness, and also serves as a guide to patients and clinicians when there is no patient preference. A simple A to Z ranking would not reflect the evidence base nor serve as a guide to choice for those who would find this helpful.

						about depression and previous experiences with depression treatment, either personally or through friends and family members, may influence patients' treatment preferences for depression (Churchill et al.2000; Houle et al., 2013; Waitzfelder et al., 2018; Winter & Barber, 2013).While recommendations relating to cost-effectiveness are of most relevance to commissioners and providers of services, since the guideline's recommendation is that "commissioners and services should ensure that people can express a preference for NICE-recommended treatments, that those treatments are available in a timely manner, particularly in severe depression, and that access to them is monitored" (1.3.6), it is our view that the tables' ranking of treatments also undermines this recommendation since ranking and choice are incompatible. We are concerned that commissioners will be more likely to offer services that match the ranking rather than considering the specific needs within their CCG and that this will undermine patient choice.Secondly, the committee's interpretation of the findings that has led to this ranking of these treatments is based on flawed analyses which, in our view, render the ranking unreliable and unsupported by the evidence and we therefore challenge this as a method of presenting treatment options to	

						patients (see also specific comments and feedback later in this document relating to the network meta-analysis (NMA) and economic analysis). In addition, while the results of the NMA include comparisons of all active treatments against placebo or TAU, the relative effects between the different active treatments are not presented, thus it remains unclear whether these were directly tested against each other and if any statistically significant differences between them were observed.We also wish to highlight that despite the emphasis on greater choice of treatment, the current draft recommendations, including the decision to present available treatments in rank-order, have not considered the multiplicity of existing qualitative evidence capturing patients' views and experiences of the different pharmacological and psychological treatments included in the draft guideline. We believe that the inclusion of qualitative evidence on patients' experiences of depression treatment would meaningfully inform the treatment guideline by increasing and prioritising service user voices to further support clinicians and patients engage in shared decisions about treatment.Finally, the recommendation to present available treatments to patients within a ranking is unacceptable within a guideline where the committee also agreed that "choice of therapy should be a personalised	

						decision", noting that "some people may prefer to use a treatment further down the table and that this is a valid choice" (p.67, lines 4-6 & p.68, line 30 – p69, line 2). In our view, the use of ranked tables of treatments is incompatible with supporting patient choice since rankings easily overpower choice and in doing so completely undermine attempts at patient empowerment through shared decision making. It is our view that the valid treatment choices of patients would be better served by the presentation of treatment options listed neutrally, for example in alphabetical order of treatment name. If this were to be adopted, we would also recommend that it be clearly stated in the guidelines that treatments are presented in alphabetical order (for example) and the neutrality of the ordering is highlighted to ensure that ranking or hierarchy is not implied.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

229	SH	British Association for Counselling and Psychotherapy (BACP)	Guideline	General	General	Failure to include longer-term psychological therapies as a treatment option: All psychological treatments recommended in the guideline are brief/short-term, with recommended duration ranging between 6 and 20 sessions. We notice that the recommendation for those classified as treatment-resistant depression, chronic depression, and depression with personality disorder default back to first or further-line treatment recommendation (i.e. once a again a short-term treatment) instead of recommending a longer-term treatment. Whilst we acknowledge that there is a robust body of research which suggests that the majority of change occurs during the initial phase of treatment, and often within 24 sessions (Robinson et al., 2020), recent research (Nordmo et al., 2021) has demonstrated that this is not true for all patients. Indeed, those experiencing more severe/complex symptoms at intake, who had access to open-ended psychological therapies, demonstrated slower rates of change, but greater overall benefits when they received longer treatments (an average of 52 sessions). There is also research evidence which supports the use of longer-term psychological therapies (specifically long-term CBT and long-term psychodynamic psychotherapy) for patients diagnosed with treatment-resistant/chronic depression (Fonagy et al., 2015; Leuzinger-Bohleber et al., 2019).	Thank you for your comment. The further-line treatment recommendation that cross-refers to psychological treatment options for more severe depression is for people whose depression has had no or a limited response to treatment with antidepressant medication alone. There was no evidence that specifically examined switching to a psychological intervention for those who have not responded to initial antidepressant treatment, however, the committee drew on the evidence for first-line treatments in more severe depression. The committee agreed that the psychological interventions that had been identified as effective and cost-effective for first-line treatment of more severe depression could be used for people who had not responded to antidepressants and wished to try a psychological therapy instead. Leuzinger-Bohleber et al 2019 was considered for the chronic depression review and was excluded. This study also did not meet eligibility criteria for the further-line treatment review as the inclusion criteria of the study was not limited to those receiving further-line treatment, participants were not randomised at the point of non-response, and it could not be regarded as an augmentation study following limited or no response to antidepressants as only 36% of

						Moreover, there are numerous qualitative studies and reviews on patient experience that highlight that GPs, service providers and service-users may perceive short-term treatments as inadequate, including two studies which have been cited in Evidence Review I (Johnston et al., 2007; Mercier et al., 2011, p52). Whilst we welcome the increased focus on patient choice in the guideline, patients' experiences should also be considered in the recommendations, including those patients who want - and need - longer-term treatments, which we feel is not adequately considered and discussed.	participants were taking antidepressants at baseline. This study has now been added to the excluded studies list in supplement D. There was only single-study evidence (Fonagy et al. 2015) for augmenting antidepressant treatment with long-term psychodynamic psychotherapy, and the committee considered the evidence too limited to make a recommendation for long-term psychodynamic psychotherapy specifically. However, a treatment option in the recommendation for people whose depression has had no or a limited response to treatment with antidepressant medication alone, includes changing to a combination of psychological therapy and medication, which could include long-term psychodynamic psychotherapy although it is not listed as an example due to the limited evidence. As specified in the scope, the experience of care section from the 2009 guideline was not included in this update. However, a new review question on patient choice was added to this update that includes a systematic review of primary qualitative studies that focus specifically on service user experience around choice of treatment.

230	SH	British Association for Counselling and Psychotherapy (BACP)	Guideline	General	General	Impact on generalizability of exclusion of studies not meeting first line treatment or non-chronic depression criteria:It is our understanding that studies with >20% of the sample receiving additional treatment (e.g., antidepressants or psychiatric care), with >20% of patients with chronic depression or with >20% of patients with a personality disorder were excluded from the network meta-analysis (NMA) and therefore excluded from systematic consideration by the guideline committee. The rationale for excluding studies with more than 20% use of antidepressants remains unclear as this is uncommon for meta-analyses of psychotherapy trials for depression (e.g. Cuijpers et al., 2020, Cuijpers et al., 2021). Indeed, antidepressant use is highly prevalent with 17% of the UK adult population receiving antidepressants between 2017-2018 (Public Health England, 2020). Furthermore, data suggest that around 80% of people presenting to UK general practices with depression receive antidepressant medication (Kendrick et al., 2015) and in recent years increases have also been observed in the average duration of treatment with antidepressants (Mars et al., 2017; McCrea et al., 2016). In addition, chronic and persistent forms of depression with a minimum duration of two years constitute a substantial proportion of depressive disorders with lifetime prevalence rates estimated	Thank you for your comment. For the first-line treatment review, studies were not included if more than 20% of participants were already receiving treatment for depression. While in the further-line treatment review, studies were required to have at least 80% of the participants showing no or limited response to previous treatment for the current episode of depression. The guideline review questions focus on specific populations – first-line treatment, further-line treatment/TRD, and there is not a question that specifically looks at a heterogeneous population where 21-79% are already on antidepressants and then have a psychological therapy added. Although the committee were aware that this may reflect standard care settings, the aim of the first-line treatment review question (RQ 2.1-2.2) is to estimate the effect size for psychological treatments, for antidepressants, and for combined psychological and antidepressant treatment and if the psychological studies include a significant proportion of participants who are actually receiving combined treatment this has the potential to give a misleading estimate of the effect of psychological treatments, and this is particularly problematic where these might be recommended as monotherapy.

						to range from 3% to 6% in the Western world (Machmutow et al., 2019). Finally, meta-analytic evidence suggests that comorbid personality disorders are found in almost 50% of patients suffering with depression and are associated with adverse clinical outcomes, including episode duration and recurrence, symptom severity, and poor psychosocial functioning (Friborg et al., 2014; Van & Kool, 2018).We recognise that including these studies within the NMA potentially presents challenges relating to homogeneity that would need to be accounted for or addressed in additional sub-group analyses. However, excluding these studies from consideration altogether is hugely problematic since doing so clearly limits representativeness and generalizability and it undermines the applicability of the guideline when recommendations are based on an over-reliance on an NMA that excludes a high proportion of people with depression. The guideline itself is not explicit that it focuses only on evidence relating to first episodes of depression in which there is no adjunctive medication, which is misleading. Given the restrictive evidence base upon which this guideline is based, it is our view that it can only apply to the small percentage of people presenting with a first episode of depression and who are not taking psychotropic medication.It is our view that if such studies cannot be incorporated reliably and	The committee discussed this at length and although it was appreciated that it was unfortunate that studies would be excluded on this basis, it was agreed that the line had to be drawn somewhere based on the rationale above. The evidence from the further-line treatment/TRD depression review is applicable to the population who are already on antidepressants, and the first-line review is applicable to those who are not, or who receive combination antidepressants and psychological therapies from the outset. Whereas, looking at the evidence from a very heterogeneous population would not provide good evidence for any of these groups. This may mean that some studies are missing, because the population doesn't fit into either review, but there is evidence for psychological therapies for people who are already on antidepressants and those who aren't, and for psychological and pharmacological interventions used in combination, and this evidence has been used to inform recommendations. It should also be noted that there are still a significant number of psychological intervention studies, conducted in standard care settings, included. Although these studies including mixed

						with confidence into the NMA, that the committee should recognise that this is a shortcoming of the NMA methodology and therefore should find another way of using the high-quality evidence that has been excluded. We note that the committee acknowledges the importance of not excluding such evidence in Evidence review B where it is stated that "the committee were aware that a number of important and well-known, often pragmatic trials, were excluded from the NMA typically because the samples in the trials were <80% first-line treatment or <80% non-chronic depression. The committee used their knowledge of these trials in the round when interpreting the evidence from the systematic review and making recommendations" (p147). However, it is not clear what is meant by "in the round", a term which does not inspire confidence or convey any sense of rigorous scientific endeavour. There are no details about which studies were considered in this way and no information about how such consideration might have been undertaken systematically. The lack of transparency undermines legitimate scrutiny of all the evidence that the committee has considered when arriving at decisions and recommendations.In our view it is essential that provision is made for the inclusion of such high-quality evidence that is more representative of the wider population of people suffering from	populations may be representative of standard care, the recommendations are for the treatment of an individual and not for the whole of primary care or IAPT, and therefore it is preferable to have the cleanest evidence about what the effects of combination treatment are (if someone is already on antidepressants) or what the effects of psychological treatment alone is if they are not. These exclusions were stipulations of the review protocol in order to create a homogenous data set, but the committee used their knowledge of these studies when interpreting the evidence from the systematic review and making recommendations. By way of illustration some of these studies were listed in Evidence report B, however, in response to stakeholder comments the committee agree that it would be more consistent to name all UK-based studies which were excluded on this basis but which the committee were aware of when making recommendations. The committee were aware of the Cuijpers et al. (2021) NMA paper that you cite. The committee considered that this study also supported their recommendations made based on their systematic review of the evidence, that all

						depression, but that it is done so in a manner than supports transparency and rigour. Furthermore, excluding well-designed pragmatic studies and restricting inclusion criteria so strictly is another example of the committee holding rigidly to a methodological design that we must challenge, rather than seeking to adapt the methodology to real world clinical practice. In our view, the resulting guideline therefore cannot possibly meet the needs of the majority of patients presenting with depression.	psychological treatments will provide some benefit, so offering a wide choice of treatments is appropriate, but that counselling may not provide the same level of treatment response. For the further-line treatment review, studies were sought that included adults with depression showing an inadequate response to at least one previous intervention for the current episode and this included the further-line treatment of psychotic depression, depression with coexisting personality disorder and chronic depression. First-line treatment or relapse prevention of chronic depression (including dysthymia), and first-line treatment or relapse prevention of depression with coexisting personality disorder were separate reviews, as the committee did not feel that it was appropriate to combine these populations for first-line treatment or relapse prevention. The committee considered that the grouping together of psychotic depression, depression with coexisting personality disorder and chronic depression for the further-line treatment review should allow the effectiveness of interventions for a more clinically complex population to be considered.

231	SH	British Association for Counselling and Psychotherapy (BACP)	Guideline	General	General	Consideration of Network Meta-Analysis (NMA):It is our understanding that from a technical point of view the analysis is robust; appropriate statistical models have been used and all software codes are provided in the supplementary material. However, we have also identified several limitations in other parts of the NMA procedure, particularly in the evaluation of the required assumptions and the selection of the interventions (we detail specific comments relating to these below). It is our view that these limitations, as well as the overall uncertainty of the results, have been overlooked to some degree and the findings have been over-interpreted. Therefore, it is our opinion that the recommendations within the guideline based on these findings are unreliable.Inclusion criteria for populations and interventions: The NMA has very broad inclusion criteria for the population under investigation with the only restriction being treatment for adults, and the only differentiating characteristic being the severity of depression. At the same time the review considers any possible type of intervention as equally applicable for all patients within these populations. Specifically, it is reported in the protocol that "for interventions in the NMA it is assumed that any patient that meets all inclusion criteria is, in principle, equally likely to be randomised to any of the interventions in the synthesis comparator set" (review protocols	Thank you for your positive feedback on the NMA and your detailed comments. Please see specific responses to your comments about the limitations of the NMA. The NMA was a complex analysis that included numerous studies and interventions across 2 populations of different depressive symptom severity. As any complex analysis, it is characterised by a number of limitations, which have been acknowledged and their impact has been explored through extensive statistical checks. The committee has taken into account the uncertainty and limitations characterising the guideline NMAs and, consequently, the guideline economic modelling, which was informed by the NMAs, when making recommendations. The inclusion criteria for the population were adults with a new episode of less or more severe depression, and the objective of the review and the NMAs, as described in the protocol (Appendix A in Evidence review B) was "to identify the most effective first-line interventions for the treatment of a new episode of depression". In principle, any intervention that has been tested in the treatment of a new episode of depression was relevant for inclusion in the review and the analysis. The RCTs included in the guideline review had the same inclusion

						document, p.18), which we understand to be an expression of the fundamental assumption of transitivity in NMA, meaning that all included interventions could, in theory, be included in the randomisation. In our view this is an unsupported assumption in relation to the treatment of depression, suggesting that age and severity of depression are the only characteristics that are considered when deciding whether an intervention is appropriate for an individual. Research evidence suggests that decisions about appropriateness for treatment depend on several factors, including: avoidance of specific side effects, clinicians' experiences of treating similar patients, clinicians' training and supervisory experiences, empirical evidence of the effectiveness of treatments, client preferences, and clients' experiences with previous treatments for depression (Amsterdam et al., 2016; Cohen & DeRubeis, 2018; Raza & Holohan, 2015; Zimmerman et al., 2004).Some interventions have been excluded without any reasonable justification. Specifically, the protocol reports that "to be included, pharmacological interventions needed to be licensed in the UK and in routine clinical use for the first-line treatment of depression" (Review protocols document, p12), but later on it states "Note that if necessary for connectivity in the network specific drugs that are excluded and 'any antidepressant' or 'any SSRI' or	criteria regarding their populations (i.e. adults with a new episode of depression), so the included populations in the guideline review and NMA were homogeneous in this aspect. It is true that preferences may have had an impact on patient selection in the individual RCTs, e.g. psychological treatment RCTs included people who were willing to receive psychological treatment, but these were not necessarily not willing to receive drugs. No RCTs excluded people because of their preference for a treatment not tested in the trial (e.g. a psychological trial would not exclude people because they might also be willing to receive drug treatment for their depression). A number of RCTs made direct comparisons between psychological, pharmacological and/or physical treatments, or compared face-to-face versus self-help treatments, and in these trials, participants were explicitly open to receiving different types of treatments. In any case, further characteristics of the population were considered at decision-making, when interpreting the results and making recommendations. When formulating treatment recommendations, the committee did take into account side effects of drugs, patient preferences and experiences with previous

						'any TCA' nodes will be added where they have been compared against a psychological or physical intervention and/or combined with a psychological or physical intervention but they will not be considered as part of the decision problem" (Review protocols document, p.12). This suggests that some interventions have been included based on data-driven criteria relating to comparators, contravening best practice recommendations and guidance for conducting NMA that clearly state that the choice of interventions should be based on clinical criteria and on the plausibility of 'joint randomisability' (Caldwell et al., 2005; Chaimani et al., 2021; Salanti, 2014;). Selection should be based on clinical criteria set out in the protocol, including all studies meeting the pre-defined criteria, rather than a data-driven approach which can lead to bias and render the findings unreliable. Evaluation of transitivity: A sensitivity analysis excluding the pharmacological interventions was performed as an evaluation of transitivity. The transitivity assumption, however, should be evaluated prior to performing the NMA by examining the similarity of the network nodes when included in studies making different comparisons and by comparing the distribution of the potential effect modifiers. If conducted, these evaluations have not been reported. It appears that transitivity has not been formally evaluated or, if evaluated, has not been	treatments for depression, and other patient characteristics and this is reflected in recommendations and the emphasis on shared decision-making. Regarding clinicians' experiences of treating similar patients, their training and supervisory experiences, it is acknowledged that these may have an impact on decisions about appropriateness of treatment. However, these should not determine evidence-based recommendations. Clinician preferences and attitudes towards treatment and how these might affect decisions is a wider consideration applying across all disease areas and not specifically to depression. Regarding inclusion/exclusion of interventions, these were applied consistently across treatments: individual drugs belonging to SSRI, SNRI, or TCA class, as well as mirtazapine and trazodone were included in the NMA as part of the decision problem (i.e. the committee considered them as appropriate first line treatments and was therefore interested in evaluating their effects). However, it is possible to include additional treatments in the NMA, if they act as connectors of interventions of interest in the network, and this was the case for (1) individual pharmacological interventions of no interest and (2) 'any antidepressant', 'any

						reported, making it impossible to assess whether a key assumption for conducting NMA has been met. If the evaluation has not been conducted, this calls the results of the analysis into question (Salanti et al., 2014). If conducted but not reported, this undermines transparency and does not allow for proper scrutiny of the analyses undertaken, weakening confidence in the reliability of the findings. Heterogeneity: The decision to perform separate analyses for participants with less severe depression and more severe depression seems reasonable given the expectation of differences between the two populations and we acknowledge that broad inclusion criteria potentially make findings more applicable to the wider population. However, in our view there remains considerable heterogeneity across the two groups which necessitates stricter inclusion criteria. It is our understanding that separate sub-group analyses can be conducted in cases where data has greater heterogeneity but that this involves considerable additional complexity, however we consider this to be an important issue that the committee should resolve. In addition, the selection of studies for analysis has ignored the fact that non-pharmacological interventions might also be very heterogeneous because their efficacy depends on several unmeasured characteristics, such as the experience of the clinicians, previous medications,	SSRI' and 'any TCA', which were not of interest per se, since the committee was interested in the effects of individual drugs within these classes. These additional nodes in the network were included only 'if necessary for connectivity' as stated in the protocol. This approach is described by Caldwell et al. (Systematic Reviews 2014, 3:109): "Treatments included in the network can be divided into a decision and supplementary set. Treatments within the decision set are the focal treatments of interest to systematic review authors. However, a supplementary set of treatments may also be incorporated into the network to provide additional evidence on relative treatment effects of the decision set." (See also Caldwell et al., Value Health 2015, 18:673-81; Ades et al., Med Decis Making 2013, 33:679–91l; Hawkins et al., Med Decis Making 2009, 29:273–81; Jansen et al., report of the ISPOR Task Force on Indirect Treatment Comparisons Good Research Practices, Value Health 2011, 14:429–37). The systematic review and NMA followed a protocol published in PROSPERO (CRD42019151328), which clearly set out the inclusion/exclusion criteria and pre-specified subgroups (by severity) and sensitivity analyses with which to explore potential effect

						and so on. Whilst it is difficult to include data and take such characteristics into account in the analysis, these should be considered and acknowledged when drawing conclusions (Cipriani et al., 2013; Kriston, 2013).In our view, the robustness of the findings that inform the guideline recommendations would be strengthened had stricter inclusion criteria for studies been applied to the NMA and had the committee also then systematically considered excluded studies separately from the NMA which also contribute high quality evidence in order to inform recommendations (see also our earlier point in this feedback relating to excluded studies). As we have previously stated, the committee's over-reliance on NMA to assess and consider trials evidence has considerable limitations which could be mitigated by the inclusion of data from routine datasets as well as ensuring the systematic consideration of trials data that does not meet the NMA inclusion criteria, but which still meets quality standards. We therefore repeat our call for the committee to consider the weight of evidence from a wider and more inclusive view of available high-quality data.Evaluation of inconsistency: Evaluation of inconsistency in NMA is required in order to avoid inaccurate or invalid conclusions (Chaimani et al,. 2021; Cipriani et al., 2013,). In this guideline, consistency was evaluated	modification as identified by the committee and previous stakeholder engagement. It is agreed that the transitivity assumption (i.e. the even distribution of effect modifiers across studies) should be evaluated (and satisfied as much as possible) prior to performing the NMA and when interpreting the results. It is important to draw a distinction between effect modifiers and prognostic factors. Effect modifiers are those that impact the relative treatment effects, and it is these that need to be balanced for the assumption of transitivity to be valid. If prognostic factors differ (as we expect they would) then this is not a problem for analysis, as NMAs (and pairwise meta-analyses) are robust to differences in prognostic factors. Tables of baseline characteristics and the similarity of network nodes will highlight study differences, but only clinical input can assess whether they are likely to be effect modifiers. The Committee had access to tables of study characteristics (which are available in Supporting documentation B1) and discussed potential effect modifiers that could impact transitivity. In the guideline NMA a considerable degree of heterogeneity was accounted for prior to the analysis by splitting populations with less and more severe depression, using detailed

						only globally comparing the model fit of the consistency model with the unrelated mean effects model. Since there is very little direct evidence in the analyses, such a method would not show any inconsistency even where this is present, meaning that this evaluation is unreliable.For instance, for less severe patients, 34 classes were available for the primary outcome (depression symptomatology) which form 561 possible comparisons. Although it is not reported in the text how many of these comparisons have available data, it seems from Figure 1 (Evidence Review B, p.17) that, roughly, there should be around 50 and most of them should only have 1 study. Consequently, with so limited direct evidence, a global evaluation for inconsistency would not provide anything useful. It is unclear why the node-splitting approach that compares direct and indirect estimates has not be conducted and we are unsure why there are tables comparing direct evidence with NMA results (which is not an appropriate way to evaluate inconsistency) but not tables comparing direct with indirect results. The committee states that, "It is important to note that these comparisons have been performed in addition to the NMA inconsistency checks (where direct and indirect evidence is compared)" (Evidence Review B p.39). It is unclear if this refers to the model fit approach or to some comparisons	treatment definitions [including treatment intensity and mode of delivery for psychological interventions] and categorising them using a class random effects model. It is agreed that assessment of transitivity needs qualitative appraisal, but to determine the impact on the resulting intervention effects requires subgroup and sensitivity analyses, which should be pre-specified if possible. A non-pharmacological subgroup of the overall dataset was analysed separately for the SMD outcome as a sensitivity analysis, to explore whether transitivity issues between pharmacological and non-pharmacological trials might have impacted on the results of the NMA, as this was a major concern of the committee and the stakeholders, as expressed in previous consultations. As you have suggested, heterogeneity was higher in analyses restricted to non-pharmacological interventions only, and this is reported in the guideline. The committee were aware that populations tested on different types of interventions (i.e. not only pharmacological versus psychological, but also physical interventions or self-help versus face-to-face modes of delivery) might be different regarding their preferences and

						not reported in the manuscript. In terms of comparing direct and indirect evidence, it would be much more informative to present them together in a forest plot to give insight on how much precision is gained with the NMA as reported in "strength could be borrowed across interventions in the same class, therefore improving precision of effects" (Review Evidence B document, p.11). For instance, Tables 14 and 15 show that for some comparisons, precision was lost and this is probably due to the increased heterogeneity and the lack of sufficient direct evidence.This issue of the lack of local consistency was raised by us in our previous consultation feedback to which the response was "It is not true that assessing for global inconsistency means that we cannot draw conclusions on local inconsistency. The terms "local" and "global" inconsistency refer simply to the methods for testing inconsistency. Both methods rely on relaxing the consistency assumption for one or all loops in the network, so both methods aim to assess the same thing (i.e. the failure of the consistency assumption in a statistical sense)" (consultation comments and responses document, p32). However, it is our understanding that this is incorrect. In the current analysis, it was assessed whether the consistency model fits the data better than a model that relaxes the consistency assumption. This is an	acceptability of specific treatments and this was taken into account when making recommendations. These concerns have been reported under 'Quality assessment of studies included in the evidence review -> Indirectness'. The committee acknowledged that treatment decisions may be influenced by individual values and goals, and people's needs and preferences for different types of interventions, which might be argued to be an effect modifier the distribution of which could potentially differ across pharmacological, psychological and physical treatment trials. These factors were taken into account when formulating recommendations. The committee's discussion in Evidence review B has now been expanded to cover additional issues considered qualitatively by the committee. A number of other potential effect modifiers and analytic decisions (in addition to restricting analyses to non-pharmacological interventions only) were explored to assess their impact on model fit and heterogeneity for SMD: • the impact of small study bias (see bias-adjusted models) (pre-specified sensitivity analysis) • the impact of excluding studies that had less than 15 participants in any arm (post-hoc

						implicit way to evaluate the plausibility of consistency and it cannot show whether there are specific comparisons for which direct and indirect evidence disagree.The previous response from NICE relating to our concerns also stated that "finding no evidence of global inconsistency is reassuring as it means there is no evidence that the consistency assumption fails to hold across all loops" (consultation comments and responses document, p.32). This statement ignores completely the limited direct evidence available and the presence of uncertainty in the results that both reduce substantially the ability of all approaches to detect statistically important inconsistency.Finally, the previous response to our concerns acknowledged that "local tests could be run in addition, although in networks of this size it is highly likely that spurious results would be found, due to multiple testing which would then be over-interpreted and unhelpful" (Consultation comments and responses document, pp. 32-33). Instead of performing "unhelpful" comparisons between direct and indirect evidence, comparisons between direct evidence and NMA results were performed – a wrong way to evaluate inconsistency because direct evidence and NMA evidence are not independent – with implicit statements that these comparisons also give insight about inconsistency. The number of local	sensitivity analysis) • the impact of assuming additivity of control arms (e.g. assuming the relative effect of TAU vs TAU + CBT was equal to No treatment + CBT) (post-hoc sensitivity analysis) • the impact of excluding studies that had >5 points' contribution to the residual deviance (post-hoc sensitivity analysis) • the impact of restricting analyses to studies classified as "low risk of bias" for attrition (additional analysis performed post-consultation). Other parameters, such as sex, socio-economic factors, therapist factors, may contribute to heterogeneity, but only if they are effect modifiers. In such a large and complex dataset, these factors were inconsistently reported and thus the impact of them is difficult to explore. Of course, this would also be a problem had exclusively pairwise MA been conducted for all 142 RCTs for less severe depression and 534 RCTs for more severe depression included in the systematic review. Considering heterogeneity when assessing the hundreds of pairwise, independent comparisons of this dataset would make interpretation of the findings and conclusions as to which interventions are the best options highly problematic.

						inconsistency tests would be equal to the number of direct comparisons, so we question why multiple testing would be a problem in that case, while at the same time it is deemed acceptable to compare direct evidence with NMA.Overall quality/confidence of the evidence and GRADE: Formal evaluation of the confidence in the evidence using one of the two available approaches, the GRADE-NMA (Puhan et al., 2014; Salanti et al., 2014;) or the CINeMA framework (Nikolakopoulou et al., 2020) has not been performed. This was a methodological concern that we raised in our previous consultation response that has not been adequately addressed and is a serious omission that undermines credibility and confidence regarding the possible risk of bias. Results on the different GRADE domains are reported but it is unclear how these assessments have been integrated with the numerical results to draw conclusions. For example, no additional analysis has been conducted to assess the impact of study risk of bias. This could be done either by excluding risk of bias studies or by using the risk of bias as covariate in a meta-regression model. In terms of indirectness, only general conclusions are reported and no study-level evaluation seems to have been performed.We are not satisfied that the limitations of the analyses as set out above have been	As you mention, there could still remain unmeasured characteristics that could be effect modifiers, but the very fact that these are unmeasured makes it impossible to quantitatively or qualitatively account for those factors specifically. However, these can contribute to higher between-study heterogeneity, which is a parameter that can be estimated and assessed in NMA. This was formally assessed for each network; results of this assessment and of potential impacts on transitivity and inconsistency were taken into account by the Committee when interpreting the results of the NMA and making recommendations. Using stricter inclusion criteria to account for additional potential effect modifiers discussed in your comment, such as clinicians' experience or types of treatment (psychological vs pharmacological vs physical) or differences in mode of delivery (e.g. self help vs face-to-face) and then to systematically consider excluding studies would result in a very complex exercise, with further assumptions, qualitative judgements, reduced transparency and more limitations. For example, how would excluded studies be systematically considered, how would

						sufficiently accounted for by the committee in drawing up their recommendations and, in our view, the findings from the NMA have been relied upon too heavily, particularly those findings upon which conclusions have been drawn about the relative effectiveness of one intervention against another. Such ranking is not sufficiently or robustly supported in these findings given the limitations and overall uncertainty of the results and is unhelpful in terms of the contextual reality.	their results be weighed against the NMA of included studies and how would this add benefit to formally considering them as part of the NMA? Moreover, this approach might likely result in several fragmented networks, and inability to run one analysis that considers all major interventions for the treatment of a new episode of depression. When interpreting the results and making recommendations, in addition to the results of the NMA (including statistical checks and sensitivity analyses), the committee also considered the results of pairwise meta-analyses, guideline economic analysis, newly reviewed qualitative evidence, as well as the results of a number of pragmatic trials conducted in the UK, which were excluded from the review as they did not meet inclusion criteria, as reported under 'The committee's discussion of the evidence' in Evidence review B. You have suggested including data from routine datasets. However, routine data is not a high quality evidence source when estimating relative effects, due to lack of randomisation, and are vulnerable to substantial bias. Pairwise MA and NMA are no longer robust to differences in prognostic factors between studies when observational studies are included, so the transitivity / consistency assumption is very

							unlikely to hold. Given that there is a large evidence base of RCTs for most of the classes of interventions in the network, routine data would add little value and would be more likely to introduce bias. Inconsistency was evaluated by undertaking both global and local tests of inconsistency using Unrelated Mean Effects (inconsistency) models, and for many of the networks there was a considerable amount of direct evidence (in addition to a lot of indirect evidence). However, as you suggest, for many of the comparisons in the less severe SMD (depression symptomology) outcome there is limited direct evidence to assess the consistency assumption statistically, but that does not mean that inconsistency is not present. Therefore, it is necessary to consider whether the balance of effect modifiers may differ between comparisons. This requires clinical understanding of which variables may be effect modifiers, and an inspection of those variables in different studies in the analyses, which the committee evaluated by looking at tables of study characteristics. To check inconsistency, model fit statistics and

							between-study SD were compared between consistency and inconsistency models for a global assessment. However, as a local test, deviance plots, which compare individual deviance contributions from both consistency and inconsistency models for each data point, were inspected. These have been presented for each outcome to allow identification of individual studies that may be causing inconsistency, which are highlighted in the plots and discussed in the report. Because methods for node-splitting have not been developed for class-effect models, the direct and indirect evidence contributions from the direct and NMA estimates (using the back-calculation method) were computed instead, resulting in estimates of direct and indirect evidence which are an approximation to those generated using node-splitting. To identify comparisons for which there was likely to be a discrepancy between direct and indirect estimates, indirect evidence contributions were estimated by subtracting the direct evidence contributions (estimated using the unrelated mean effects model) from the NMA estimates (estimated using the consistency model), assuming normality of the posterior distributions. The difference between direct and

							indirect estimates was subsequently estimated, and a Wald test was used to test whether direct and indirect evidence were in agreement. It has been acknowledged that the posterior distributions may not be normally distributed, so this approach was used to highlight comparisons in which direct and indirect evidence were likely to strongly disagree. The methods and results of these checks are provided in Appendix M of Evidence review B, and supplements B5 and B6. Supplement B6 provides the results of the comparison between the direct and indirect effects for every outcome assessed in the NMA. As stated before, undertaking a formal node-splitting approach was not feasible to do for all comparisons due to the size and complexity of the networks. It would produce a very large amount of comparisons to analyse and interpret, leading to a very high risk of finding spurious results. Furthermore, the methodology for node-splitting for more complex NMAs has not yet been developed. Pedder et al (https://doi.org/10.1002/sim.9270) have developed node-splitting for dose-response models, but the methodology is complex and not yet been extended to class effect models. It is correct that the presence of high uncertainty

							reduces the ability of approaches to detect statistically important inconsistency. If heterogeneity is high then inconsistency is unlikely to be detected. However, inconsistency and heterogeneity are two sides of the same coin – they both arise from an imbalance in effect modifiers. It has already been concluded that heterogeneity is high in some networks and therefore that this increases uncertainty in the results and their applicability. The committee noted this when making recommendations and this is also highlighted in the guideline. The tables comparing direct evidence from pairwise meta-analysis with NMA results were presented following stakeholders' requests in previous consultations, and their concerns that results of the NMA for treatments where head-to-head comparisons are available might be very different from results that would be obtained had pairwise MA been conducted. In no case was their purpose to assess inconsistency, and from a technical point of view they were not considered essential for interpretation of the results. Tables comparing direct with indirect results within the NMA have been produced, as described above, and presented for each outcome in the respective excel files in Supplement B6 (under tabs 'Treatment direct effects' and 'Class direct

							effects'). This is where the statement "It is important to note that these comparisons [i.e. comparisons between pairwise MA and NMA] have been performed in addition to the NMA inconsistency checks (where direct and indirect evidence is compared) [i.e. comparisons made within the NMA and presented in Supplement B6]" refers to. As it can be seen, there is a very large number of comparisons between direct and indirect evidence for each outcome and across outcomes presented in Supplement B6, so presenting them all, together in a forest plot, would be impractical. The quality of the NMA evidence was assessed by examining the factors considered in a GRADE profile (risk of bias, publication bias, inconsistency, indirectness and imprecision). The Cochrane risk of bias tool for RCTs was used to assess potential bias in each study included in the review. Risk of bias ratings for each RCT included in the NMA are provided in Supplement B1. The model goodness of fit and inconsistency were assessed for each NMA. In a network with 99 treatments evaluating certainty using GRADE-NMA is onerous because it requires separate, manually generated, assessments over all five domains for the direct and indirect evidence informing each pairwise comparison (of which

							there are 4851 in total). GRADE-NMA focuses on triangular loops of evidence only and the confidence in an indirect comparison, is determined solely by the two direct comparisons informing it. In complex networks, the CINeMA approach is to be preferred, as it fully takes account of the whole network of evidence. However, CiNeMA could not be performed due to the complexity of the NMA models fitted, as the class effect model cannot easily be incorporated into the CiNeMA framework. Bias-adjusted models were run to explore and adjust for potential bias associated with small study size. Transitivity between populations participating in pharmacological and non-pharmacological studies was assessed in a sensitivity analysis which excluded pharmacological trials. Several other post-hoc sensitivity analyses were also conducted to explore the impacts of other potential effect modifiers (see responses to related comments above). A sensitivity analysis in the various risk of bias domains was planned, but the only domain for which this was feasible given the small number of studies rated as low risk of bias was Attrition. A subgroup analysis of this was thus performed

							as a post-consultation sensitivity analysis but found no evidence that this was an effect modifier. Although there are sufficient studies to analyse a low risk of bias subgroup for Blinding (participants), Blinding (care administrator) and Performance, these studies are almost exclusively pharmacological studies, and the analysis is equivalent to performing a subgroup analysis of pharmacological studies only. Given that a pre-specified sensitivity analysis of non-pharmacological studies only was performed and found that results were not sensitive to this factor, it would be unlikely to detect any differences that might arise from a subgroup of pharmacological studies only (equivalent to low risk of bias for Blinding or Performance). The adopted approach of exploring the impacts of small study bias is a way of controlling for various quality factors and biases that are typically more prevalent in small studies (small study effects), with the added benefit that all studies can be included in the analyses simultaneously, thus increasing power to detect any effect. Finally, indirectness was considered by qualitatively assessing potential differences across the populations, interventions and

							outcomes of interest, and those included in the relevant studies that informed the NMA. Details of quality assessment, which were considered by the committee when interpreting the results of the NMAs, are provided under 'Quality assessment of studies included in the evidence review' separately for less and more severe depression, in Evidence review B. These factors were considered by the committee when making recommendations. A threshold analysis was also planned, as an alternative to GRADE for assessing confidence in guideline recommendations based on the NMA (Phillippo et al., Ann Intern Med 2019, 170(8):538-546). However, it was noted that, in addition to the results of the NMA, the committee took other pragmatic factors into consideration when making recommendations, including the uncertainty and limitations around the clinical and cost-effectiveness data, and the need to provide a wide range of interventions to take into account individual needs and allow patient choice. For this reason, it was difficult to identify a clear decision rule to link the recommendations directly to the NMA results, and so it was determined that conducting a threshold analysis would not add value to decision making. This is reported under 'Quality

							assessment of studies included of studies included in the evidence review and the evidence' and, also, under 'The committee's discussion of the evidence -> Interpreting the evidence -> The quality of the evidence'. It is agreed that the NMA intervention rankings alone would not be robust for decision-making given the high degree of uncertainty in the results. When interpreting the results and making recommendations, the committee assessed the results of the NMAs (including uncertainty and limitations, inconsistency checks and sensitivity analyses), along with the results of pairwise meta-analysis (e.g. for quality of life and functioning outcomes), newly reviewed qualitative evidence, results of the guideline economic analysis, also taking into account other factors such as side effects of drugs, the applicability of the evidence (e.g. regarding individual problem solving and combined acupuncture with antidepressants), implementation issues (step 2 and current structure of IAPT services), treatment acceptability (expressed in discontinuation rates, which were incorporated into the economic analysis), as well as patient clinical needs and preferences.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

232	SH	British Association for Counselling and Psychotherapy (BACP)	Guideline	General	General	Economic analysis:Having carefully assessed the economic analysis, we welcome the transparency of the methodology used for both the economic literature review and the economic modelling, including the exclusion and inclusion criteria for the analyses.We also welcome the finding from the modelling that counselling is recognised as a cost-effective option for the treatment of both less severe and more severe depression, and that the modelling demonstrates that potentially there is a case for a wide range of interventions given that expected net monetary benefits for most of them are very similar. However, we note that the models also show high levels of uncertainty around all interventions, and relatively modest differences in overall quality of life gains, cost per QALY gains and net monetary benefits between most interventions. We recognise that this uncertainty is not a limitation of the economic modelling, but rather a limitation of the available evidence, reflecting that virtually all counselling/psychotherapy trials studies are underpowered for cost-effectiveness analysis (Cuijpers et al., 2016). This again supports our call for more methodological diversity in the types of evidence used - including the IAPT dataset - to inform and contribute to the development of NICE guidelines.Nonetheless, it is clear from the analyses undertaken by NICE that there is	Thank you for your comment and your positive feedback on the guideline economic literature review and the economic modelling. It is noted that counselling was found to be less cost-effective than GP care (reference treatment) for less severe depression, but it was agreed that for some sub-groups of people that may benefit from supportive empathetic counselling, particularly those with psychosocial, relationship or employment problems contributing to their depression, counselling may be more cost-effective than for the wider population of people with less severe depression. For more severe depression, counselling ranked in a lower place compared with other high intensity psychological interventions (such as individual BA and individual CT/CBT alone or combined with antidepressants), but was found to be more cost-effective than GP care. The fact that the economic analysis is characterised by uncertainty does not mean that all interventions have similar cost-effectiveness. For example, in less severe depression, individual CBT was found to dominate counselling, as it resulted in a higher number of QALYs and a lower overall cost. In more severe depression, the ICER of individual CBT vs counselling (which can be estimated from reported costs and QALYs) was £8,321/QALY, which is well below the NICE lower

						considerable uncertainty around differences in effectiveness and cost effectiveness between different treatment options. In this context, we support the committee's recommendation for - and emphasis on - individual patient treatment preference from a range of treatments. However, it is our view that offering choice of treatment from a menu of options offered in a questionable ranking based on uncertain and severely limited findings from economic analyses and network meta-analysis (NMA), undermines the committee's recommendation to support patient choice. It is our view that genuine patient choice and shared-decision making with clinicians would be better supported by treatment options that have been shown to be effective being offered in a more neutral format, such as an alphabetical list.	cost-effectiveness threshold of £20,000/QALY. The fact that the counselling/psychotherapy trials are underpowered for cost-effectiveness analysis is not an issue for economic modelling, as this uses different approaches than economic studies conducted alongside RCTs. For the guideline economic modelling the RCT evidence across all interventions was pooled and synthesised using NMA on a number of outcomes (discontinuation, response and remission), which, in turn, informed the economic model. Other clinical model input data were derived from epidemiological studies, whereas resource use was derived from the RCTs included in the NMAs, supplemented by the committee's expert opinion on the optimal delivery of interventions in the UK. Wider healthcare costs associated with depression were derived from a UK observational study. It is true though, that the uncertainty characterising the NMA results is reflected in the uncertainty around some of the cost-effectiveness results. This uncertainty may be higher for interventions in close places in ranking, but is lower between interventions ranked further apart, e.g. at the top and at the bottom of the ranking. When assessing clinical effectiveness derived from the NMAs, the committee considered not only the mean effects of treatment classes vs the

							reference treatment, but the uncertainty around them (as expressed in 95%CrI), the volume of the evidence base for each treatment, and the evidence of effect or the lack of it (as shown by 95%CrI crossing or not the no effect line) of the classes but also of individual interventions within each class, versus the reference treatment. They also considered results of pairwise meta-analysis (of follow-up data and other outcomes such as functioning and quality of life). Based on the clinical and the economic findings as well as other considerations (e.g. availability of treatments and the structure of IAPT services), the committee constructed Tables 1 and 2. Interventions are arranged in the tables in the suggested order in which options should be considered, based on the committee's interpretation of their clinical and cost effectiveness and consideration of implementation factors. However, this is not a rigid hierarchy, all treatments included in Tables 1 and 2 can be used as first-line treatments, and it may be appropriate to recommend an intervention from lower down in the table where this best matches the person's preferences and clinical needs. The committee were aware of the need to provide a wide range of interventions to take into account individual needs and allow patient choice. However, a simple alphabetical

							listing would not reflect the evidence base nor serve as a guide to choice for those who do not have pre-existing preferences. Regarding the use of IAPT data, to make decisions about the relative effectiveness of interventions (which also informed the cost-effectiveness analysis), RCTs were prioritised in line with the NICE guidelines manual. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context (including drawing on their knowledge of the IAPT dataset) so that the 'reality' for people experiencing depression was taken into consideration. In January 2020 NICE published a statement of intent signalling the ambition for the future use of wider sources of data and analytic methods (including sources commonly referred to as real-world data and evidence). To make decisions about the relative effectiveness of interventions, RCTs will continue to be prioritised in line with the NICE guidelines manual, in order to ensure that the populations treated with various interventions are equivalent. However it is possible that in the future, high-quality real-world datasets such as the IAPT dataset, could inform questions about access and engagement.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

233	SH	UK University Mindfulness Centres	Guideline	General	General	We would like to thank the committee for producing the updated guideline and for all the work they have contributed to the update.	Thank you for your comment and support of this guideline update.
234	SH	UK University Mindfulness Centres	Guideline	General	General	Less severe depression is defined in the consultation document as sub-threshold or mild depression and more severe depression is defined as moderate or severe depression. However, our understanding is that many trials of psychological interventions for depression, including MBCT, had inclusion criteria that would map on to sub-threshold, mild or moderate depression, whilst potentially excluding at least some people experiencing severe symptoms (e.g., with exclusion criteria concerning current suicidality). Therefore, whilst we agree a distinction between less and more severe depression may be warranted, we suggest that the cut-off should be between sub-threshold/mild/moderate symptoms and severe symptoms as this would be more in line with the research evidence.	Thank you for your comment. The committee considered the distinction between less severe (subthreshold/mild) and more severe (moderate/severe) depression to be clinically meaningful in terms of supporting effective clinical decision making and being aligned with how clinicians conceptualize depression (in particular, GPs and other primary care staff, given that the majority of people with depression and almost all first line presentations of depression are managed in primary care). Based on this distinction, an anchor point of 16 on the PHQ-9 was selected as the cut-off between less severe and more severe depression, on the basis of alignment with the clinical judgement of the committee and eligibility criteria in the included studies. Published standardization of depression measurement crosswalk tables (Carmody 2006; Rush 2003; Uher 2008; Wahl 2014) were used in order to 'read-across' different symptom severity scales that were used in different studies.

235	SH	Newham Talking Therapies	Guideline	General	General	The proposal is for the appointment to be for 15 minutes. This could be manageable for the "perfect IAPT client" but when there is risk, safeguarding concerns and MDS to complete it will be difficult to get all of that done in 15 minutes, and will then difficult to also discuss an intervention.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.
236	SH	Newham Talking Therapies	Guideline	General	General	Newham has a very diverse population, and we are concerned that a meaningful appointment will be not be achieved in 15 minute when there are often language barriers, stigma around attending appointments and mental health, and the need for more time to build a therapeutic relationship. Will there be more time allowed when an interpreter is needed?	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.
237	SH	Newham Talking Therapies	Guideline	General	General	We have concerns that risk assessments will not be completed thoroughly in that timeframe and important aspects will be missed which could have serious implications.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.
238	SH	Newham Talking Therapies	Guideline	General	General	We feel that it will be a very different way of working in the sessions (currently a guided self help appointment is 30 minutes long). We are wondering whether there will be some top up training for the PWP's so that they are able to work in this way, and would the university training going forward be different.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.

							Consequently, no need for top up training for the PWPs is anticipated.
239	SH	Newham Talking Therapies	Guideline	General	General	All IAPT services have continuing difficulties with the burnout and retention of PWP's, and this is something that services have been proactively trying to address. Working in this way will double the patient contact that PWP's will have in a day, and only increase burnout. We have concerns that moving to this way of working will cause further difficulties in recruitment and training of PWP's.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.

240	SH	University of Essex	Guideline	General	General	Psychological treatments recommended for further line/chronic/ depression with personality disorder“Further line” recommended psychological treatments default to the ‘more severe’ first episode list for no clear reason. Recommendations for “Chronic depression” allow only for CBT. Depression with PD allows for BA, CBT, IPT or STPP - which all feature on the ‘more severe’ list. This is confusing, inconsistent and does not support patient choice.Taking a range of evidence into account, we suggest that:- the list of recommended psychological treatments for these three depression categories (further-line, chronic and ‘with PD’) be combined and for there to be a general principle applied that: - psychological treatments may be offered for longer treatment periods up to a maximum of 18 months based on shared decision making, clinical judgement and patient choice, taking into account: severity, chronicity, treatment resistance, level of functioning, comorbid personality disorder, degree of past trauma. Rationale:As advised consistently by a large group of stakeholders throughout previous consultations: further line, chronic depression (CD) and depression with PD overlap in practice and/or are difficult/impractical to classify in practice outside the context of a formal research study. At the University of Essex we have examined this in further detail to illustrate the issue (see	Thank you for your comment. The further-line treatment recommendation that cross-refers to psychological treatment options for more severe depression is for people whose depression has had no or a limited response to treatment with antidepressant medication alone. There was no evidence that specifically examined switching to a psychological intervention for those who have not responded to initial antidepressant treatment, however, the committee drew on the evidence for first-line treatments in more severe depression. The committee agreed that the psychological interventions that had been identified as effective and cost-effective for first-line treatment of more severe depression could be used for people who had not responded to antidepressants and wished to try a psychological therapy instead. For the further-line treatment review, studies were sought that included adults with depression showing an inadequate response to at least one previous intervention for the current episode and this included the further-line treatment of psychotic depression, depression with coexisting personality disorder and chronic depression. First-line treatment or relapse prevention of chronic depression (including dysthymia), and first-line treatment or relapse

						McPherson, 2019, BMJ MedHum https://mh.bmj.com/content/46/3/162.) Our analysis shows that two studies in the further line review were classified in appendices as also fulfilling the criteria for CD but were not analysed in the CD category (Study IDs: Fonagy 2015 and Kocsis 2009). Our analysis indicates that about half of the 'further line' trials do not report the mean duration of episode, meaning that it is not possible to know what percentage of participants also met the criteria for CD. Of further line trials that do report episode duration, more than half report a mean duration longer than 24 months. While the standard deviations vary in size or were unreported, the mean indicates a good likelihood that a significant proportion of the participants across the trials in these categories meet criteria for CD. For more detailed examination of overlap between these three categories specific to trials in the current NICE evidence reviews, see our full analysis referenced above.There is very limited clear RCT evidence for psychological treatments for these longer term/complex forms of depression which relate to the current UK context in which psychological treatments are now the preferred first line option. In the absence of clear strong RCT evidence for treatments for persistent depression (in a health care setting where psychological treatments are first line options), other factors	prevention of depression with coexisting personality disorder were separate reviews, as the committee did not feel that it was appropriate to combine these populations for first-line treatment or relapse prevention. The committee considered that the grouping together of psychotic depression, depression with coexisting personality disorder and chronic depression for the further-line treatment review should allow the effectiveness of interventions for a more clinically complex population to be considered. There was only single-study evidence (Fonagy et al. 2015) for augmenting antidepressant treatment with long-term psychodynamic psychotherapy, and the committee considered the evidence too limited to make a recommendation for long-term psychodynamic psychotherapy specifically. However, a treatment option in the recommendation for people whose depression has had no or a limited response to treatment with antidepressant medication alone, includes changing to a combination of psychological therapy and medication, which could include long-term psychodynamic psychotherapy although it is not listed as an example due to the limited evidence.

						should to be taken into account as is the case elsewhere in the guideline: clinical expertise, patient choice, qualitative evidence.Evidence that is available to support longer-term psychological therapy includes Fonagy (2015) which has the longest duration of treatment and longest follow up period of any RCT in this review. The long term and complex nature of depression in this category (serious functional impairment, high comorbidity, high trauma) and meeting criteria for further line and CD merits taking account of the promising effect size at 24 months follow-up on both symptoms and QOL/functioning. See McCrone et al 2017 for more details on complexity of this trial population www.tandfonline.com/doi/full/10.1080/09638237.2017.1417562 - this study indicates that the cost burden of the Fonagy 2015 sample prior to entering the RCT was at least 7 times greater than the COBALT study sample of Hollinghurst et al 2014.The overall symptom effect size at 24 months Follow-up (SMD=0.68) for Fonagy 2015 is conservative given that 27% and 19% of the control group were receiving counselling and CBT respectively (as noted earlier, the study was incorrectly described in Table 7 as having a medication control group rather than a TAU control group). The control group was therefore more similar to UK current practice than other	Data could not be extracted from the Fonagy et al. (2015) study for quality of life or functioning outcomes as Ns were not reported by arm. Given the size of the evidence base it was not possible to contact all authors for missing data. Selective reporting bias is included under risk of bias in GRADE, and assessments have been made by study in Supplement D. If a study reported a protocol this was checked against reported outcomes and rated as at high risk of bias if all the outcomes specified a priori were not reported. Studies were also rated as at high risk of selective reporting bias if outcomes were not reported (in an extractable form) for all measures mentioned in the paper. If a protocol was not registered risk of selective reporting bias was rated as unclear. Leuzinger-Bohleber et al 2019 was considered for the chronic depression review and was excluded. This study also did not meet eligibility criteria for the further-line treatment review as the inclusion criteria of the study was not limited to those receiving further-line treatment, participants were not randomised at the point of non-response, and it could not be regarded as an augmentation study following limited or no response to antidepressants as only 36% of

						RCTs since treatment resistance criteria included resistance to first line psychological treatments and TAU was provided in a UK context and did not exclude other psychological treatments.Quality of life outcomes in Fonagy 2015 (incorrectly left out of the draft guideline review) show promise for LTPP. Note that many other RCTs have clearly collected QOL outcomes and not reported them, which indicates risk of bias for those trials and which is not taken account of in the current GRADE approach.Many psychological therapy RCTs across all categories demonstrate variation in clinical benefits within study samples – some benefit and some do not – this emphasises the need for offering a wide range of options for all types of depression and the need for further research addressing individual differences.Evidence from a good quality treatment comparison study (CBT vs LTPP) for Chronic Depression suggests long term psychological therapies are equally effective for long term depression over 3 years. See Leuzinger-Bohleber et al 2018 https://journals.sagepub.com/doi/full/10.1177/0706743718780340 . This RCT did not meet criteria for the CD review but pre-study treatment history described in the study suggests it probably meets criteria for the 'further line' review (70% had previous psychotherapy; AND more than a third had inpatient treatment; AND 36% were on	participants were taking antidepressants at baseline. This study has now been added to the excluded studies list in supplement D. As specified in the scope, the experience of care section from the 2009 guideline was not included in this update. However, a new review question on patient choice was added to this update that includes a systematic review of primary qualitative studies that focus specifically on service user experience around choice of treatment.

						antidepressants – study authors could no doubt confirm whether altogether over 80% had had previous treatment to meet the “further line” inclusion criteria).“Knowledge and experience” of clinicians suggesting longer term psychological therapy is needed should be taken into account (as is done elsewhere in the guideline) e.g. “GPs raised the time-limited nature of the psychotherapies that they could offer, and questioned whether a relatively small number of sessions over a short timescale would be sufficient for all people with depression (Johnston 2007; Mercier 2011).” (From NICE 2021 review on Patient Choice, p52)A recommendation to allow the option of longer term psychological therapies for longer term depression would fit with evidence from research and reviews on patient experience/patient choice: “In terms of making an informed choice, participants made the following suggestions for a decision guide…Honesty and transparency about the chronic aspects of depression, it will not go away with a short spell of therapy”National Survivor User Network (2020) Informing a Decision Guide for Psychological Treatments for Depression“Issues that came up around therapy and experiences of therapy were remarkably similar; for example: the difference between what people felt they wanted or needed and what they actually got, the absence of explicitly culturally	

						informed and racism-aware therapy, little or no choice of type of therapy offered, and long waiting times alongside short durations of therapy”National Survivor User Network (2020) Informing a Decision Guide for Psychological Treatments for Depression“It could take a long time to form the basis of a trusting relationship in which the individual could open up and talk about what mattered to them. One person said they had only just begun to trust the therapist by the time the ten sessions had come to an end.”National Survivor User Network (2020) Informing a Decision Guide for Psychological Treatments for Depression“Although short courses of cognitive behavioural therapy were useful, those like Belinda, who identified that they had deep and complex problems, felt they needed longer term therapy”From Ridge & Ziebland (2006) using healthtalkonline data (this study was drawn on in the 2009 NICE guideline and now excluded inappropriately) “There was a strong feeling within the service user and carer topic group that the excerpt from Howe (1995) in the section above highlights the reasons why many people opt for private therapy; that is, that psychological treatment offered by the NHS in the form of CBT does not go far enough in addressing the trauma experienced in childhood. The study by Ridge and Ziebland (2006) confirms the opinions of the topic	

						group and the testimony from the personal accounts that people with 'deep and complex problems felt the need for longer term therapy'. Those that have had long-term psychodynamic therapy report that it has been helpful in their under- standing of themselves and their depression and that until they have worked through and repaired the damage experienced in childhood, depression will be a major factor in the person's life."From 2009 NICE guideline patient experience chapter "Specifically relating to individual face-to-face CB approaches, it was found that people could be left feeling as though they had not had the chance to explore the underlying causes of their depression properly. This and other factors meant that people appeared to be left feeling they had missed out on potential benefits from therapy and a common finding was that participants expressed a wish for more therapy or a different type of therapy."From (McPherson et al 2020) – a qualitative systematic review of patient experiences of psychological treatment for depression https://bmcpsychiatry.biomedcentral.com/articles/10.1186/s12888-020-02682-1 "There was a fairly consistent view that for the client group in the trial, short-term therapies were unlikely to lead to real recovery, largely because of the connection to deep-seated trauma discussed above. This was	

						coupled for some with a sense that short-term therapies were often all that was on offer and could not be refused".From McPherson et al 2018 https://journals.sagepub.com/doi/10.1177/1363459318785720	

241	SH	Olly's Future Suicide Prevention Charity	Guideline	General	General	Olly's Future is pleased to comment on this draft NICE guideline, focussing on two main points which we feel are key to helping prevent suicide when treating and managing people with depression. This insight comes from the tragic death by suicide of Oliver Hare, aged 22, in February 2017. This young man, who graduated with a first class degree in History from UCL just six months earlier, was prescribed an anti-depressant for the first time by a GP he had never before spoken to or met. This was done over the phone. Oliver was told to pick up the medication from the in-house pharmacy. After four days of taking Citalopram, his mood deteriorated to the point where he took his own life. Oliver had never before received any help or support for a mental health issue and at the inquest the parents were told by the GP that there was no NICE guideline in place to stipulate that first time patients should be prescribed face-to-face. We would like a guideline added into this guidance (perhaps under 1.4.8) which would recommend that all patients being prescribed anti-depressants for the first time should be seen face-to-face by the healthcare professional prescribing them. We understand that as many as 48% of consultations with primary healthcare services are carried out over the phone, with a recent surge due to the pandemic The Guardian, 2020). However, there are indications that primary care	Thank you for your comment. The committee discussed that face-to-face consultations may not always be possible or preferred by people with depression and so they did not agree to mandate this, but have amended the recommendations to state that starting antidepressants in people at risk of suicide should ideally be carried out in-person.

						providers may be inclined to continue operating remotely after the pandemic (Carter, 2020). Evidence strongly suggests that telephone consultations are not appropriate for individuals being prescribed anti-depressants for the first time and we would welcome a guideline to reflect this. Whilst we recognise that 'tele-medicine' has a valuable place in healthcare, it has been noted by many studies that telephone consultations are not appropriate in every situation (John Mills et al, 2019, and Car & Sheikh 2003) . Many organisations, including the National Association for Patient Participation do not support telephone triage. Evidence suggests that telephone consultations are best suited to the routine management of long-term health conditions, and not the diagnosis and treatment of new conditions(McKinstry et al 2008). Further, it has been noted that telephone consultations "are not always the best approach for everyone…including… those in mental health crisis" (The Times, 2021) . Moreover, studies indicate that mental health patients themselves are, at best, ambivalent towards telephone consultations, therefore suggesting that they favour face-to-face appointments (Health Innovation Network, 2021). Furthermore, research suggests that patients disclose more issues to healthcare providers face-to-face than they do the phone, which is crucial for	

						the correct diagnosis and treatment of depression (Rosen, 2020). This is particularly important as these guidelines suggest different interventions for the treatment of mild and more severe depression. Other studies suggest that telephone consultations tend to contain less data gathering, counselling, advice, and rapport building, which are crucial for the effective diagnosis and treatment of depression (Mckinstry, 2010). We note that in guideline 1.4.21 (12) it is recommended that patients under 25 (those at increased risk of suicide after starting anti-depressants) should be reviewed 1 week after starting antidepressant medication or after a dose is increased, and this review should ideally be carried out in person, or video-call, or by telephone if neither of these are possible nor preferred. We feel it is an oversight that this has not been recommended for the initial prescription of anti-depressants. Considering this evidence, we would welcome a guideline added into this guidance to the effect that all patients being prescribed anti-depressants for the first time should be seen face-to-face by their healthcare provider. We believe that this small change will improve the quality of care and save lives.	

242	SH	Olly's Future Suicide Prevention Charity	Guideline	General	General	We would welcome a guideline to introduce the explicit use of safety planning when prescribing anti-depressants to individuals. Some anti-depressants carry with them an increased risk of suicide. Notwithstanding this, depression is a major predictor of suicide, therefore presenting a strong case for the implementation of safety planning throughout all treatment for depression. Studies suggest that the most effective prevention strategies for suicidal people are follow ups from healthcare teams (which we are pleased to see implemented under guideline 1.4.21) and safety planning (American Psychiatric Association, 2019) . Research has shown that personalised safety planning can prevent people taking their own lives (Nuji et al, 2021 and Moscardini et al, 2020). Whilst it is not known why there is a link between taking anti-depressants and increased risk of suicide in some groups, it is an observed (yet disputed) phenomenon. Therefore, whilst, as we have already noted, there is guidance for health care professionals to follow-up with their patients (which we welcome), this may not be enough to mitigate the risk of suicide. People who take anti-depressants and experience the side-effects of suicidal thoughts and ideation report feeling suddenly compelled to take their own lives. Therefore, a follow up appointment may be insufficient alone, and we believe there is a strong	Thank you for your comment. The guideline already contained a section on risk assessment and safety planning as you have described, so a cross-reference to this section, from the section on starting antidepressants for people at risk of suicide, has been included.

						case for the implementation of safety planning to those being prescribed anti-depressants. Safety planning could include a list of coping strategies for people to use if they experience suicidal thoughts or feelings and pre-throughout pathways to activate if the individual becomes suicidal. Safety planning could involve a trusted adult(s) of the individual's choosing. The benefits of a trusted adult are that they can be vigilant of the person's mood and behaviour changes that could indicate suicidal thoughts and ideation in a way that remote healthcare professionals cannot. We strongly believe that safety planning should be discussed as a precaution when anti-depressants are prescribed. It is crucial that safety plans are formed before an individual reaches crisis point, and that the individual always has access to it.	
243	SH	Leeds Community Healthcare NHS trust	Guideline	General	General	Use of the word "practitioner" makes it unclear whether this is a step 2 psychological wellbeing practitioner or Step 3 counsellor, cognitive behavioural therapist or interpersonal therapist.	Thank you for your comment. All NHS staff are part of the target audience for this guideline. How the recommendations in the guideline are put into practice will be a matter for local implementation.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

244	SH	Leeds Community Healthcare NHS trust	Guideline	General	General	Does not follow “stepped care model” as is it currently the case if a patient does not recover at step 2, they would be “stepped up” to high intensity therapy.	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice.

245	SH	Psychotherapy & Counselling Union	Guideline	General	General	Stakeholder perspectiveAs a union representing psychotherapists, counsellors, and related professions, our concern is to ensure that the expertise of our members is properly understood and that their skills are appropriately utilised in all situations where they can make a contribution.We recognise the enormous importance of NICE guidelines in relation to psychological interventions, especially for frequently-encountered conditions such as depression. The guidelines will affect not only treatment recommendations by GPs and other healthcare professionals, but also the provision of different services for instance within IAPT settings, and more broadly the public perception of the effectiveness of different interventions.Acknowledgement of latest draftWe are therefore encouraged by a number of aspects of the latest draft guideline, when compared to both the currently approved guideline (NICE, 2009) and the previous consultation draft (NICE, 2018). In particular, we welcome:The inclusion of both Counselling and Short-term psychodynamic psychotherapy (STPP) as first-line treatments for both less severe and more severe depression (Guideline, pp. 29-30, 33-35), rather than only as secondary options (NICE, 2018, pp. 23, 25).The new section 1.3 on choice of treatments (Guideline, pp. 10-11), emphasising shared decision-making and respect for the	Thank you for your comment and support for much of this updated guideline. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context (including drawing on their knowledge of the IAPT dataset) so that the 'reality' for people experiencing depression was taken into consideration. In response to stakeholder comments, the committee have re-structured treatment recommendations in order to take into account implementation factors. In January 2020 NICE published a statement of intent signalling the ambition for the future use of wider sources of data and analytic methods (including sources commonly referred to as real-world data and evidence). To make decisions about the relative effectiveness of interventions, RCTs will continue to be prioritised in line with the NICE guidelines manual, in order to ensure that the populations treated with various interventions are equivalent. However it is possible that in the future, high-quality real-world datasets such as the IAPT dataset, could inform questions about access and engagement.

						preferences of people with depression (in line with the new NICE guideline NG197), and the requirement for commissioners to ensure that all NICE-recommended treatments are available in practice (Guideline, p. 11).Underpinning section 1.3, the inclusion of evidence relating to service user experiences, and the use of a range of qualitative studies for this purpose (Evidence review I).The full discussion of issues related to antidepressant withdrawal (sections 1.4.10 to 1.4.20, Guideline, pp. 15-18), especially as compared to the cursory overview in the 2009 guideline (NICE, 2009, p. 34-35, cp. NICE, 2018, pp. 14-17).Real-world practiceOur members work on the front line helping people with depression, and they see the full range of presentations and contexts that can appear in depression. We therefore remain concerned that the draft guideline does not encompass the complexities of real-world practice, as it continues to focus on a narrow evidence base, narrowly-defined outcome measures, and questionable classifications of both depression and counselling.	

246	SH	Psychotherapy & Counselling Union	Guideline	General	General	ConclusionAlthough we welcome some aspects of the current draft guideline, we remain very concerned about the underlying conceptualisation, which seems to regard depression and its treatment as almost a matter of “hard” science, where the application of sophisticated mathematics can lead to a precise set of criteria for determining the single best treatment in any situation.This conceptualisation does not fit with the real-world experience of our members, where depression is likely to be just one aspect of a complex client situation, and the choice of appropriate psychological and/or pharmacological treatment will be affected by many personal and practical considerations, alongside which theoretical treatment efficacy may be a comparatively minor issue (cp. Wampold, 2015, p. 275, https://onlinelibrary.wiley.com/doi/pdf/10.1002/wps.20238, note d=0.20 for treatment differences).We appreciate the steps that have been taken over the course of an unprecedented three rounds of consultation to address at least some of the issues raised above, and we are aware that NICE is now determined to publish the revised guideline on 12 May 2022 as planned. Consequently there will be little room for further major change between now and then. However, we will look forward to continuing to engage in	Thank you for your comment. In addition to the results of the network meta-analysis (NMA), the committee took other pragmatic factors into consideration when making recommendations, including the uncertainty and limitations around the clinical and cost-effectiveness data, and the need to provide a wide range of interventions to take into account individual needs and allow patient choice. The committee agreed that decisions on treatment should be made in discussion with the person with depression, and recommended that a shared decision should be made. The committee cross-referred to the guideline recommendations on choice of treatment which provided more detailed recommendations on how this shared decision should be made and what should be included in the discussion. It was recognised by the committee that people who have had prior episodes of depression may also have preferences for their treatment based on prior experience or insight into their own depression patterns. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context (including drawing on their knowledge of the IAPT dataset) so that the 'reality' for people experiencing

						constructive dialogue with NICE (in coalition with other stakeholders) to ensure that the skills and expertise of our members are appropriately included within future provision for psychological therapies.	depression was taken into consideration. In response to stakeholder comments, the committee have re-structured treatment recommendations in order to take into account implementation factors. In January 2020 NICE published a statement of intent signalling the ambition for the future use of wider sources of data and analytic methods (including sources commonly referred to as real-world data and evidence). To make decisions about the relative effectiveness of interventions, RCTs will continue to be prioritised in line with the NICE guidelines manual, in order to ensure that the populations treated with various interventions are equivalent. However it is possible that in the future, high-quality real-world datasets such as the IAPT dataset, could inform questions about access and engagement.

247	SH	Sport England	Guideline	General	General	We support the inclusion of exercise as an optional first line treatment for people experiencing mild depression. However, feel there is significant opportunity for clinicians to promote a broader 'move more' message and integrate physical activity in adjunct to all treatment pathways for patients experiencing mild or severe depression.This is because of the positive relationship that exists between sport, physical activity and mental wellbeing. There are a broad range of beneficial outcomes within this relationship, including positive impact on enjoyment and happiness, building confidence and self-esteem and reducing stress, anxiety and mild depression (Review of evidence on the outcomes of Sport and Physical Activity, 2017). Exercise is effective in the management of mental health conditions. Sport England have seen an increase in people using exercise as a support tool through the Covid pandemic '67% of all adults and 72% of people with a mental condition or illness agree that they exercise to help manage their mental health during the outbreak.' (Savanta ComRes, Attitudes and Behaviours. Wave 21, 05.11.2021 - 08.11.2021)There are many ways to be more physically active and a vast amount of national, free resources that support both clinicians and patients to move more and improve mental and physical health. We recommend referencing and	Thank you for your comment and your support. In response to stakeholder comments, the committee supported less intense 'move more' exercise for general wellbeing (although not a treatment for depression) and made a new recommendation to reflect this. Thank you for telling us about the existing physical activity programmes and campaigns. These will be passed on to the NICE shared learning team.

						signposting to the following existing support resources within the guideline:1. We Are Undefeatable – we have developed the inspiring, inclusive, and empathetic 'We are Undefeatable' campaign (https://weareundefeatable.co.uk/about-us) alongside 16 leading health and social care charities. This supports and encourages people with health conditions to find ways to be active. 2. Moving Medicine (https://movingmedicine.ac.uk) – a central hub developed with the Faculty of Sport and Exercise Medicine to support healthcare professionals integrate physical activity conversations into routine clinical care (includes depression consultation guides and resources).	

248	SH	Sport England	Guideline	General	General	We would welcome the consideration within the methodology of the inclusion of broader research (including real-life setting research, physical activity non-randomised trials and physical inactivity research) to enrich the guideline development. The current methodology only takes into account randomised control trials (RCTs) and structured exercise programmes which we feel is limiting. It excludes a vast amount of data and qualitative, practical research in relation to what is effective when supporting people with mental health conditions to become more physically active and manage symptoms.When considering exercise as a treatment option, the inclusion of wider inactivity data and research sources would be beneficial, this is because people with a diagnosed mental health condition are more likely to be inactive. The national physical activity survey for England Active Lives demonstrates people with a diagnosed mental health condition are 1.6 times more likely to be inactive.Much of Sport England's work and expertise is focused on supporting people with long term conditions (including mental health conditions) to manage and improve the symptoms associated with their conditions and improve quality of life through being more physically active. Evidence from Sport England's inactivity investment portfolio, We Are Undefeatable campaign and our partnership with	Thank you for your comment. The committee agreed that, although the evidence for exercise had indicated that a certain level of exercise (in terms of duration and intensity) was most effective for the treatment of depression, based on their knowledge and experience it would be useful to include advice that any level of exercise may be beneficial and so have added a recommendation stating this. The committee considered RCTs as the most appropriate study design to assess clinical and cost effectiveness. This is consistent with the NICE guidelines manual which recognises RCTs as the most valid evidence of the effects of interventions. This was outlined a priori in the review protocols, and on this basis non-randomised trials and real-life research were not included. Thank you for telling us about the existing physical activity programmes and campaigns. These will be passed onto the NICE shared learning team.

						the Richmond Group of Charities suggests the most effective behaviour change principles and messages to apply in supporting people with long term conditions (including depression) to manage symptoms through moving more are; find something you enjoystart slowlybuild up graduallymake the most of good days. Enjoyment is an important consideration. Literature suggests that if people do not enjoy an activity to at least some extent then they are unlikely to persist and continue with it over a long period of time (Ryan. Frederick. Lepes, et all.; 1997). We would welcome the opportunity to share this insight to aid the development of the guidelines.	

249	SH	Sport England	Guideline	General	General	Whilst structured, group exercise may be appropriate for some individuals, broader options that are person-centred and individualised should be considered due to their proven effectiveness such as social prescribing, community provision and self-led activity for those experiencing mild or severe depression.Our portfolio of physical activity investments supporting people living with long term conditions (including mental health conditions) suggests a 'one size fits all' approach is unlikely to be effective. Whilst structured, supervised, group activity may be appropriate for some individuals i.e. those with multiple complex health conditions or unstable health conditions, in practice, many patients referred to exercise on referral style pathways fail to take up or complete the exercise offer. We also know from our latest IAPT physical activity interventions (unpublished 2021) many patients do not feel comfortable exercising as part of a group due to fear of judgement and lack of confidence exercising.Based on evidence (Moving for Mental Health: How physical activity, sport and sport for development can transform lives after Covid-19, Mind 2022) we recommend guidelines also incorporate broader self-led activity to include We Are Undefeatable, Active 10, 10 Today and Couch to 5k,plus widely accessible and affordable community based provision such as OurParks and Parkrun.Providing a	Thank you for your comment. The committee noted that the evidence was for a structured formal exercise programme, with exercise of moderate to high intensity, but recognise there may be challenges to implement this. The committee has now removed the suggested duration of exercise sessions and modified the recommended frequency to allow more flexibility in the delivery of exercise programmes. In response to stakeholder comments, the committee also supported less intense 'move more' exercise for general wellbeing (although not as a treatment for depression) and made a new recommendation to reflect this.

						range of activities and ways to be active will help patients find something they enjoy. Literature suggests enjoyment is a very important factor. If people do not enjoy an activity to at least some extent then they are unlikely to persist and continue with it over a long period of time (Ryan. Frederick. Lepes, et all.; 1997)Person centred approaches are most likely to lead to longer-term adoption of physical activity behaviours if choice about when and how people engage with exercise and opportunities for optimal challenge are provided (Self-Determination Theory. Basic Psychological Needs in Motivation, Development, and Wellness. Ryan and Deci, 2017).	
250	SH	Sport England	Guideline	General	General	The barriers to being active for those living with a mental health condition should be addressed in any exercise treatment pathway created. This will support patient attrition rates.Britain thinks (2016) identified the top barriers for people living with a long-term condition (including mental health conditions):Physical pain before, during or after exerciseFeeling tired before, during or after	Thank you for your comment and for telling us about your work to improve participation in exercise. This information will be passed to the NICE team responsible for ensuring guidelines are up to date, for consideration in a future update.

						exerciseLack of motivationOur latest IAPT investment has demonstrated behaviour change workshops have been successful in supporting people with depression to be more active and manage symptoms. These practical workshops identify the barriers people experience and incorporate behaviour change support tools. We would welcome the opportunity to share this insight to support the development of the guidelines.	

251	SH	Department for Environment, Food & Rural Affairs	Guideline	General	General	We are disappointed to see that there is no recommendation on using nature-based health interventions to help treat depression. This is despite a growing body of evidence (outlined below, although please note this is not an exhaustive list), on the benefits of interventions such as green social prescribing for treating depression. For example, people with high nature connectedness were 1.7 times more likely to report that their lives were worthwhile than those with low nature connectedness (Natural England, 2020).Ideally, we would like to see green social prescribing included as a recommendation for treating depression. However, we understand that nature-based health interventions were not included in the original scope of these guidelines and so may not have been included in your research review questions. We would therefore like to ensure that future research will include nature-based health interventions in the review criteria. Public Health England (2020), Improving access to greenspace: A new review for 2020, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/904439/Improving_access_to_greenspace_2020_review.pdfDefra (2018), Health and the Natural Environment: A review of evidence, policy, practice and opportunities for the future, http://randd.defra.gov.uk/Document.aspx?Docum	Thank you for your comments. The committee did not consider nature-based activities to be interventions that were in regular clinical use for the treatment of depression. Therefore these interventions were not specified in any of the review protocols and consequently the studies that you cite would not have met the inclusion criteria for the reviews. However, in response to stakeholder comments, the committee supported less intense 'move more' exercise for general wellbeing (although not as a treatment for depression) and made a new recommendation to reflect this. The recommendation also emphasised the benefits of outdoors activities.

						ent=14290_HealthandtheNaturalEnvironment_Full Report_29.08.18.pdfUK Parliament Research Briefing (2020), Mental health statistics: prevalence, services and funding in England, Mental health statistics: prevalence, services and funding in England - House of Commons Library (parliament.uk) ENCA Services Databook - ONS (2019) UK Natural Capital AccountsHealth matters: obesity and the food environment - GOV.UK (www.gov.uk)Natural England, A review of nature-based interventions for mental health care, A review of nature-based interventions for mental health care - NECR204 (naturalengland.org.uk)Natural England (2020), Nature connectedness among adults and children in England Mourato et al., Economic Analysis of Cultural Services (2010)Public Health England, Improving access to greenspace (2020)Cross government project on preventing and tackling mental ill health through green social prescribing (research on the effectiveness of green social prescribing included below):Willis et al, Green space and health benefits: a QALY and cost-effectiveness analysis of a mental health programme (2016)Maughan DL et al, Primary-care-based social prescribing for mental health: an analysis of financial and environmental sustainability (2016)Dayson and Bashir, The social and economic impact of the Rotherham Social	

						Prescribing Pilot: main evaluation report (2014)Natural England, Good practice in social prescribing for mental health: the role of nature-based interventions' (2017) Cross government paper on 'Why society needs nature: Lessons learned from research during Covid-19'White et al, 'Would you be happier living in a green urban area?' (2013) Van den Berg et al, Health benefits of green spaces in the living environment (2015)Natural England, A rapid scoping review of health and wellbeing evidence for the Framework of Green Infrastructure Standards (2020)White et al, 'Spending at least 120 minutes a week in nature is associated with good health and wellbeing', (2019)Social Return on Investment analysis of the health and wellbeing impacts of Wildlife Trust programmeshttps://www.nature.com/articles/s41598-021-87675-0https://www.euro.who.int/en/health-topics/environment-and-health/urban-health/publications/2017/urban-green-space-interventions-and-health-a-review-of-impacts-and-effectiveness.-full-report-2017https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4410252/https://pubmed.ncbi.nlm.nih.gov/25631858/https://www.exeter.ac.uk/news/homepage/title_830601_en.htmlhttps://www.mentalhealth.org.uk/sites/default/files/MHAW21_NATURE%20REPORT_ENG_web.pdf (includes a number of	

						studies)https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7688424/	

252	SH	Parkinson's UK	Guideline	General	General	Context of Parkinson's UK's response: We know that for the majority of people living with Parkinson's, their symptoms of anxiety or depression are the most distressing aspect of their condition. At any given time, up to 40% will have depression (Aarsland D et al (2012) 'Depression in Parkinson's disease – epidemiology, mechanisms and management' Nature Reviews Neurology; 8: 35–47) and up to 31% will experience anxiety (Broen MPG et al (2016) 'Prevalence of anxiety in Parkinson's disease: a systematic review and metaanalysis' Movement Disorders; 31: 1125–1133).This is considerably higher than the 17% of the general population who will experience a common mental health problem (Mind. 'Mental health facts and statistics', https://bit.ly/3JSzweP, accessed 4 January 2022). The mental health of people with Parkinson's is often overlooked, with treatment focusing on movement-related symptoms.In our research into the mental health of our community, Parkinson's UK found that while three quarters of people with Parkinson's surveyed felt that their mental health problems impacted their quality of life, 65% were not confident that their needs were being met by healthcare professionals (Parkinson's UK. 'Mental health matters too', 2018, p. 9).There is considerable unmet mental healthcare need among our community. It is therefore critical that any	Thank you for your comment. This guideline is about the treatment and management of depression in adults. People with depression and a chronic physical health problem, such as Parkinson's, are not within the scope of this guideline. Therefore it is not possible to make recommendations for people with Parkinson's in this guideline. CG91 on 'Depression in adults with a chronic physical health problem' covers identifying, treating and managing depression in people aged 18 and over who also have a chronic physical health problem such as cancer, heart disease or diabetes. Your feedback will be passed on to the NICE surveillance team so that people with Parkinson's who are experiencing depression can be considered for inclusion in future updates of CG91.

						guidance that NICE produces regarding the management and treatment of depression accounts for the specific needs of people with Parkinson's.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

253	SH	Parkinson’s UK	Guideline	General	General	It is worth noting that the NICE guidelines on Parkinson’s - NG71 (NICE. Parkinson’s disease in adults, https://www.nice.org.uk/guidance/ng71, 2017, accessed 10 January 2022) do not adequately deal with the issues that people with Parkinson’s face in relation to receiving high-quality mental health care. The guidance simply refers people to generic NICE guidelines for anxiety and depression in chronic long-term health conditions which are over 12 years old - CG91 (NICE, https://www.nice.org.uk/guidance/cg91, 2009, accessed 10 January 2022). Parkinson’s UK strongly believes there is a pressing need for, and recommends developing, NICE guidance on diagnosis of mental health symptoms, treatment, and support for people with Parkinson’s tailored to their specific need. This would enable the spread of best practice across the NHS to areas where it is sorely needed. Research suggests that people experiencing Parkinson’s and depression or anxiety have poorer health outcomes, with reduced quality of life, poor functional status and worsened cognition (Parkinson’s UK. ‘Mental health matters too’, 2018, p. 9). Depression and anxiety are key determinations of quality of life for the person with Parkinson’s, as well as friends and family. It is therefore especially important that NICE guidance on the treatment of mental health conditions such	Thank you for your comment. This guideline is about the treatment and management of depression in adults. People with depression and a chronic physical health problem, such as Parkinson's, are not within the scope of this guideline. Therefore it is not possible to make recommendations for people with Parkinson's in this guideline. CG91 on 'Depression in adults with a chronic physical health problem' covers identifying, treating and managing depression in people aged 18 and over who also have a chronic physical health problem such as cancer, heart disease or diabetes. Your feedback will be passed on to the NICE surveillance team so that people with Parkinson's who are experiencing depression can be considered for inclusion in future updates of CG91.

						as depression accounts for the needs of people with neurological conditions such as Parkinson's.	
254	SH	Parkinson's UK	Guideline	General	General	The proposed guideline heavily focuses on symptom outcomes, without accounting for other areas of patient experience which have long been called for, such as quality of life, relationships and ability to participate in work. While the guideline scope lists adaptive functioning, carer wellbeing and a range of other outcomes among the list of main outcomes to be considered, it takes no account of these outcomes. Echoing the British Association for Counselling and Psychotherapy, we encourage NICE to run a re-analysis of studies using quality of life and/or functional outcomes, where these are available, and prioritise recommendations based on these measures, given	Thank you for your comment. The committee agree that quality of life and functioning outcomes are important, and these outcomes were included in the treatment reviews. The committee noted the limited evidence for these outcomes, and included quality of life and functioning outcomes for the research recommendations in the guideline. The committee agreed that the results for these outcomes in the limited evidence base confirmed that there may be additional benefits on quality of life and functioning with some of the interventions for depression that had shown benefit for the critical (depression) outcomes.

						that these are the measures of greatest priority to patients. (BACP. 'Protect and promote counseling: NICE consultation on Depression in Adults: treatment and management guidance', https://bit.ly/3F9xjIz, accessed 6 January 2022).	This provided reassurance, but there was not enough evidence on these important outcomes to alter their recommendations.

255	SH	International Society of Interpersonal Psychotherapy	Guideline	General	General	Guidelines should be based on objective evaluation of the breadth of available evidence. Having conducted clinical research and worked on depression guidelines, members of our organization are familiar with the risks of bias due to treatment allegiance (Falkenström et al., 2013). Disturbingly, the current proposed NICE guideline excludes numerous available randomized controlled trials (RCTs) from consideration. Although your panel appears to have located and listed many RCTs, many vanish at the point of evaluating them. Interpersonal psychotherapy (IPT), empirically proven and the second best studied intervention for major depression, has fallen victim to this in your proposed guidelines. This needs correction. A case in point is your review of chronic depression. Section E of the proposed draft appropriately lists five RCTS: Agosti and Ocepek-Welikson (1997); de Mello et al. (2001), Browne et al. (2002), Markowitz et al. (2005), and Markowitz et al. (2008). Excepting Browne et al., all evaluated fairly small samples and are thus underpowered to find differences between active therapies. Nonetheless, in neither of the two head-to-head comparisons does IPT look inferior to CBT. Of the relevant IPT studies, the Agosti study is the one least designed to find differences among treatments for chronic depression. It's small and underpowered, based	Thank you for your comment. For the chronic depression review (first-line treatment or relapse prevention), the studies that you cite are included in the analyses in different comparisons, so Agosti 1997 is included in the comparisons of CBT versus pill placebo, CBT versus antidepressants, CBT versus IPT, IPT versus pill placebo, and IPT versus antidepressants. de Mello 2001 is included in the comparison of IPT + antidepressant versus antidepressant-only. Browne 2002 is included in the comparisons of IPT versus antidepressants, and IPT + antidepressant versus antidepressant-only. Markowitz 2005 is included in the comparisons of IPT versus antidepressants, IPT versus counselling, IPT + antidepressant versus antidepressant-only, and counselling versus antidepressants. Markowitz 2008 is included in the comparison of IPT versus counselling. For the chronic depression review, for IPT versus pill placebo, there was only single-study evidence suggesting no significant difference. For IPT versus antidepressants, there was data from 3 studies for the depression symptoms outcome showing a statistically significant effect in favour of antidepressants. For IPT versus counselling, data from 2 studies for the depression symptoms outcome shows no

						on a subsample from a larger trial of patients presenting with acute depression. Yet Section E (page 66) lists only one of the IPT RCTs: Agosti. The four IPT trials actually focused on chronic depression have disappeared. So have the IPT comparisons with medication (Agosti, de Mello, Brown, Markowitz 2005). With the evidence thus excluded, IPT goes unmentioned, entirely absent from the discussion weighing the findings that begins on page 84. The psychiatric consensus is that chronic depression is harder to treat than acute major depression and that the combination of pharmacotherapy and evidence-based psychotherapy is usually the optimal approach, particularly if monotherapy has failed. There is little evidence that any one evidence-based psychotherapy works better than another. Your draft document does not recognize this. Returning to the draft review of depression more generally, questions 2.1 and 2.2 omit thirteen RCTs because required data could not be extracted, seven more RCTs because <80% of the sample had non-chronic depression, and an additional five RCTs for lack of precise baseline severity. That amounts to 25 RCTs, which constitutes more than the total empirical corpus for most psychotherapies and other antidepressant interventions. Failure to extract data, apparently often for secondary measures, is an arbitrary	significant differences. For the CBT versus IPT comparison, there is only small single-study evidence showing no significant difference. For the comparison of IPT + antidepressants versus antidepressants-only, data from 3 studies for the depression symptoms outcome shows no significant differences. Based on this limited and equivocal evidence, and bearing in mind that none of these studies was sufficiently powered for non-inferiority trials, the committee did not consider it appropriate to recommend IPT for the first-line treatment of chronic depression. For the first-line treatment review, studies were excluded if data (including baseline severity data) could not be extracted in an analysable form. Given the size of the evidence base it was not possible to contact all authors for missing data. The exclusion of studies from the first-line treatment review due to less than 80% of participants having non-chronic depression was a stipulation of the review protocol in order to create a homogenous data set. The guideline review questions focus on specific populations, and there is a separate review question for chronic depression (first-line treatment and relapse prevention) and a further-line treatment review question (that includes those with chronic depression).

						standard and a failure of the evaluating panel rather than an absence of vetted literature. Some IPT research findings date to the 1970s, hence data extraction may no longer be simple; but this is no reason to throw out important findings. Unsurprisingly, the draft proposal then arrives at different conclusions than the extant literature (cf., Cuijpers et al., 2020) and other extant guidelines (APA Workgroup on Major Depressive Disorder, 2010). Inasmuch as IPT is so well tested, tolerated, and has such clear effectiveness, it is bizarre to find in the main document of NICE recommendations that IPT is listed near the bottom of the list in the key Tables 1 and Table 2. Their order depends upon "the committee's interpretation of their clinical and cost effectiveness" (page 23). IPT is equipotent or more so than other listed interventions such as "self-help," and far better proven. It has comparable length, efficacy, and presumptively comparable cost to CBT. Why, then, is individual CBT listed third in Table 1 and IPT eighth? The committee's interpretation appears overtly biased. Table 2 appears similarly skewed. The initial recommendation is for "combination of individual cognitive behavioural therapy (CBT) and an antidepressant" (page 31), with IPT again listed eighth (page 35), trailing among other things individual problem-solving, counselling, and short-	The committee were aware of the Cuijpers et al. (2021) NMA paper that you cite. The committee considered that this study also supported their recommendations made based on their systematic review of the evidence, that all psychological treatments will provide some benefit, so offering a wide choice of treatments is appropriate, but that counselling may not provide the same level of treatment response. Based on their overall review of the clinical evidence the committee agreed that some treatment classes and interventions appeared to be more effective than others, but there was otherwise little to choose between treatments. The committee therefore reviewed the results of the health economic modelling which determined which treatments were cost-effective, and used this to develop a suggested prioritisation of which treatments should be offered to people with depression, or considered for use. In the guideline economic analysis of treatments for less severe depression, IPT ranked 12th out of the 16 options assessed, just above GP care, which was the reference treatment (Table 98, results of guideline economic analysis, evidence review B). It is noted that included RCTs in less severe

						term psychodynamic psychotherapy. There is no listing for the combination of IPT with an antidepressant. These rankings cannot be based on data. The proposed draft reads as a political document. This skewed finding raises questions about the objectivity or expertise of your review panel and suggests the need for re-evaluation before you finalize these potentially important NICE guidelines. The document repeatedly cites the Cochrane GRADE rating system, yet seems to use it to exclude massive quantities of evidence and to arrive at conclusions discordant with Cochrane Reviews. As it stands, the draft proposal tarnishes the respected reputation of your organization and does enormous disservice to UK patients, clinicians, and administrators. References Cuijpers P, Noma H, Karyotaki E, Vinkers CH, Cipriani A, Furukawa TA: A network meta-analysis of the effects of psychotherapies, pharmacotherapies and their combination in the treatment of adult depression. World Psychiatry 2020;19:92-107 Falkenström F, Markowitz JC, Jonker H, Philips B, Holmqvist R: Can psychotherapists function as their own controls? Meta-analysis of the "crossed therapist" design in comparative psychotherapy trials. J Clin Psychiatry 2013;74:482-491 Workgroup on Major Depressive Disorder: Practice guideline for the treatment of patients with major depressive disorder, third	depression reported a higher number of sessions for IPT relative to individual BA and individual CT/CBT<15 sessions (which was the intervention considered in the economic analysis) – this information has now been added in evidence review B, under Appendix N. So, even though the effects of IPT, CT/CBT and BA may be similar, these were achieved with a lower number of sessions of BA and CT/CBT compared with IPT. In the guideline economic analysis of treatments for more severe depression, IPT ranked 17th out of 20 treatment options and was less cost-effective than GP care, which was the reference treatment (Table 101, bias-adjusted results of guideline economic analysis). These results affected the place of IPT in the suggested order in which treatments should be offered for an episode of less and more severe depression, which is shown in Tables 1 and 2 of the guideline, respectively. Regarding the combination of IPT with antidepressants, there were no data for less severe depression and insufficient data (N<50) on discontinuation and remission in completers in more severe depression, as the committee decided to look only at treatment classes tested on at least 50 participants across RCTs included in each NMA, after looking at the total size of the

						edition. Am J Psychiatry 2010;167 (Oct. supplement):S1-S152	evidence base in this area (treatment of a new episode of depression) and noticing that there were several treatment classes with larger volume of evidence (see Appendix M in evidence review B). The size of the available evidence base on these outcomes was also a criterion for inclusion of treatment classes in the guideline economic modelling (as stated in Appendix J of evidence review B, under 'Interventions assessed'). Due to lack of sufficient data on discontinuation and remission in completers that were crucial for the economic modelling, combined IPT with antidepressants was not possible to include in the guideline economic analysis and therefore its cost-effectiveness relative to other treatments was not possible to estimate. Consequently, combined IPT with antidepressants was not possible to consider when formulating recommendations. In response to stakeholder comments some changes have been made to the tables guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. Interventions are arranged in the tables in the suggested order in which options should be considered, based on the committee's

							interpretation of their clinical and cost effectiveness and consideration of implementation factors. However, this is not a rigid hierarchy, all treatments included in Tables 1 and 2 can be used as first-line treatments, and it may be appropriate to recommend an intervention from lower down in the table where this best matches the person's preferences and clinical needs. The committee were aware of the need to provide a wide range of interventions to take into account individual needs and allow patient choice.

256	SH	Citizens Commission on Human Rights	Guideline	General	General	This comment is being included to counter the general acceptance of psychiatric opinions and the consequent prescribing of psychiatric drugs that can create the very difficulties they are prescribed to treat.There is considerable difference between medical diseases and psychiatric disorders. In medicine, strict criteria exist for calling a condition a disease: a predictable group of symptoms and the cause of the symptoms or an understanding of their physiology must be proven and established. Diseases are proven to exist by objective evidence and physical tests. Mental diseases have not been proven to medically exist.Psychiatric drugs disrupt the normal biochemistry of the body. The drugs can speed up the normal functions of a body, slow them down, dam them up or overwhelm them, thus creating side effects that can be more pronounced than the intended effects of a prescribed drug.People do experience troubles and upsets in life that may result in mental troubles. It is however a matter of sound medical fact that undiagnosed physical illness or injury can trigger emotional difficulties. Thorough and searching physical examinations can be done to find undiagnosed physical conditions manifesting as a mental disorder and effectively treating them with medical interventions. This has the potential of saving the NHS considerable funds by preventing a	Thank you for your comment.The committee recognised that physical disorders, as well as personal, social and environmental factors, can contribute to people's moods and have included consideration of these factors in their recommendations on initial assessment, as well as the section of the guideline on further-line treatment. The committee were also aware that psychiatric drugs can cause side effects, but that there is evidence that they are effective in treating depression and so there remains a place for them in this guideline.

						person from becoming a long-term psychiatric patient.	

257	SH	British Psychological Society	Guideline	General	General	The categorisation of mild/moderate vs. severe depression is concerning. As stated in previous consultations there is no evidence of both the methodological/ statistical and clinical validity of such a split. Given that most services wouldn't routinely objectively differentiate 'less severe' vs 'very severe' etc. meaning that the recommendations would not be easily applied in such a way in practice. Some services use patient measures to guide this, but this can be very crude and wouldn't ever fully replace a clinical assessment.	Thank you for your comment. The committee agrees that a proper assessment of severity cannot be based solely on a symptom scale and the guideline includes a recommendation to conduct a comprehensive assessment that does not rely simply on a symptom count but also takes into account both the degree of functional impairment and/or disability associated with the possible depression and the length of the episode. The committee considered the studies identified by the review and agreed that although baseline symptom scores have limitations as an indicator of severity, this information was available for the majority of studies, whereas other factors such as duration of disorder or functional impairment were not reported in a sufficiently consistent manner for them to be of use in determining severity. The committee considered the distinction between less severe (subthreshold/mild) and more severe (moderate/severe) depression to be clinically meaningful in terms of supporting effective clinical decision making and being aligned with how clinicians conceptualize depression (in particular, GPs and other primary care staff, given that the majority of people with depression and almost all first line presentations of depression are managed in primary care).

258	SH	British Psychological Society	Guideline	General	General	Given the many social determinants and maintainers of depression, we suggest that the guideline group incorporate evidence on a much wider range of psychological and social therapies and community-based responses to demoralisation, isolation and social defeat, which can be experienced as or contribute to depression. This should include social prescribing to arts or physical activities, online ways of connecting, and various forms of social and community support and involvement. Many of these may not show amelioration beyond that achieved by other 'active controls' or medication in randomised trials without longer follow-up, but increasing their availability or enhancing support to participate in them offers greater choice, which in itself can have benefits. Increased social connection is often a secondary benefit of such involvement (beyond mood enhancement) and has the potential to sustain well-being over the longer term. At minimum, we suggest that the Guideline should recommend more and high quality research into a wider range of responses to depression.	Thank you for your comment. Art therapy and music therapy were listed as interventions of interest for the treatment reviews. However, only one study of music therapy (Albornoz 2011) is included in the network meta-analysis for the treatment of a new episode of more severe depression. There was also only one eligible study for art therapy (Nan 2017), in the further-line treatment review. The committee considered the evidence too limited to make a recommendation for art therapy or music therapy. Peer support was listed as an intervention of interest in the treatment review protocols and evidence for peer support interventions was searched for and included where eligible. Only a single study of peer support for more severe depression was included. On the basis of the limited evidence for the effectiveness of peer support the committee made a research recommendation. The committee noted that the evidence reviewed for exercise was for a structured formal exercise programme. However, in response to stakeholder comments, the committee also supported less intense 'move more' exercise for general wellbeing (although

							not as a treatment for depression) and made a new recommendation to reflect this. The committee also recognised that people with depression, like everyone, might benefit from a healthy lifestyle and outdoor activities, but recognised that people with depression might find this harder to achieve. On this basis, a new recommendation was added to advise people with depression that maintaining a healthy lifestyle may help improve their sense of wellbeing. A link to the NHS advice on mental wellbeing was also added, which lists 5 steps to mental wellbeing: connect with other people; be physically active; learn new skills; give to others; pay attention to the present moment (mindfulness).

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

259	SH	British Psychological Society	Guideline	General	General	We welcome the inclusion of psychological therapies as the primary treatment for depression. However, we note that the array of options within the psychological therapies is limited. We know that services use NICE guidelines to develop their staffing and provision and we have seen examples of where people have been denied jobs as they were not mentioned within NICE Guidelines. Psychological intervention of various kinds is currently very important due to the increase in demand as a result of the Covid-19 pandemic. It would be a shame to see colleagues who are already working successfully within the NHS overlooked in this guidance.As well as workforce issues, the lack of treatment options narrows patient choice. NICE and NHS advocate shared decision making. True shared decision making involves exploring all the options, the evidence for those options and the limitations of the evidence. This should mean that NICE guidance could include more treatment options along with their evidence base for use by clinicians.Specific examples of alternative therapy types are included in the relevant sections below.	Thank you for your comment. The interventions included in the guideline were those for which to committee had identified evidence of effectiveness and cost-effectiveness. A much wider range of interventions were included in the review protocols but for many of these interventions there was a lack of evidence, or a lack of evidence of effectiveness, so the committee were unable to recommend them.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

260	SH	British Psychological Society	Guideline	General	General	Whilst we support the addition of increased attention to social and environmental factors that can contribute to the causation and maintenance of depression; we suggest there is a need for clinicians to be more aware of them and able to signpost to relevant support agencies. The risk is that if this is not changed, it may contribute to large numbers of people remaining depressed, with medication and psychological therapy continuing to be needed and ever-increasing costs to the NHS, as well as unsustainable public demand. An example of alternative approaches (relating to general health but highly relevant here given the known links between debt and depression) is seen in Health Equity in England: The Marmot Review 10 Years On (https://www.health.org.uk/publications/reports/the-marmot-review-10-years-on), This highlighted a scheme for general practitioners to have debt advice services housed at the practice was experienced as helpful by both patients and doctors.	Thank you for your comment. A recommendation to consider how other agencies may be able to provide support to people with depression has been added to the recommendations on initial assessment.

261	SH	British Psychological Society	Guideline	General	General	Why was the extremely large IAPT dataset (https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/improving-access-to-psychological-therapies-data-set) comparing outcomes from different types of therapies, which has been collected for over a decade, and is high quality practice-based evidence, not included alongside RCT evidence?	Thank you for your comment. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context (including drawing on their knowledge of the IAPT dataset) so that the 'reality' for people experiencing depression was taken into consideration. In response to stakeholder comments, the committee have re-structured treatment recommendations in order to take into account implementation factors. In January 2020 NICE published a statement of intent signalling the ambition for the future use of wider sources of data and analytic methods (including sources commonly referred to as real-world data and evidence). To make decisions about the relative effectiveness of interventions, RCTs will continue to be prioritised in line with the NICE guidelines manual, in order to ensure that the populations treated with various interventions are equivalent. However it is possible that in the future, high-quality real-world datasets such as the IAPT dataset, could inform questions about access and engagement.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

262	SH	British Psychological Society	Guideline	General	General	Why were family interventions for depression not considered such as family therapy for depression based on the McMaster model, (Miller et al., 2005; Ryan et al., 2005); behavioural family therapy for families of depressed mothers of children with disruptive behaviour disorders (Sanders and McFarland, 2000); and various types of individual family and multifamily therapy for older adults with depression (Stahl et al., 2016)?	Thank you for your comment. Studies on family interventions were sought for the reviews on depression with coexisting personality disorder, and psychotic depression. However, no eligible studies were identified. For other review questions, these interventions were not specified in the review protocols as the committee did not consider family interventions to be in regular clinical use for the treatment of depression and consequently the evidence was not reviewed and the committee were not able to recommend family interventions.
263	SH	Psychological Professions Network	Guideline	General	General	The Psychological Professions Network (PPN) is a multi-professional network bringing together psychological professionals and other stakeholders in publicly funded health and social care to maximise the benefits of the psychological professions to the public.The PPN is commissioned by Health Education England (HEE) to provide a joined-up voice for the psychological professions in workforce planning and development, and to support excellence in practice.The aim of the PPN is to inform, enable and influence publicly funded health and social care to maximise the benefits of the psychological professions for the public. To achieve this the PPN will:Engage and connect all psychological professionals so that we can have a strong voice together;Advise policy-makers,	Thank you for your comment and providing background information on your organisation. Each of your individual comments has been responded to separately.

						workforce planners and commissioners;Support the safe and effective expansion of the existing and new psychological professions.	

263	SH	Psychological Professions Network	Guideline	General	General	The key points we wish to make are:Absence of expertise in the committee members for mild and sub-threshold depression services and IAPT service delivery specificallyAlmost all the evidence considered for self help with support/self help with minimal support relates to computerised interventions, but these are not separated out and appear to be conflated with low intensity delivery. These need to be separated out.There is no differentiation of low intensity and high intensity interventions when considering the evidence base and delivery of these – need to be clear that a high intensity intervention would be delivered by a high intensity practitioner and not as part of self-help with support	Thank you for your comment. The committee included 2 GPs as well as professionals working in services delivering talking therapies in the community and so there was adequate expertise relating to sub-threshold and mild depression. Different self-help approaches (with or without support) were searched for and were eligible for inclusion. In addition to computerised approaches, there are also RCTs of cognitive bibliotherapy, behavioural bibliotherapy, expressive writing, mindfulness meditation CD, relaxation training CD, and third-wave cognitive therapy CD, included in the network meta-analyses (NMAs) for treatment of a new episode of depression. One intervention per class was used as an exemplar in the economic analysis, as it was not feasible to model all interventions included in the NMA. cCBT was selected as the exemplar from the class of self-help with support as it had a large evidence base and a high effect compared with other interventions in the same class. Thus, the clinical evidence and resource use data used to inform the economic analysis were specific to cCBT; consequently, the results of the economic analysis were specific to cCBT (but could also be extrapolated to any other intervention with similar acceptability,

							effectiveness and resource use). However, the treatment class effect size for self-help (with or without support) that was estimated from the NMA and reported in the clinical evidence sections of evidence review B, was informed by evidence from all interventions included in the treatment class. In addition, individual intervention effects have been reported in the evidence review B for all interventions within each class for the SMD outcome (for both less and more severe depression). In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The low intensity and high intensity differentiation is provided in the tables of interventions through the description of therapists.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

264	SH	Psychological Professions Network	Guideline	General	General	There is no mention of PTSD as a comorbidity. The NICE PTSD guidelines make reference to treating depression. At the very least these should be cross-referenced.	Thank you for your comment. A link has been added to the PTSD guideline from the section of the guideline on initial assessment.
265	SH	Psychological Professions Network	Guideline	General	General	There is no mention of substance misuse as a comorbidity.	Thank you for your comment. The use of drugs (prescribed or illicit) and alcohol are included in the recommendations on the initial assessment of depression.

266	SH	Institute of Psychoanalysis	Guideline	General	General	Treatment recommendations for further-line treatment, chronic depression, and depression with PD (guideline section 1.9. 1.10. and 1.11)Recommended psychological treatments for the above groups default for no clear reason to the 'more severe' first episode list. As studies that include more than 20% of PD or chronic depression were specifically excluded from the first episode analysis, this seems rather odd. In addition, there seems to be an error in Table 17 (Evidence review B) with regard to the effect size of the combined short-term psychodynamic therapy (SMD=-0.51) which is much smaller than the one reported in Figure 10 (SMD between -1 and -2). Furukawa et al. reported a large effect size for psychodynamic therapy combined with antidepressants, too, which was descriptively larger than those of other treatments (Furukawa et al., 2021, p. 394, Figure 6).We therefore suggest that (a) the inclusion/exclusion criteria are amended accordingly, and (b) these three categories be combined in one analysis.	Thank you for your comment. The further-line treatment recommendation that cross-refers to psychological treatment options for more severe depression is for people whose depression has had no or a limited response to treatment with antidepressant medication alone. There was no evidence that specifically examined switching to a psychological intervention for those who have not responded to initial antidepressant treatment, however, the committee drew on the evidence for first-line treatments in more severe depression. The committee agreed that the psychological interventions that had been identified as effective and cost-effective for first-line treatment of more severe depression could be used for people who had not responded to antidepressants and wished to try a psychological therapy instead. For the further-line treatment review, studies were sought that included adults with depression showing an inadequate response to at least one previous intervention for the current episode and this included the further-line treatment of psychotic depression, depression with coexisting personality disorder and chronic depression. First-line treatment or relapse

							prevention of chronic depression (including dysthymia), and first-line treatment or relapse prevention of depression with coexisting personality disorder were separate reviews, as the committee did not feel that it was appropriate to combine these populations for first-line treatment or relapse prevention. The committee considered that the grouping together of psychotic depression, depression with coexisting personality disorder and chronic depression for the further-line treatment review should allow the effectiveness of interventions for a more clinically complex population to be considered. The point estimates for short-term psychodynamic psychotherapy + antidepressant are consistent in Table 17 and Figure 10. However, the alignment of labels and bars in the forest plot may have been confusing. The pink line labelled 28 in Figure 10 shows a SMD point estimate of -0.51. The Furukawa et al. (2021) NMA that you cite in your response does not report a list of included studies and it is therefore not possible to speculate as to why a larger effect size was found for combined short-term psychodynamic

							psychotherapy + antidepressant than found for the evidence review for this guideline.

267	SH	Faculty of Public Health	Guideline	General	General	The context in which mental health problems occur and are treated is key. While we welcome the inclusion of treatment options for subclinical and mild depressive symptoms, future guidelines should include a section on prevention to focus on tackling root causes of common mental health problems. Mental wellbeing promotion, including the role of primary care in developing strategies for community resilience, should be included alongside prevention of mental health problems (as per WHO's Mental Health Action Plan 2013–2020: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5810155/)	Thank you for your comment. The committee agree that prevention of mental health problems is an important area but prevention strategies were not included in the scope of this update. However, your suggestion will be passed to the NICE surveillance team who monitor guidelines to ensure they are up to date.
268	SH	Faculty of Public Health	Guideline	General	General	Linked to the above - we welcome the addition of social risk factors, but recognise identification of social risk factors could be further expanded. There is one line on living conditions (and this doesn't include domestic violence). It is important for clinicians to be able to signpost to wider services and support (e.g. via social prescribing) to help address underlying causes and support recovery over the longer term.	Thank you for your comment. Additional considerations have been added into the recommendations on initial assessment, including more factors that might be contributing to depression. A recommendation to consider how other agencies may be able to provide support has also been added.

269	SH	Faculty of Public Health	Guideline	General	General	We welcome widening of treatment options and stronger emphasis on patient choice and experience. However, there is a need for greater recognition of trauma sensitive approaches in treatments.	Thank you for your comment. The guideline did not review evidence for a trauma-informed approach as an intervention or service delivery model, so the committee did not consider it appropriate to make a stand-alone recommendation. The committee were also aware of differing definitions and meanings of trauma-informed care. In response to your comment, a recommendation about initial assessment has been amended to include trauma as a factor to discuss with the person that may have affected the development, course and severity of their depression. This recommendation is also cross-referred to in a choice of treatment recommendation, so trauma should also be considered when making a shared decision about which intervention is right for the individual.
270	SH	Faculty of Public Health	Guideline	General	General	There is a need for research recommendations on efficacy of models of treatment designed to meet the needs of groups who are at higher risk of depression and less likely to be offered treatment choice, including culturally appropriate models etc.	Thank you for your comment. The committee did make a research recommendation on this topic: 'What are the most effective and cost-effective methods to promote increased access to, and uptake of, treatments for people with depression who are under-served and under-represented in current services?' This research recommendation is listed in the guideline and further details are provided in appendix L of evidence review H.

271	SH	Tavistock Relationships	Guideline	General	General	Why was the extremely large IAPT dataset comparing outcomes from different types of therapies, which has been collected for over a decade and is high quality practice-based evidence, not included alongside RCT evidence?	Thank you for your comment. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context (including drawing on their knowledge of the IAPT dataset) so that the 'reality' for people experiencing depression was taken into consideration. In response to stakeholder comments, the committee have re-structured treatment recommendations in order to take into account implementation factors. In January 2020 NICE published a statement of intent signalling the ambition for the future use of wider sources of data and analytic methods (including sources commonly referred to as real-world data and evidence). To make decisions about the relative effectiveness of interventions, RCTs will continue to be prioritised in line with the NICE guidelines manual, in order to ensure that the populations treated with various interventions are equivalent. However it is possible that in the future, high-quality real-world datasets such as the IAPT dataset, could inform questions about access and engagement.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

272	SH	Tavistock Relationships	Guideline	General	General	Why were family interventions for depression not considered such as family therapy for depression based on the McMaster model, (Miller et al., 2005; Ryan et al., 2005); behavioural family therapy for families of depressed mothers of children with disruptive behaviour disorders (Sanders and McFarland, 2000); and various types of individual family and multifamily therapy for older adults with depression (Stahl et al., 2016)?	Thank you for your comment. Studies on family interventions were sought for the reviews on depression with coexisting personality disorder, and psychotic depression. However, no eligible studies were identified. For other review questions, these interventions were not specified in the review protocols as the committee did not consider family interventions to be in regular clinical use for the treatment of depression and consequently the evidence was not reviewed and the committee were not able to recommend family interventions.
273	SH	Tavistock Relationships	Guideline	General	General	The committee made the recommendations on the use of lithium and the use of antipsychotics by informal consensus and based on their knowledge and experience. This seems inconsistent with recommendations made about other interventions including psychological therapies.	Thank you for your comment. The sections of the guideline on antipsychotics and lithium cover the practical aspects of prescribing, monitoring and stopping these medications. More detail on the indications for lithium and antipsychotics are included in the later sections of the guideline on treatment for different types and severity of depression (which is based on evidence reviews). The practical advice contained in this section of the guideline is based on the committee's experience, the BNF, and the NICE guideline on psychosis and schizophrenia, as this sort of practical information would not be identified in an evidence review.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

274	SH	Sussex Partnership NHS Foundation Trust	Guideline	General	General	We are concerned that though occupational therapy is a usual method in practice of assessment, treatment and management for 'Social functioning', 'personal functioning', 'global functioning' and 'functioning', occupational therapy is not suggested as assessment, treatment and management.	Thank you for your comment. The guideline does not specify who should carry out the recommendations in the guideline, as that is a matter for local implementation and may vary. While the committee recognise that occupational therapists may play an important role in working with people with depression, we have not therefore specified that any particular actions should be carried out by an occupational therapist.
275	SH	Sussex Partnership NHS Foundation Trust	Guideline	General	General	We are concerned that the terms 'occupational therapy' and 'occupational therapist' are entirely absent from the guideline.	Thank you for your comment. The guideline does not specify who should carry out the recommendations in the guideline, as that is a matter for local implementation and may vary. While the committee recognise that occupational therapists may play an important role in working with people with depression, we have not therefore specified that any particular actions should be carried out by an occupational therapist.
276	SH	Sussex Partnership NHS Foundation Trust	Guideline	General	General	For the sake of clarity, we recommend the terms 'Social functioning', 'personal functioning', 'global functioning' and 'functioning' are defined in the abbreviations and acronyms guide.	Thank you for your comment. These terms have been rationalised to 'personal and social functioning' and a definition of this has been included in the terms used and in the glossary supplement.

277	SH	Sussex Partnership NHS Foundation Trust	Guideline	General	General	There is concern from a number of practitioners in our trust regarding the severity thresholds used. In some trials it is the case that only severe depression is an exclusion, and hence conflating moderate and severe depression may mean that those with moderate depression are not offered the full range of potentially effective treatments.	Thank you for your comment. The committee considered the distinction between less severe (subthreshold/mild) and more severe (moderate/severe) depression to be clinically meaningful in terms of supporting effective clinical decision making and being aligned with how clinicians conceptualize depression (in particular, GPs and other primary care staff, given that the majority of people with depression and almost all first line presentations of depression are managed in primary care). Based on this distinction, an anchor point of 16 on the PHQ-9 was selected as the cut-off between less severe and more severe depression, on the basis of alignment with the clinical judgement of the committee and eligibility criteria in the included studies. Published standardization of depression measurement crosswalk tables (Carmody 2006; Rush 2003; Uher 2008; Wahl 2014) were used in order to 'read-across' different symptom severity scales that were used in different studies.

278	SH	We Are With You	Guideline	General	General	Improving Access to Psychological Therapies (IAPT) services have been commissioned to provide brief interventions for common mental health difficulties (anxiety and depression) and operate a stepped-care model. Treatments are either low intensity (for presentations that are mild/moderate in severity) or high intensity (for presentations that are moderately severe or severe). IAPT practitioners and therapists are trained to deliver either low intensity or high intensity treatments – the training/qualifications and roles are different for the two types of therapeutic practice. ****The treatment guidance in this guideline refers to 'less severe depression' which includes 'subthreshold symptoms and mild depression' and 'more severe depression' which includes moderate and severe depression. The draft guideline is therefore not well aligned to current IAPT service delivery models and practitioner roles and will be challenging to implement in practice because low intensity practitioners in IAPT work with both 'subthreshold and mild depression – as well as moderate depression but do not provide high intensity treatments which are recommended for moderately severe and severe depression. And IAPT practitioners trained to deliver high intensity therapy (including CBT, IPT, STPP) do not ordinarily treat subthreshold or mild depression.	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The low intensity and high intensity differentiation is provided in the tables of interventions through the description of therapists.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

279	SH	We Are With You	Guideline	General	General	IAPT services, providing much of the psychological therapies treatments for people with depression at a mild, moderate or severe level, are generally not funded to provide therapy at the intensities (number of appointments) that are being recommended in this draft guidance.	Thank you for your comment. The recommended resource use for all interventions was based on relevant information reported in the RCTs that informed the guideline NMA and economic analysis of treatments for a new episode of depression, supplemented by the committee's clinical experience on optimal delivery of interventions within the NHS. This information has now been added in evidence review B, under Appendix N. The frequency and duration of sessions of psychological therapies has now been removed from the recommendations, to allow more flexibility in the delivery of interventions. However, the committee considered it important to include guidance on the usual number of sessions, informed by the resource use in the RCTs included in the review, in order to ensure that interventions are delivered at an intensity that the evidence suggests is effective.

280	SH	The Breastfeeding Network	Guideline	General	general	We note that there is no reference in this draft guideline to pregnancy, the post-natal period or breastfeeding. We are aware that CG192 (Antenatal and post-natal mental health) covers the treatment and management of depression of women who are planning pregnancy, pregnant or have had a baby or been pregnant in the last year. We suggest that a paragraph should be inserted into this guideline noting that this population will need particular support and consideration, particularly in terms of prescribing. We suggest this refers the reader to CG192 for more information, and also highlights the importance of consulting specialist sources of information, in addition to the SPC and BNF, when making prescribing decisions. Prescribers should refer to the UK Teratology Information Service (UKTIS, https://www.medicinesinpregnancy.org/) when discussing prescribing options with women who are pregnant or planning pregnancy, and ensure that they are adequately considering the needs of the woman as well as the safety of the baby, rather than simply erring on the side of caution when prescribing. The latest MBBRACE report released this year (Saving Lives, Improving Mothers' Care, Knight et al 2021, https://www.npeu.ox.ac.uk/mbrrace-uk/reports) gives a number of examples of failure to prescribe, or de-prescribing, medications such as	Thank you for your comment. Women with antenatal or postnatal depression were not included in the scope of this guideline and the committee agreed that prescribing to women who were pregnant or breastfeeding would always need an individualised approach and the level of detail you suggest would not be appropriate to include in this guideline. However, a link to the NICE guideline on antenatal and postnatal mental health has been included in the section of the guideline on the delivery of treatments, to remind healthcare professionals to consider the care of these women separately.

						antidepressants due to pregnancy unnecessarily and at serious detriment to the woman's own health and mortality. It is important that the information on prescribing to breastfeeding parents in particular be included here, as CG192 covers parents only until one year after birth, whilst breastfeeding can continue beyond one year (The world health organisation recommends continuing to two years and beyond). The information in CG192 remains valid for all breastfeeding parents, regardless of the age of the nursling, but as prescribers may not refer to it for breastfeeding mothers who gave birth over a year ago, the information should be included here as well.From contacts to our Drugs in Breastmilk service (DiBM, https://www.breastfeedingnetwork.org.uk/detailed-information/drugs-in-breastmilk), we know that many women are concerned about taking medications such as antidepressants whilst breastfeeding, or have been advised by healthcare professionals that these medications are not compatible with breastfeeding, even when this is not the case. It is essential that the risks and benefits of taking a medication or not, to both the mother and child, are discussed, alongside the risks and benefits of breastfeeding or not, and that an informed choice is made. Research shows that stopping breastfeeding before she wanted to can	

						have significant negative impacts on a mother's mental health (Brown A. (2018). What do women lose when they are prevented from meeting their Breastfeeding Goals? Clinical Lactation, Nov 1;9(4):200-7) and this should be considered.Whilst it will be possible to take many medications whilst breastfeeding, the mother may require reassurance that this is safe, and advice on safety considerations for the baby, for example, not bed-sharing if their medication makes them drowsy or sleep more deeply, and being aware of side effects to be alert for in the baby.The British National Formulary and summary of product characteristics (SPC) for such medications frequently take an excessively conservative stance on prescribing to breastfeeding women. Reference to these alone could result in the woman not receiving necessary treatment, or discontinuing breastfeeding unnecessarily. We would therefore like to see the guideline emphasise the importance of protecting breastfeeding wherever possible whilst also ensuring the mother receives the care that she needs. The guideline should refer prescribers to the NHS Specialist pharmacy service UK Drugs in Lactation Advisory Service (UKDILAS, https://www.sps.nhs.uk/articles/ukdilas/), the Drugs in Lactation database (LactMed, https://www.ncbi.nlm.nih.gov/books/NBK501922/) and the Breastfeeding Network DiBM service for	

						the most accurate information on prescribing to breastfeeding women, to allow fully informed, shared decision making.These recommendations have been discussed within the Safer Medicines in Pregnancy and Breastfeeding Consortium to enable women and professionals to make evidence based decisions. https://www.gov.uk/government/publications/safer-medicines-in-pregnancy-and-breastfeeding-consortiumWe have also commented on the guideline in development on Medicines associated with dependence or withdrawal symptoms: safe prescribing and withdrawal management for adults [GID-NG10141], which we note is referred to in this draft guideline (page 14, lines 28-29, page 18, lines 3-4). We hope that our comments on prescribing to pregnant and breastfeeding women will be incorporated into that final guideline, and if so, suggest that readers also be specifically referred to it for further information when prescribing to women who are planning pregnancy, pregnant or breastfeeding.	

281	SH	The Association of Clinical Psychologists UK	Guideline& Evidence Review B	023 - 031	Table 1Table 2Visual summary 1 & 2	Service-user choice and shared decision-makingThe results of the NMAs and cost analysis for individuals with first episode of depression showed that the treatments included in this synthesis were all found to be clinically effective. Furthermore, the economic models overall show high levels of uncertainty related to the relative effectiveness and cost effectiveness of all the interventions, including a very high degree of uncertainty about estimates of cost. This is expressed in the relatively modest difference in overall quality of life gains, cost per QALY gains, and net monetary benefits between most interventions, and wide 95% credible intervals (CIs)around their mean rankings. In other words, all included interventions have been found to be cost effective. Notwithstanding the methodological concerns pertaining to these analyses, these findings stress the need to offer a menu (non-ranked) of treatment options to be made available.With respect to this, we suggest that the text, the tables within the document and the helpful visual summaries be amended accordingly. Interventions could be displayed in alphabetical order. Given the rising demand for mental health services, particularly in the wake of the wider impacts of the pandemic, and considerable waiting times for treatment in parts of the UK, it has never been more important to ensure that evidence-	Thank you for your comment. Although NMA and economic results were characterised by uncertainty, they did not suggest that all treatments were similarly clinically and cost-effective. For example, in less severe depression, the effect of group CT/CBT class vs TAU (based on an evidence base of N=480) was -1.01 (95%CrI -1.76 to -0.06), whereas the respective effect of counselling (based on a narrower evidence base of N=55) was -0.20 (95%CrI -2.82 to 2.50), i.e. one fifth of the effect of group CT/CBT class, although both treatments were recommended – see bias-adjusted results in Table 9, evidence report B. Similarly, in more severe depression, the effect of individual CT/CBT + AD class vs placebo (based on an evidence base of N=192) was -1.18 (95%CrI -2.07 to -0.44), whereas the respective effect of IPT (based on an evidence base of N=145) was -0.45 (95%CrI -1.36 to 0.47), i.e. almost a third of the effect of individual CT/CBT + AD class – see bias-adjusted results in Table 24, evidence report B. Regarding clinical effectiveness derived from the NMAs, the committee considered not only the mean effects of treatment classes vs the reference treatment, but the uncertainty around them (as expressed in 95%CrI), the volume of the evidence base for each treatment, and the evidence of effect or the lack of it (as shown by

						based support is available to whoever needs it. This guideline has a direct, real-world impact on centralised NHS workforce planning, as well as localised decision making by commissioners. Given NICE's assessment that all the listed treatments are clinically and cost-effective, removing the hierarchical ranking of treatments is a simple way to enable capacity-building in the NHS mental health workforce, which is required to meet rising demand, as well as offering commissioners' greater flexibility in assessing both the needs of a local population and the immediate local workforce capacity. This would not preclude the Guideline from commenting on the relative strength of evidence for different treatments.As pointed out above, we strongly welcome the stronger focus on individualised care and the emphasis on the importance of service user choice and shared decision-making throughout this third iteration of the treatment guideline. This could be a hugely positive step forward in patient care. We welcome the recognition in the guideline that any additional resource invested in longer consultations with service users to have a meaningful discussion around treatment options will be repaid through greater adherence and better outcomes. However, we remain concerned that through not addressing some of our key methodological concerns, this guideline will still be falling short of achieving that	95%CrI crossing or not the no effect line) of the classes but also of individual interventions within each class, versus the reference treatment. They also considered the results of pairwise meta-analysis. Regarding cost-effectiveness, highly ranked interventions in the guideline economic analysis were more cost-effective than interventions lower in ranking, although there was uncertainty in the results and differences might be small in some cases (especially for interventions in close ranking places). Some interventions were found to be less cost-effective than GP care (reference treatment) in less or more severe depression (or both). For example, counselling was found to be less cost-effective than GP care in less severe depression, IPT was found to be less cost-effective than GP care in more severe depression, and short-term psychodynamic psychotherapy was found to be less cost-effective than GP care in both less and more severe depression. Interventions are arranged in Tables 1 and 2 in the guideline in the suggested order in which options should be considered, based on the committee's interpretation of their clinical and cost effectiveness, and consideration of other issues such as side effects (antidepressants), applicability of the evidence (e.g. individual

						goal in practice. As pointed out by utilising very stringent inclusion criteria, many studies that have shown to provide an evidence base for many interventions were not considered. We notice, for example, the omission and therefore non-recommendation of the creative therapies, which many service users may benefit from (e.g. Nan & Ho, 2017; Albornoz, Y., 2011), and may want to choose. We also notice the absence of longer-term psychological treatments. Research and clinical practice have shown that many individuals with chronic or complex forms of depression have tried the available and recommended first or second-line short-term treatments without success (e.g. Leichsenring & Rabung 2011; Maj et al. 2020). In complex mental disorders, longer-term psychotherapy proved to be superior to short-term psychotherapy (Leichsenring & Rabung, 2011, Leichsenring et al., 2013). However, in the guideline the recommendation for those classified as having treatment-resistant depression, chronic depression, and depression with PD defaults back to first or further-line treatment recommendation - i.e. once again to a short-term treatment, instead of recommending a longer-term treatment. This is particularly perplexing as there is evidence of the effectiveness of longer-term treatments, both for long-term CBT (e.g. Leuzinger-Bohleber et al., 2019) and long-term psychodynamic	problem solving), structure of IAPT services. However, this is not a rigid hierarchy, all treatments included in Tables 1 and 2 can be used as first-line treatments, and it may be appropriate to recommend an intervention from lower down in the table where this best matches the person's preferences and clinical needs. The committee were aware of the need to provide a wide range of interventions to take into account individual needs and allow patient choice. Listing interventions in alphabetical order would not reflect the evidence base nor serve as a guide to choice for those who do not have pre-existing preferences. Considering cost-effectiveness issues when making recommendations ensures most efficient use of NHS resources and maximum health gains for the whole population. Prioritisation of treatments according to cost-effectiveness benefits not only the patient receiving the selected treatment but other patients whose needs must be covered by existing NHS resources. Nevertheless, the guideline also recommends shared decision on treatment choice, based on patients' clinical needs and preferences. It is reassuring that you acknowledge and agree with the stronger focus of the guideline on individualised care and the

						psychotherapy (e.g. Fonagy et al., 2015; Leuzinger-Bohleber et al., 2019; Knekt et al., 2008/2013/ 2016) for individuals diagnosed with treatment-resistant/chronic depression.Although the Leuzinger-Bohlehber et al (2019) study was excluded from the chronic depression review as >20% had previous treatments, it should have been included under the further-line treatment review. We also cannot find any reason as to why the Knekt study (2008, 2013, 2016) was also not included there. Although the Fonagy et al., 2015 study was included, their important findings that both depression severity and functioning improved over the long-term have been ignored. All three studies not only provide important evidence of the effectiveness of long-term treatment, but moreover that the effects sustained over a 2–3-year follow-up. Given the scarcity of studies on longer-term psychological treatments, the omission of those is futile.As a consequence, all recommended treatment options are brief interventions (with an average of 8 sessions). As pointed out above, given that these have already been shown to be non-beneficial for many individuals who experience more persistent and complex depression, we are not only concerned that this guideline may exacerbate the existing revolving-door problem, but would also deny people the choice of longer-term treatments.	emphasis on the importance of service user choice and shared decision making. Albornoz 2011 is included in the network meta-analysis for the treatment of a new episode of more severe depression. However, this was the only included study for music therapy, and the committee considered the evidence too limited to make a recommendation. Nan 2017 is included in the further-line treatment review. However, this was the only included study for art therapy, and the committee considered the evidence too limited to make a recommendation. There was only single-study evidence (Fonagy et al. 2015) for augmenting antidepressant treatment with long-term psychodynamic psychotherapy, and the committee considered the evidence too limited to make a recommendation for long-term psychodynamic psychotherapy specifically. However, a treatment option in the recommendation for people whose depression has had no or a limited response to treatment with antidepressant medication alone, includes changing to a combination of psychological therapy and medication, which could include long-term

							psychodynamic psychotherapy although it is not listed as an example due to the limited evidence. The further-line treatment recommendation that cross-refers to psychological treatment options for more severe depression is for people whose depression has had no or a limited response to treatment with antidepressant medication alone. There was no evidence that specifically examined switching to a psychological intervention for those who have not responded to initial antidepressant treatment, however, the committee drew on the evidence for first-line treatments in more severe depression. The committee agreed that the psychological interventions that had been identified as effective and cost-effective for first-line treatment of more severe depression could be used for people who had not responded to antidepressants and wished to try a psychological therapy instead. Leuzinger-Bohleber et al 2019 was considered for the chronic depression review and was excluded. This study also did not meet eligibility criteria for the further-line treatment review as the inclusion criteria of the study was not limited to those receiving further-line treatment, participants were not randomised at the point of

							non-response, and it could not be regarded as an augmentation study following limited or no response to antidepressants as only 36% of participants were taking antidepressants at baseline. This study has now been added to the excluded studies list in supplement D. Knekt et al 2008/2013/2016 was considered under first-line treatment as detailed in your comment, and did not meet criteria. It also did not meet criteria for the further-line treatment review as the inclusion criteria of the study was not limited to those receiving further-line treatment (in fact those receiving psychotherapy within the previous 2 years were excluded), participants were not randomised at the point of non-response, and it could not be regarded as an augmentation study following limited or no response to antidepressants as only 22% of participants were receiving psychotropic medication at baseline. This study has now been added to the excluded studies list in supplement D.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

282	SH	International Society of Interpersonal Psychotherapy	Guideline	066-084	General	Section E of the proposed draft appropriately lists five IPT RCTS: Agosti and Ocepek-Welikson (1997); de Mello et al. (2001), Browne et al. (2002), Markowitz et al. (2005), and Markowitz et al. (2008).Excepting Browne et al., all evaluated fairly small samples and are thus underpowered to find differences between active therapies. Nonetheless, in neither of the two head-to-head comparisons does IPT look inferior to CBT. Of the relevant IPT studies, the Agosti study is the one least designed to find differences among treatments for chronic depression. It's small and underpowered, based on a subsample from a larger trial of patients presenting with acute depression. Yet Section E (page 66) lists only one of the IPT RCTs: Agosti. The four IPT trials actually focused on chronic depression have disappeared. So have the IPT comparisons with medication (Agosti, de Mello, Brown, Markowitz 2005). With the evidence thus excluded, IPT goes unmentioned, entirely absent from the discussion weighing the findings that begins on page 84. The psychiatric consensus is that chronic depression is harder to treat than acute major depression and that the combination of pharmacotherapy and evidence-based psychotherapy is usually the optimal approach, particularly if monotherapy has failed. There is little evidence that any one evidence-based	Thank you for your comment. For the chronic depression review (first-line treatment or relapse prevention), the studies that you cite are included in the analyses in different comparisons, so Agosti 1997 is included in the comparisons of CBT versus pill placebo, CBT versus antidepressants, CBT versus IPT, IPT versus pill placebo, and IPT versus antidepressants. de Mello 2001 is included in the comparison of IPT + antidepressant versus antidepressant-only. Browne 2002 is included in the comparisons of IPT versus antidepressants, and IPT + antidepressant versus antidepressant-only. Markowitz 2005 is included in the comparisons of IPT versus antidepressants, IPT versus counselling, IPT + antidepressant versus antidepressant-only, and counselling versus antidepressants. Markowitz 2008 is included in the comparison of IPT versus counselling. For the chronic depression review, for IPT versus pill placebo, there was only single-study evidence suggesting no significant difference. For IPT versus antidepressants, there was data from 3 studies for the depression symptoms outcome showing a statistically significant effect in favour of antidepressants. For IPT versus counselling, data from 2 studies for the depression symptoms outcome shows no

						psychotherapy works better than another. Your draft document does not recognize this.	significant differences. For the CBT versus IPT comparison, there is only small single-study evidence showing no significant difference. For the comparison of IPT + antidepressants versus antidepressants-only, data from 3 studies for the depression symptoms outcome shows no significant differences. Based on this limited and equivocal evidence, and bearing in mind that none of these studies was sufficiently powered for non-inferiority trials, the committee did not consider it appropriate to recommend IPT for the first-line treatment of chronic depression. For the first-line treatment review, studies were excluded if data (including baseline severity data) could not be extracted in an analysable form. Given the size of the evidence base it was not possible to contact all authors for missing data. The exclusion of studies from the first-line treatment review due to less than 80% of participants having non-chronic depression was a stipulation of the review protocol in order to create a homogenous data set. The guideline review questions focus on specific populations, and there is a separate review question for chronic depression (first-line treatment and relapse prevention) and a further-line treatment review question (that includes those with chronic depression).

							The committee were aware of the Cuijpers et al. (2021) NMA paper that you cite. The committee considered that this study also supported their recommendations made based on their systematic review of the evidence, that all psychological treatments will provide some benefit, so offering a wide choice of treatments is appropriate, but that counselling may not provide the same level of treatment response. Based on their overall review of the clinical evidence the committee agreed that some treatment classes and interventions appeared to be more effective than others, but there was otherwise little to choose between treatments. The committee therefore reviewed the results of the health economic modelling which determined which treatments were cost-effective, and used this to develop a suggested prioritisation of which treatments should be offered to people with depression, or considered for use. In response to stakeholder comments some changes have been made to the tables guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. Interventions are arranged in the tables in the suggested order in which options should

							be considered, based on the committee's interpretation of their clinical and cost effectiveness and consideration of implementation factors. However, this is not a rigid hierarchy, all treatments included in Tables 1 and 2 can be used as first-line treatments, and it may be appropriate to recommend an intervention from lower down in the table where this best matches the person's preferences and clinical needs. The committee were aware of the need to provide a wide range of interventions to take into account individual needs and allow patient choice.

283	SH	British Beauty Council	Guideline	023-030	General	p.23-30 of the draft guidance outlines "Table 1: Treatment options for less severe depression listed in order of recommended use, based on the committee's interpretation of their clinical and cost effectiveness." It is disappointing that such a limited number of physical treatments, and more specifically no massage, aromatherapy, reflexology or touch therapy options, are included in this section. Touch therapy refers to a type of therapeutic treatment in which the therapist physically touches the subject in a specific way and plays an important role within the services offered in the personal care sector. There is an increasing understanding that social touch plays a powerful role in human life, with important physical and mental health benefits in development and adulthood[4].The understanding of the link between mental health with physical and biochemical changes within the body has also developed in recent years. Levels of four key chemicals within the body have been shown to change significantly with physical/social touch:Oxytocin, a key hormone, is released by touch. Many of the positive effects caused during interaction, such a wellbeing, stress reduction and even health promotion, are linked to oxytocin released in response to activation of various types of sensory nerves[5].Cortisol levels can also be significantly reduced through a simple hug or	Thank you for your comment. The committee did not consider massage, aromatherapy, reflexology or touch therapy to be interventions that were in regular clinical use for the treatment of depression. Therefore these interventions were not specified in any of the review protocols and consequently the studies that you cite would not have met the inclusion criteria for the reviews. As such the evidence on massage, aromatherapy, reflexology and touch therapy has not been appraised and the committee were not able to make any recommendations on their use.

						massage[6]. High levels of cortisol are linked to type 2 diabetes, obesity, cholesterol and blood pressure and heart disease[7].Conversely, the reduction in cortisol from touch has been shown to lower blood pressure and heart rate.Serotonin and dopamine levels, key hormones associated with mental health and pain relief, are also stimulated by touch[8][9]. Research on increasing serotonin levels without drug intervention to address depression and other mental health symptoms has also proved successful[10].Recent research repeated by the BBC working with Prof Fulvio D'Acquisto, an immunologist from the University of Roehampton and the Bodyology Massage School, demonstrated a 70% boost in white blood cell count from massage[11].Massage Therapy (MT) is a service offered by a significant section of the Personal Care sector. It is broadly defined as the manual manipulation of muscles and certain other soft tissues in the body, including connective tissue, ligaments, and tendons, with the purpose of improving a person's health and wellbeing. MT can be a part of physical therapy or practiced on its own[12].The history of massage therapy dates back to approximately 3000 BCE in India, where it was considered a sacred system of natural healing. "Life health" medicine, massage therapy was a practice passed down through generations to heal injuries, relieve pain, and prevent and cure	

						illnesses. In the early 1800s, Swedish doctor and gymnast, Per Henrik Ling created a massage method to help relieve chronic pain. Since then, the health service has focused more on drug (chemical) therapy for the management of pain and other ailments. It has only been since 1970's that massage moved out of the medical realm into being seen as part of a healthy lifestyle in the UK and US[13]. MT is now considered an alternative or complementary therapy rather than a medical discipline although it is still taught in physiotherapy courses.Mental illness has been a growing health crisis for some time. Mental ill-health is the single largest cause of disability in the UK, contributing up to 22.8% of the total burden, compared to 15.9% for cancer and 16.2% for cardiovascular disease. The wider economic costs of mental illness in England have been estimated at £105.2 billion per annum[14]. Mental Health problems have increased by 8% during the pandemic[15]. It has been estimated that optimal treatment for mental disorders will only avert 28% of the burden of mental illness[16]. There is now significant global evidence that touch therapy, including massage, aromatherapy, reflexology can have a significant effect on reducing mental health problems. Whilst massage therapy (MT) has been seen as an important part of healthcare in mainland Europe and Asia, it has been less well supported in the UK.	

						The National Institute for Health and Care Excellence reference a number of uses for MT including: back, neck and shoulder pain[17], osteoarthritis[18], cancer symptoms and treatment side effects, fibromyalgia, HIV/AIDs, premature infant care. As research has developed globally, the benefits of MT, aromatherapy and reflexology to mental health have become clearer. With the advent of improved technologies such as Magnetic Resonance Imaging (MRI), Electroencephalography (EEG) and chemical analysis, it has been possible to demonstrate not only the medical benefits of MT but the emotional and mental benefits[19]. This includes stimulation of the vagus nerve including the parasympathetic system[20]. A randomised controlled trial in Australia carried out by Most & Wallis, demonstrated the effectiveness of a 15-minute weekly massage in reducing physical and psychological stress in nurses[21]. Research by Moyer et al[22], supported by the National Institute for Health Research (NIHR), cites that a course of massage therapy treatment provides similar benefits in magnitude to those of psychotherapy, with MT's greatest efforts being in reducing trait anxiety and depression. Further work by Moyer claimed cortisol levels were not significantly reduced by MT and as such, it cannot be the cause of MT's well-established and statistically larger beneficial effects on anxiety,	

						depression, and pain. They conclude that other causal mechanisms, which are still to be identified, must be responsible for MT's clinical benefits[23]. History of Aromatherapy - Gattefossé coined the term aromatherapy in 1928 within an article where he supports the use of using essential oils in their whole without breaking them down into their primary constituents. Aromatherapy is highly respected early 20th century aromatherapists include Jean Valnet, Madam Marguerite Maury, and Robert B. Tisserand. Jean Valnet is most remembered for his work using essential oils to treat injured soldiers during the war and for his book, The Practice of Aromatherapy, originally entitled Aromathérapie in French. Austrian Madam Marguerite Maury is remembered as a biochemist who avidly studied, practiced and taught the use of aromatherapy for primarily cosmetic benefit. Robert B. Tisserand is an English aromatherapist who is responsible for being one of the first individuals to bring knowledge and education of aromatherapy to English speaking nations. He has written books and articles including the highly respected 1977 publication The Art of Aromatherapy. The Art of Aromatherapy was the first aromatherapy book published in English. From the late 20th century and on into the 21st century, there is a growing resurgence to utilize more natural products including essential oils for	

						therapeutic, and aromatic benefits.Research into Aromatherapy shows its effectiveness for depression, stress etc. The Effectiveness of Aromatherapy for Depressive Symptoms: A Systematic Review (nih.gov)****Effectiveness of Aromatherapy for Depression and Stress (nursinganswers.net)****History of reflexology in more modern form of reflexology was first pioneered by an ear, nose and throat surgeon by the name of Dr William Fitzgerald (1872-1942). Dr Fitzgerald was the founder of Zone Therapy, which was an earlier form of reflexology. He discovered that exerting pressure on the tips of the toes or fingers caused corresponding parts of the body to become anaesthetised. From this, Dr Fitzgerald divided the body into ten equal zones, which ran from the top of the head to the ends of the toes. By using tight elastic bands on the middle sections of the fingers or using small clamps on the tips of the fingers, minor surgery could be carried out with no further anaesthetic agents required.********However, reflexology as we know it today was pioneered by a woman called Eunice Ingham (1889 - 1974), or the mother of modern reflexology. Eunice Ingham was a physiotherapist working in a doctor's practise using the zone therapy developed by Dr Fitzgerald. Ms Ingham thought, however, that it would be more effective to be practised on the feet rather than	

						the hands. After extensive research, she developed the map of the entire body on the feet - where one point on the foot corresponds to a certain part of the body. By using acupressure or massage techniques on these points, a positive effect is created in the corresponding body part.********Eunice Ingham spent 30 years travelling around America teaching her reflexology first to medical staff, and then to non-medical practitioners. Modern Western reflexology uses the charts and theories developed by her and now called the Ingham Method. Ingham's work is carried on by the International Institute of Reflexology.Research into Reflexology shows its effectiveness for depression, anxiety etc. Effect of Foot Reflexology Intervention on Depression, Anxiety, and Sleep Quality in Adults: A Meta-Analysis and Metaregression of Randomized Controlled Trials - PubMed (nih.gov)The effects of foot reflexology on depression during menopause: A randomized controlled clinical trial - PubMedDespite the global evidence, NICE is yet to be satisfied that massage therapy, aromatherapy and reflexology can be used to address mental health issues. They have cited that their position is formed on the basis of further, more robust research being needed rather than because existing research has not shown evidence. We have therefore proposed the expansion of the	

						recommendations for Research outlined from p.60 to include these treatment options.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

284	SH	NHS Sheffield CCG	Guideline	023-030	General	The table on page 23 – 30 is useful, however lengthy. Are there plans to create a patient/clinician friendly format to support shared decision-making conversations?	Thank you for your comment. There is a visual summary of these tables that has been created to accompany the guideline.

285	SH	UK Spa Association	Guideline	023-030	General	p.23-30 of the draft guidance outlines "Table 1: Treatment options for less severe depression listed in order of recommended use, based on the committee's interpretation of their clinical and cost effectiveness." It is disappointing that such a limited number of physical treatments, and more specifically no massage, aromatherapy, reflexology or touch therapy options, are included in this section. Touch therapy refers to a type of therapeutic treatment in which the therapist physically touches the subject in a specific way and plays an important role within the services offered in the personal care sector. There is an increasing understanding that social touch plays a powerful role in human life, with important physical and mental health benefits in development and adulthood[24].The understanding of the link between mental health with physical and biochemical changes within the body has also developed in recent years. Levels of four key chemicals within the body have been shown to change significantly with physical/social touch:Oxytocin, a key hormone, is released by touch. Many of the positive effects caused during interaction, such a wellbeing, stress reduction and even health promotion, are linked to oxytocin released in response to activation of various types of sensory nerves[25].Cortisol levels can also be significantly reduced through a simple hug or	Thank you for your comment. The committee did not consider massage, aromatherapy, reflexology or touch therapy to be interventions that were in regular clinical use for the treatment of depression. Therefore these interventions were not specified in any of the review protocols and consequently the studies that you cite would not have met the inclusion criteria for the reviews. As such the evidence on massage, aromatherapy, reflexology and touch therapy has not been appraised and the committee were not able to make any recommendations on their use.

						massage[26]. High levels of cortisol are linked to type 2 diabetes, obesity, cholesterol and blood pressure and heart disease[27].Conversely, the reduction in cortisol from touch has been shown to lower blood pressure and heart rate.Serotonin and dopamine levels, key hormones associated with mental health and pain relief, are also stimulated by touch[28][29]. Research on increasing serotonin levels without drug intervention to address depression and other mental health symptoms has also proved successful[30].Recent research repeated by the BBC working with Prof Fulvio D'Acquisto, an immunologist from the University of Roehampton and the Bodyology Massage School, demonstrated a 70% boost in white blood cell count from massage[31].Massage Therapy (MT) is a service offered by a significant section of the Personal Care sector. It is broadly defined as the manual manipulation of muscles and certain other soft tissues in the body, including connective tissue, ligaments, and tendons, with the purpose of improving a person's health and wellbeing. MT can be a part of physical therapy or practiced on its own[32].The history of massage therapy dates back to approximately 3000 BCE in India, where it was considered a sacred system of natural healing. "Life health" medicine, massage therapy was a practice passed down through generations to heal injuries, relieve pain, and prevent and cure	

						illnesses. In the early 1800s, Swedish doctor and gymnast, Per Henrik Ling created a massage method to help relieve chronic pain. Since then, the health service has focused more on drug (chemical) therapy for the management of pain and other ailments. It has only been since 1970's that massage moved out of the medical realm into being seen as part of a healthy lifestyle in the UK and US[33]. MT is now considered an alternative or complementary therapy rather than a medical discipline although it is still taught in physiotherapy courses.Mental illness has been a growing health crisis for some time. Mental ill-health is the single largest cause of disability in the UK, contributing up to 22.8% of the total burden, compared to 15.9% for cancer and 16.2% for cardiovascular disease. The wider economic costs of mental illness in England have been estimated at £105.2 billion per annum[34]. Mental Health problems have increased by 8% during the pandemic[35]. It has been estimated that optimal treatment for mental disorders will only avert 28% of the burden of mental illness[36]. There is now significant global evidence that touch therapy, including massage, aromatherapy, reflexology can have a significant effect on reducing mental health problems. Whilst massage therapy (MT) has been seen as an important part of healthcare in mainland Europe and Asia, it has been less well supported in the UK.	

						The National Institute for Health and Care Excellence reference a number of uses for MT including: back, neck and shoulder pain[37], osteoarthritis[38], cancer symptoms and treatment side effects, fibromyalgia, HIV/AIDs, premature infant care. As research has developed globally, the benefits of MT, aromatherapy and reflexology to mental health have become clearer. With the advent of improved technologies such as Magnetic Resonance Imaging (MRI), Electroencephalography (EEG) and chemical analysis, it has been possible to demonstrate not only the medical benefits of MT but the emotional and mental benefits[39]. This includes stimulation of the vagus nerve including the parasympathetic system[40]. A randomised controlled trial in Australia carried out by Most & Wallis, demonstrated the effectiveness of a 15-minute weekly massage in reducing physical and psychological stress in nurses[41]. Research by Moyer et al[42], supported by the National Institute for Health Research (NIHR), cites that a course of massage therapy treatment provides similar benefits in magnitude to those of psychotherapy, with MT's greatest efforts being in reducing trait anxiety and depression. Further work by Moyer claimed cortisol levels were not significantly reduced by MT and as such, it cannot be the cause of MT's well-established and statistically larger beneficial effects on anxiety,	

						depression, and pain. They conclude that other causal mechanisms, which are still to be identified, must be responsible for MT's clinical benefits[43]. From the late 20th century and on into the 21st century, there is a growing resurgence to utilise more natural products including essential oils for therapeutic, and aromatic benefits. Aromatherapy forms a key part of this. A 2018 study 'Effectiveness of Aromatherapy for Depression and Stress' looked specifically at nursing students. The research found that aromatherapy was able to reduce level of depression, anxiety and stress during clinical practice[44].Reflexology as it is understood today, was pioneered by physiotherapist Eunice Ingham. Modern Western reflexology is carried on by the International Institute of Reflexology using the theories developed by Ingham, now called the 'Ingham Method'.2020 research into reflexology by Wei-Li Wang et al. highlighted that foot reflexology may provide additional nonpharmacotherapy intervention for adults suffering from depression, anxiety, or sleep disturbance, recommending further research and greater study samples[45]. A similar picture is drawn from the 2019 study by Elsevier Ltd. whose findings indicated that reflexology can be effective for reducing women's depression during menopause[46] but also recommending larger control groups.Despite the	

						global evidence, NICE is yet to be satisfied that massage therapy, aromatherapy and reflexology can be used to address mental health issues. They have cited that their position is formed on the basis of further, more robust research being needed rather than because existing research has not shown evidence. We have therefore proposed the expansion of the recommendations for Research outlined from p.60 to include these treatment options.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

286	SH	British Psychological Society	Guideline	023 - 030	Table 1	Table 1 Behavioural couples therapy should be included in this table and the visual summary. This intervention is in the guidelines but it appears the decision to leave it out was in part based on an incorrect assumption that it is more or only appropriate for a subgroup of people with depression. Studies were excluded from the research evaluation on this basis. If it is excluded from the tables and visual summaries, is very unlikely to be considered as an option. Options such as counselling and STPP were included as the committee recognised that these treatments, although with less evidence of effectiveness, may be helpful for some people. This argument also applies to behavioural couples therapy. The committee agreed this treatment was available through the Improving Access to Psychological Therapy (IAPT) services and should be included as an option in the guideline but if listed in isolation and not in the table and visual summary there is a real risk it will be overlooked by commissioners and providers. The NHS constitution (Department of Health, 2015) pledges that services should work in partnership with clients, their families and carers. The WHO's (2013) Mental Health Action Plan calls for greater collaboration with families. Despite this, behavioural couples therapy is the only family-inclusive therapy option listed. This type of therapy can be of particular value to some	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA). The committee did not consider it appropriate to include behavioural couples therapy in the tables of treatment options in the guideline as the evidence and recommendation for behavioural couples therapy was for a subgroup of people with depression, unlike the other interventions listed in these tables. There is a recommendation in the access section of the guideline for commissioners and providers of mental health services to ensure that pathways have a number of components in place in order to promote access and increased uptake of services and these include: services delivered in culturally appropriate or culturally adapted language and formats; and procedures to support active involvement of families, partners, and carers.

						minority ethnic and cultural groups who may find it harder to engage with services and do not all share individualistic and/or Western values. Couple therapy by definition involves the partner of the person with depression. Carers often feel ignored by healthcare professionals in decisions about their loved ones and want to be involved in discussions about treatment options (Healthwatch, 2020 What people want from the next ten of the NHS Newcastle: author). Couples therapy for depression should be more widely available to depressed people to help reduce the burden on partners and potentially prevent relationship breakdown (Priestley, J and McPherson, SJ and Davies, F (2018) Couples Disease: The Experience of Living with a Partner with Chronic Depression. Journal of Couple and Relationship Therapy, 17 (2). 128 - 145. ISSN 1533-2683).If couples therapy is not included in the tables and visual summaries, it will be less likely to be considered as an option. This could mean that people with depression, people from black, Asian and minority ethnic communities, and carers, will be particularly negatively impacted. It is very important that the choice of couples therapy alongside individual and group interventions is made more widely available within NHS services. We also suggest that this table should include arts therapies, arts on prescription and compassion-focused therapy and yoga given	There are also recommendations in the choice of treatment section of the guideline that people with depression should be given the option to include family members or carers in the discussion of treatment options, and to attend (some or all of) treatment with a family member or friend. Art therapy was listed as an intervention of interest for the treatment reviews. However, no eligible evidence was identified for art therapy as a first-line treatment. The committee considered the evidence too limited to make a recommendation for art therapy . As outlined in the review protocols, yoga was included as an intervention for all treatment reviews, with studies sought by the searches, and eligible evidence included in the reviews. However, the committee considered this evidence too limited to make a recommendation for yoga. Blomdahl 2018 was identified by the searches but is not included as baseline severity could not be categorised (outcome measure outside protocol MADRS-self-report).This study is listed under excluded studies in Supplement B1.

						the existence of evidence, listed below: Blomdahl et al. (2018). A manual-based phenomenological art therapy for individuals diagnosed with moderate to severe depression (PATd): A randomized controlled study. Psychiatric Rehabilittion Journal, 41(3), 169-182; Choi et al. (2020). The effects of combining art psychotherapy with pharmacotherapy in treating major depressive disorder: Randomized control study. The Arts in Psychotherapy, 70, ArtID 101689; Ciasca et al. (2018). Art therapy as an adjuvant treatment for depression in elderly women: A randomized controlled trial. Brazilian Journal of Psychiatry, 40(3), 256-263; Nan & Ho (2017). Effects of clay art therapy on adults outpatients with major depressive disorder: A randomized controlled trial. Journal of Affective Disorders, 217, 237-245; Thyme et al. (2007). The outcome of short-term psychodynamic art therapy compared to short-term psychodynamic verbal therapy for depressed women. Psychoanalytic Psychotherapy, 21(3), 250-264. Arts on prescription: All Party Parliamentary Group on Arts, Health and Wellbeing (2017) Creative health: The arts for health and wellbeing, https://www.culturehealthandwellbeing.org.uk/appg-inquiry/Publications/Creative_Health_Inquiry_Report_2017_-_Second_Edition.pdf Compassion	Ciasca 2018 was identified by the searches but is not included as the outcome measure is outside protocol (GDS-15). This study is listed under excluded studies in Supplement D. Choi et al. (2020) was not identified by the searches. However, in response to your comment the study has been assessed for eligibility for the further-line treatment review (as all participants receiving pharmacological treatment). However, it does not meet inclusion criteria as participants were not randomised at the point of non-response. This study has now been added to the excluded studies list of Supplement D. Nan 2017 is included in the further-line treatment review. However, this was the only included study for art therapy, and the committee considered the evidence too limited to make a recommendation. Thyme 2007 was identified by the searches but is not included in the first-line treatment review as less than 80% of partipants had non-chronic depression (64% diagnosed with dysthymic disorder). This study is listed under excluded studies in Supplement B1.

						focused therapy: Craig, C. (2020) Compassion focused therapy: a systematic review of its effectiveness and acceptability in clinical populations. Expert Review of Neurotherapeutics, 20(4) ISSN: 1473-7175 Online ISSN: 1744-8360 Prathikanti S, Rivera R, Cochran A, Tungol JG, Fayazmanesh N & Weinmann E (2017). Treating major depression with yoga: A prospective, randomized, controlled pilot trial. PLOS ONE, March 16, https://doi.org/10.1371/journal.pone.0173869Other relevant evidence-based treatments that psychologists commonly use or draw from in the NHS (but aren't listed in the current guidelines) which should be considered for inclusion for depression:Acceptance and Commitment Therapy (ACT)Hayes, S. C. (2004).Behavior Therapy, 35, 639-665.Hayes, S. C. (2004). Acceptance and Commitment Therapy and the new behavior therapies: Mindfulness, acceptance and relationship. In S. C. Hayes, V. M. Follette, & M. Linehan (Eds.), Mindfulness and acceptance: Expanding the cognitive behavioral tradition (pp. 1-29). New York: Guilford.Hayes, S. C. (2000). Acceptance and Commitment Therapy in the treatment of experiential avoidance disorders.Hayes, S. C., Luoma, J., Bond, F., Masuda, A., & Lillis, J. (2006). Acceptance and Commitment Therapy: Model, processes, and	The Arts on prescription: All Party Parliamentary Group on Arts, Health and Wellbeing (2017) citation was not considered by the committee as it does not meet study design eligibility criteria. The committee did not consider compassion focused therapy or motivational interviewing to be interventions that are in regular clinical use for the treatment of depression. Therefore these interventions were not specified in any of the review protocols and consequently the studies that you cite would not have met the inclusion criteria for the reviews. As such the evidence on compassion focused therapy and motivational interviewing has not been appraised and the committee were not able to make any recommendations on their use. Prathikanti 2017 is included in the NMA for the first-line treatment of less severe depression. However, the committee considered the evidence too limited to make a recommendation for yoga. Acceptance and commitment therapy (ACT) is included under the cognitive and cognitive behavioural therapies class as a third-wave cognitive therapy. However, Hayes 2004 is not included in the first-line treatment review as

						outcomes. Behaviour Research and Therapy, 44(1), 1-25Motivational Interviewing Miller, W.R. & T.B. Moyers (2017) Motivational Interviewing and the clinical science of Carl Rogers. Journal of Consulting and Clinical Psychology, 85(8), 757-766Miller, W.R. & Rollnick, S. (2013) Motivational Interviewing: Helping people to change (3rd Edition). Guilford Press.	more than 20% of participants have a coexisting personality disorder (52% had an Axis II disorder). This study is listed in the excluded studies list of Supplement B1. The other Hayes references cited in your comment do not meet study design eligibility criteria and were not considered for inclusion.

287	SH	British Beauty Council	Guideline	031-037	General	p.31-37 of the draft guidance outlines “Table 2: Treatment options for more severe depression listed in order of recommended use, based on the committee’s interpretation of their clinical and cost effectiveness.”Again, no massage, aromatherapy, reflexology or other touch therapy options are included in this section. Please refer to the comments made in ‘Comment 1'.	Thank you for your comment. The committee did not consider massage, aromatherapy, reflexology or touch therapy to be interventions that were in regular clinical use for the treatment of depression. Therefore these interventions were not specified in any of the review protocols and consequently the evidence on massage, aromatherapy, reflexology and touch therapy has not been appraised and the committee were not able to make any recommendations on their use.
288	SH	NHS Sheffield CCG	Guideline	031-037	General	As above	Thank you for your comment. The committee did not consider massage, aromatherapy, reflexology or touch therapy to be interventions that were in regular clinical use for the treatment of depression. Therefore these interventions were not specified in any of the review protocols and consequently the evidence on massage, aromatherapy, reflexology and touch therapy has not been appraised and the committee were not able to make any recommendations on their use.

289	SH	UK Spa Association	Guideline	031-037	General	p.31-37 of the draft guidance outlines “Table 2: Treatment options for more severe depression listed in order of recommended use, based on the committee’s interpretation of their clinical and cost effectiveness.”Again, no massage, aromatherapy, reflexology or other touch therapy options are included in this section. Please refer to the comments made in ‘Comment 1'.	Thank you for your comment. The committee did not consider massage, aromatherapy, reflexology or touch therapy to be interventions that were in regular clinical use for the treatment of depression. Therefore these interventions were not specified in any of the review protocols and consequently the evidence on massage, aromatherapy, reflexology and touch therapy has not been appraised and the committee were not able to make any recommendations on their use.

290	SH	International Society of Interpersonal Psychotherapy	Guideline	031-037	General	Inasmuch as IPT is so well tested, tolerated, and has such clear effectiveness, it is bizarre to find in the main document of NICE recommendations that IPT is listed near the bottom of the list in the key Tables 1 and Table 2. Their order depends upon "the committee's interpretation of their clinical and cost effectiveness" (page 23). IPT is equipotent or more so than other listed interventions such as "self-help," and far better proven. It has comparable length, efficacy, and presumptively comparable cost to CBT. So why, in Table 2 is the initial recommendation is for "combination of individual cognitive behavioural therapy (CBT) and an antidepressant" (page 31), with IPT again listed eighth (page 35), trailing among other things individual problem-solving, counselling, and short-term psychodynamic psychotherapy. There is no listing for the combination of IPT with an antidepressant. (Why not?)These rankings cannot be based on data. The proposed draft reads as a biased political document.	Thank you for your comment. Based on the results of the guideline NMAs, the committee agreed that some treatment classes and interventions appeared to be more effective than others, but there was otherwise little to choose between treatments. It is noted that when assessing clinical effectiveness derived from the NMAs, the committee considered not only the mean effects of treatment classes vs the reference treatment, but the uncertainty around them (as expressed in 95%CrI), the volume of the evidence base for each treatment, and the evidence of effect or the lack of it (as shown by 95%CrI crossing or not the no effect line) of treatment classes but also of interventions within each class, versus the reference treatment. They also considered the results of pairwise meta-analysis of follow-up data, functioning and quality of life data. The committee then reviewed the results of the guideline economic analysis which determined which treatments were cost-effective, and used this to develop a suggested prioritisation of which treatments should be offered to people with depression, or considered for use. In the guideline economic analysis of treatments for less severe depression, IPT ranked 12th out of the 16 options assessed, just above GP care, which was the reference treatment (Table 98,

							results of guideline economic analysis, evidence review B). It is noted that included RCTs in less severe depression reported a higher number of sessions for IPT relative to individual BA and individual CT/CBT<15 sessions (which was the intervention considered in the economic analysis) – this information has now been added in evidence review B, under Appendix N. So, even though the effects of IPT, CT/CBT and BA may be similar, these were achieved with a lower number of sessions of BA and CT/CBT compared with IPT. In the guideline economic analysis of treatments for more severe depression, IPT ranked 17th out of 20 treatment options and was less cost-effective than GP care, which was the reference treatment, whereas combined CBT with antidepressant ranked 2nd (Table 101, bias-adjusted results of guideline economic analysis). These results affected the place of IPT in the suggested order in which treatments should be offered for an episode of less and more severe depression, which is shown in Tables 1 and 2 of the guideline, respectively. Regarding the combination of IPT with antidepressants, there were no data for less severe depression and insufficient data (N<50) on discontinuation and remission in completers in more severe depression, as the committee

							decided to look only at treatment classes tested on at least 50 participants across RCTs included in each NMA, after looking at the total size of the evidence base in this area (treatment of a new episode of depression) and noticing that there were several treatment classes with larger volume of evidence (see Appendix M in evidence review B). The size of the available evidence base on these outcomes was also a criterion for inclusion of treatment classes in the guideline economic modelling (as stated in Appendix J of evidence review B, under 'Interventions assessed'). Due to lack of sufficient data on discontinuation and remission in completers that were crucial for the economic modelling, combined IPT with antidepressants was not possible to include in the guideline economic analysis and therefore its cost-effectiveness relative to other treatments was not possible to estimate. Consequently, combined IPT with antidepressants was not possible to consider when formulating recommendations. In response to stakeholder comments some changes have been made to the tables guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice.

							Interventions are arranged in Tables 1 and 2 in the guideline in the suggested order in which options should be considered, based on the committee's interpretation of their clinical and cost effectiveness and consideration of implementation factors. However, this is not a rigid hierarchy, all treatments included in Tables 1 and 2 can be used as first-line treatments, and it may be appropriate to recommend an intervention from lower down in the table where this best matches the person's preferences and clinical needs. The committee were aware of the need to provide a wide range of interventions to take into account individual needs and allow patient choice.

291	SH	Janssen	Guideline	030-036	General	We are generally supportive of providing people with depression with as many treatment options as possible. We note however the level evidence supporting each treatment option is highly variable, as shown on page 82-85 of Evidence Review B. We also note that many of these treatment options may not be readily available or accessible in the NHS currently. This will cause significant implementation issues in the NHS if the aim is to allow equitable access to these treatments and require significant investment, facilities and training to make these options widely available. We note that the costs of implementation have not been factored into the cost effectiveness of the psychological or psychosocial treatments currently in the guideline model in Evidence Review B. We strongly believe these should be considered, as has been done in the recent review of a new treatment option for treatment resistant depression (NICE ID1414). We would therefore suggest that further consideration should be given to the treatment recommended based on the relative evidence base of each treatment, the current availability of such treatment options and the cost of implementing these treatments (staff training, infrastructure set up etc) before a final recommendation on what treatments should be made available. This is especially because not all psychological and	Thank you for your comment. The guideline recommends a range of evidence-based treatment options for depression, taking into account their risks, benefits and cost-effectiveness. Only interventions with adequate evidence of clinical and cost-effectiveness, supported by the committee's clinical expertise around service delivery and implementation issues within the NHS, were recommended. So, although the review included several treatments with limited evidence, these were not further considered so that the guideline does not recommend any interventions with a relatively poor evidence base. The vast majority of the recommended treatments is currently available in the NHS. Very few of the recommended interventions (for example group exercise, individual problem solving) are currently not available or have limited availability in routine practice, but the committee decided to recommend them based on the favouring available clinical and economic evidence. Training costs (in terms of qualification costs of low- and high-intensity therapists and additional training required for low-intensity therapists and for some therapies such as MBCT) have already been considered in the guideline economic modelling. As argued above, the vast majority of

						psychosocial options recommended are currently widely available across the country and would require significant investment to make them more widely available. The risk of this inconsistent decision making is that other potentially cost effective options being squeezed out at the margin through the use of a different threshold of evidence and cost effectiveness being made in the NICE Guideline compared to the NICE technology appraisal program, especially when in comparison the evidence base for some of these psychological and psychosocial interventions is relatively poor.	recommended interventions is already available in current routine practice, so they are not new or untested. Implementation issues relating to these interventions may be relevant regarding the scale of delivery. Where recommended treatments are currently not available or where their availability is limited, NICE will consider implementation issues when producing supporting tools for implementation of the guideline. Such treatments were recommended on the basis of their clinical and cost-effectiveness, as demonstrated by the available evidence.

292	SH	International Society of Interpersonal Psychotherapy	Guideline	023-027	General	Inasmuch as IPT is so well tested, tolerated, and has such clear effectiveness, it is bizarre to find in the main document of NICE recommendations that IPT is listed near the bottom of the list in the key Tables 1 and Table 2. Their order depends upon "the committee's interpretation of their clinical and cost effectiveness" (page 23). IPT is equipotent or more so than other listed interventions such as "self-help," and far better proven. It has comparable length, efficacy, and presumptively comparable cost to CBT. Why, then, is individual CBT listed third in Table 1 and IPT eighth? The committee's interpretation appears overtly biased.	Thank you for your comment. Based on the results of the guideline NMAs, the committee agreed that some treatment classes and interventions appeared to be more effective than others, but there was otherwise little to choose between treatments. It is noted that when assessing clinical effectiveness derived from the NMAs, the committee considered not only the mean effects of treatment classes vs the reference treatment, but the uncertainty around them (as expressed in 95%CrI), the volume of the evidence base for each treatment, and the evidence of effect versus the reference treatment or the lack of it (as shown by 95%CrI crossing or not the no effect line) of treatment classes but also of interventions within each class, versus the reference treatment. They also considered the results of pairwise meta-analysis of follow-up data, functioning and quality of life data. The committee then reviewed the results of the guideline economic analysis which determined which treatments were cost-effective, and used this to develop a suggested prioritisation of which treatments should be offered to people with depression, or considered for use. In the guideline economic analysis of treatments for less severe depression, IPT ranked 12th out of the 16 options assessed, just above GP care, which was the reference

							treatment (Table 98, results of guideline economic analysis, evidence review B). It is noted that included RCTs in less severe depression reported a higher number of sessions for IPT relative to individual BA and individual CT/CBT<15 sessions (which was the intervention considered in the economic analysis) – this information has now been added in evidence review B, under Appendix N. So, even though the effects of IPT, CT/CBT and BA may be similar, these were achieved with a lower number of sessions of BA and CT/CBT compared with IPT. In the guideline economic analysis of treatments for more severe depression, IPT ranked 17th out of 20 treatment options and was less cost-effective than GP care, which was the reference treatment (Table 101, bias-adjusted results of guideline economic analysis). These results affected the place of IPT in the suggested order in which treatments should be offered for an episode of less and more severe depression, which is shown in Tables 1 and 2 of the guideline, respectively. In response to stakeholder comments some changes have been made to the tables guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice.

							Interventions are arranged in Tables 1 and 2 of the guideline in the suggested order in which options should be considered, based on the committee's interpretation of their clinical and cost effectiveness and consideration of implementation factors. However, this is not a rigid hierarchy, all treatments included in Tables 1 and 2 can be used as first-line treatments, and it may be appropriate to recommend an intervention from lower down in the table where this best matches the person's preferences and clinical needs. The committee were aware of the need to provide a wide range of interventions to take into account individual needs and allow patient choice.

293	SH	UK Mindfulness Centres Collaboration	Guideline	038 - 041	general	Section 1.8 entitled Continuation of treatment for relapse prevention is confusing. It would be preferable to have a section Relapse Prevention that considers various options. One of the options would be to continue with an existing / previous treatment. Another option would be to introduce a new intervention purely for relapse prevention purposes. Mindfulness Based Cognitive Therapy was designed primarily for relapse prevention purposes and has a strong evidence base for its effectiveness in this regard. Many people have experienced multiple previous episodes of depression without coming to the attention of services. In the current draft of the guideline this sizeable group of people is excluded from consideration of relapse prevention because 'continuation of treatment' is not applicable to them.	Thank you for your comment. In response to your comment, this section has been renamed 'preventing relapse'
294	SH	Janssen	Guideline	041-044	General	In the further lines of treatment section, we are concerned that there is no specific recommendation for when a patient should be referred to secondary mental health services. We are supportive of multiple options that are recommended for patients if they fail initial treatment options, but strongly feel that there should be a cut off in terms of number of treatments that are tried and possibly a timeline, which should then lead to a referral to a secondary care setting, especially for those patients with	Thank you for your comment. The committee agreed that the appropriate time to refer a person to specialist care services was highly variable, and did not feel able to stipulate this in a recommendation. However, the treatments that need to be initiated, managed and/or stopped in specialist mental health settings or after consulting a specialist are already specified in the guideline recommendations.

						severe depression. Currently many people with depression cycle through several treatment lines in primary care when they would benefit from being referred to a specialist (Denee et al, 2021).Several mental health trusts suggest referral to specialist mental health services after the failure of 2 antidepressants and we believe this definition classed as treatment resistant depression is an appropriate cut off for referral to a specialist to ensure efficient treatment and management of depression.	
295	SH	Janssen	Guideline	051-054	General	We are very supportive of these new recommendation contained in this section 1.5 Access, coordination and delivery of care. Unfortunately, the access to treatments in mental health is not equitable across the country and does vary between mental health trusts. So, we are supportive of statements to allow equitable access and uptake of the treatments more widely, plus on the uniform assessment of people with depression and their monitoring and collection of data to improve the delivery of better outcomes for patients and reduce the variability of outcomes across the country. We especially welcome the recommendation to support the integrated delivery of services across primary and secondary care to avoid individuals falling into gaps between levels of service provision. This reflects comment 7, where we believe that NICE guideline has a role to	Thank you for your comment and support of these recommendations. We have addressed comment 7 separately.

						play here in making a stronger set of recommendations within the guideline around when patients should be referred into secondary services.	

296	SH	Healthwatch Bristol	Guideline	049 - 051	General	Section 1.13.6, 1.13.7 and 1.13 GeneralWe have received comments about people's experiences being denied and dismissed, in the face of complaints and poor practice:(Last had ECT in 2018): The ECT resulted in a mild improvement in mood. The doctors continued to prescribe more treatments as it was recommended to until a plateau in mood, regardless of how mild the improvement was. During this time I reported memory and cognitive issues which were disregarded. They even increased the dose. They weren't concerned about these side effects at all, the epilepsy/seizure symptoms I was presenting with and concerned about were dismissed, as "there's nothing in the literature"... I've been referred for neuropsychological testing which has shown problems with multiple types of memory but this has not been put down to ECT. It has been suggested that it is due to depression. I was not tested for any other types of injury by the brain injury service that assessed my memory, despite requests. (Last had ECT in 2015): My psychiatrists have consistently denied my injury, and have instead attributed my condition to my so called 'depression'. Not being listened to, and not being taken seriously caused me to become suicidal, and I attempted on four occasions to take my own life. I must stress that this was due to the hopelessness of my situation, that no one was listening, and not	Thank you for your comment. The committee discussed the fact that people need to be fully informed about the risks and benefits of ECT prior to its administration, and need to make an informed decision to have ECT. For this reason the committee stregthened the recommendations from the previous version of the guideline and added the requirement for clinics providing ECT to be ECTAS-accredited, with board level accountability for compliance with ECTAS standards.

						'depression'. It's difficult to convey the feeling of hopelessness and powerlessness their attitude caused. It took me years of asking for neuropsych testing, but eventually was granted this. When I asked for a copy of the report, the NHS were unable to produce it, but I was given an fMRI and Qeeg, and these showed damage to areas of my brain. My autism specialist assessed me as functioning at 1/10th of my former level. I have not been referred to a brain injury rehabilitation unit, presumably as the damage to my brain has been denied. I did lodge a formal complaint with the hospital about my treatment and injury, but their response was an internal investigation, and my complaint was dismissed. (Man who had ECT in his fifties) Psychiatrist did not acknowledge any damage. My wife has raised lots of issues and complaints and I support her. Including CEO of hospital, ward manager, nurses, PALS, MP.****(Mother whose daughter has had ECT) The SOAD was never helpful. His signature was just needed to protect the Consultant's decision, but SOAD really doesn't care about the welfare of the individual. They try to avoid contact with the family. The SOADs are just keeping up their Report according to the Hospital and Consultant's opinion. SOAD writes Report Even without seeing the patient…. SOAD excuse themselves that they have a very narrow duty to just to see if the treatment	

						was lawfully implemented. ….I complained of side effects of ECT verbally all the time, but the staff just ignored my complaints and were not writing the side effects in the medical records. The same ECT unit, they never record any of my constant complaints to them. The Advocate has written a complaint, but nothing has changed since. I complained to PALS, CQC, local MP, but the ECT continued.	

297	SH	University of Essex	Guideline	010-012	General	Choice of treatments (Guideline - section 1.3)As noted above, the joint stakeholder group position statement we endorsed was explicit that the review of patient experience of treatments requested should inform treatment recommendations. Section 1.3 of the guideline is a welcome addition, prioritising shared decision making as a guiding principle. Yet in our opinion this must be backed up by an increase in menu options for patients to choose from. The absolute number of choices of psychological therapy has decreased overall with the removal of CBASP. We note that this version of the guideline has been heavily influenced in certain places by “knowledge and experience” of the committee members in terms of treatment recommendations, especially where the RCT evidence based has serious limitations. In order for the guideline to be truly in keeping with the principle of shared decision making and choice, it should also centre patient expertise and knowledge when considering the list of treatment options on the menu.We therefore further emphasise that the menu of psychological treatments should be as inclusive as possible for all forms of depression. A key feature of patient experience research (noted in earlier points) is that psychological treatments on offer are often felt to be too short for people with long standing difficulties such as those with background trauma	Thank you for your comment. The committee agreed that a qualitative evidence review identifying the factors that can promote choice and act as barriers to choice, would enable recommendations to be made that improved the implementation of shared decision-making and ensured the people's preferences were taken into consideration, better than qualitative review looking at people's experiences of individual treatments. The menu of psychological treatments was based on the evidence for clinical effectiveness and cost-effectiveness identified as part of the network meta-analysis and described in Evidence review B. The patient's knowledge and expertise is also taken into consideration and this is described in the recommendations on principles of care and choice. The committee has, based on stakeholder feedback, amended the recommendations on the number and duration of psychological sessions to allow more flexibility for services to provide the number of sessions a patient requires, taking into account the factors you have listed.

						and adversity. We strongly recommend that the list of psychological treatments should include the possibility that the duration of all forms of psychological treatment be allowed to be extended beyond the limited number of weeks currently allowed. We reiterate our earlier suggestion that treatment recommendations allow that:- psychological treatments may be offered for longer treatment periods up to a maximum of 18 months based on shared decision making, clinical judgement and patient choice taking into account: severity, chronicity, treatment resistance, level of functioning, comorbid personality disorder, degree of past trauma.	
298	SH	British Psychological Society	Guideline	019 - 021	General	Regarding lithium, we advise that more attention be paid to reviewing medication and considering the possibility of reduction or gradual withdrawal given the risks (to which the many precautions listed in this section attest) and paying due attention to patient choice and any locality-based possibilities for social prescribing or other psychological or social therapies.	Thank you for your comment. This section of the guideline covers the practical aspects of prescribing, monitoring and stopping lithium. More detail on the indications for lithium are included in the later sections of the guideline on treatment for different types and severity of depression and there is no suggestion they should be prescribed without considering patient

							choice or in preference to psychological and social therapies where these would be more appropriate. The recommendations cover the ongoing review of people taking lithium and its discontinuation.
299	SH	British Psychological Society	Guideline	019 - 021	General	The committee made the recommendations on the use of lithium and the use of antipsychotics by informal consensus and based on their knowledge and experience. This seems inconsistent with recommendations made about other interventions including psychological therapies.	Thank you for your comment. This section of the guideline covers the practical aspects of prescribing, monitoring and stopping antipsychotics and lithium. The practical advice contained in this section of the guideline is based on the committee's experience and the BNF, as this sort of practical information would not be identified in an evidence review.

300	SH	British Psychological Society	Guideline	049-51	General	We welcome some aspects of this section on ElectroConvulsive Therapy, and are pleased to see the recommendations to inform people about the risks of ECT, especially for older people (1.13.2); take advance treatment decisions into account (1.13.4); monitor ECTAS standards by board-level performance management (1.13.7); document assessment and consent discussions (1.13.2); and aim for ECT clinics to be ECTAS-accredited (1.13.6). However, we believe the Guideline is a significant missed opportunity to reiterate and uphold the unimplemented recommendations from the 2003 NICE Guidance on the Use of Electroconvulsive Therapy (and subsequently in NICE 2009); including its Appendix D on audit standards. The Guideline also fails to take into account recent research and evidence relating to outcome and potential harms, and does not adequately address evidence on serious deficiencies in safety, effectiveness, monitoring and regulation. The Guidelines fail to address the serious and ongoing issue of lack of firm support for ECT's effectiveness, as shown in various reviews since 2003. A literature review by READ, J., & BENTALL, R 2010 (The effectiveness of electroconvulsive therapy. Epidemiology and Psychiatric Sciences, 19, 333-347) found that placebo controlled studies show minimal support for the effectiveness of ECT either at the end of the course or beyond the treatment period.	Thank you for your comment. The committee discussed the care and considerations that need to be taken into account when delivering ECT, such as informing people of the risks and benefits, obtaining consent, monitoring cognitive function and stopping ECT. The committee amended the existing recommendations on these topics but agreed that there are now recognised up to date standards produced by the Royal College of Psychiatrists, which provide guidance on how a safe and effective ECT service should be delivered, in the context of an ECT accreditation service (ECTAS). The committee added a recommendation, and subsequently strengthened this recommendation in response to stakeholder comments, that clinics should only provide ECT if they are ECTAS-accredited, provide ECT in accordance with ECTAS standards, and submit data (including outcomes) on each course of acute and maintenance ECT they deliver as needed for the ECTAS minimum dataset. There is also a recommendation that trusts which provide ECT services should ensure compliance with the ECTAS standards for administering ECT through board-level performance management.

						Subsequently, READ, J., et al. 2019 (Electroconvulsive Therapy for depression: A Review of the quality of ECT vs sham ECT trials and meta-analyses. Ethical Human Psychiatry and Psychology, 21, 64-103) came to similar conclusions. The reviews also found no clear evidence that ECT saves lives or prevents suicides. Neither of these papers appears to have been included in the Guideline.The Draft Guideline fails to recommend robust auditing of outcomes, both short term and long term, although these are at the moment lacking. READ, J., et al. 2018 (An audit of ECT in England 2011-2015: Usage, demographics, and adherence to guidelines and legislation. Psychology and Psychotherapy: Theory, Research and Practice, 91, 263-277) found that about half of the 56 Trusts that responded were not using validated measures of efficacy. Only four provided data for positive outcomes, mostly derived from a brief 3 question measure completed by the referring clinician themselves. No Trusts provided outcome data beyond the end of treatment. Subsequently, READ, J., et al. 2021 (A second independent audit of ECT in England: Usage, demographics, consent, and adherence to guidelines and legislation in 2019. Psychology and Psychotherapy: Theory, Research and Practice, 94, 603-619) found only six Trusts keeping data on positive outcomes and none keeping data on	The committee noted the limitations of the evidence for ECT for further-line treatment, both in terms of quantity and quality in the committee discussion of the evidence section. However, the committee were also aware that ECT may be beneficial for some people and that removing it as an option would be detrimental to some people with depression. The recommendations on ECT limit its use (to when a rapid response is needed, when other treatments have failed, or based on patient preference). On this basis, the committee did not consider it appropriate to remove this recommendation, but did amend the wording to emphasise that ECT should generally not be used, and should only be considered in the limited circumstances described. Recent meta-analyses on the effectiveness of ECT including those included in Read 2019 (Janicak 1985; Kho 2003; Mutz 2019; Pagnin 2004; UK ECT Review Group 2003) have been checked for additional relevant eligible studies. Read 2019 is listed in the excluded studies of Supplement D (further-line treatment) as it is not eligible for inclusion in its entirety (but has been checked for relevant additional primary studies). Read et al. (2010) had not been previously identified but in response to your comment, it

						efficacy beyond the end of treatment. We are concerned about the ongoing use of an invasive and potentially harmful intervention based on such weak evidence for beneficial outcomes and the apparent lack of effective mechanisms for ensuring that data is collected.We would like to see a statement about safe dosage, frequency or duration of treatment, since NICE 2003 noted that '…. stimulus parameters impact on the safety and efficacy of the technique, and recent research needs to be augmented.' Current ECT devices are 'set at 800−900 milliamperes (mA) on modern ECT devices without any clinical or scientific rationale' (Abbott et al. Electroconvulsive Therapy Pulse Amplitude and Clinical Outcomes. Am J Geriatr Psychiatry. 2021 29(2):166-178.) Psychiatrists are not trained in the biophysics of electrical dosing or in electrical injury. Further research and medical training in these areas is urgently needed if harms are to be avoided. There is no statement about the need for regular cognitive testing, with appropriate measures, for adverse effects after every treatment and at follow up. This appears to overlook NICE 2003's recommendation that 'the individual's cognitive function is monitored on an ongoing basis and at a minimum at the end of each course of treatment.' It is unacceptable to continue to recommend an intervention where the assessment of potential harms is acknowledged to	has been checked for additional eligible studies and no new studies have been identified for inclusion. The committee did not review the audit evidence for ECT (such as the papers cited: Read et al. 2018, 2021), as this was outside the scope of this update. However, the committee were aware that the ECTAS standards were developed with a wider range of ECT experts than were available on the guideline committee, and were updated on a regular basis, and therefore agreed that it was more appropriate to refer to these standards than create new recommendations. The committee have reiterated their call for more research into the place in therapy of ECT, and will also recommend to NICE that it explore doing future work on neuromodulatory techniques (and/or rapidly acting treatments) including ECT.

						be lacking, and, as NICE 2003 noted, a number of individuals find their memory loss extremely damaging and for them this negates any benefit from ECT. There is no statement about the known inadequacies of patient information leaflets and the implications for informed consent. An audit by Harrop et al, 2021 ('How accurate are ECT patient information leaflets provided by mental health services in England and the Royal College of Psychiatrists? An independent audit'. Ethical Human Psychology and Psychiatry, doi: 10.1891/EHPP-D-21-00003 shows that current leaflets are often based on serious inaccuracies, confirming NICE 2003's concerns about informed consent: '….the potential for cognitive impairment following ECT may not be highlighted during the consent process.' There is a risk of breaching the Montgomery (2015) ruling which requires all risks, even rare ones, to be mentioned. A 2018 regulatory update to Thymatron ECT machines (which are widely used in the UK) required doctors to warn patients about a long list of potential adverse effects, including 'permanent brain damage' http://www.thymatron.com/downloads/System_IV_Regulatory_Update.pdf A systematic review by Rose et al in 2003 (Patients' perspectives on electroconvulsive therapy: systematic review BMJ 2003; 326 :1363 doi:10.1136/bmj.326.	

						7403.1363) which was cited in earlier NICE documents, found that a third of patients report long-term cognitive impairment. Such a warning is almost never given to ECT recipients. There is no comment on the huge variation in ECT usage between different Trusts (up to 47-fold per capita of the population) documented in recent audits, although this suggests that prescribing ECT is largely based on clinician preference rather than on evidence. (READ, J., et al. 2018 An audit of ECT in England 2011-2015: Usage, demographics, and adherence to guidelines and legislation. Psychology and Psychotherapy: Theory, Research and Practice, 91, 263-277; Read, J., Harrop, C., Geekie, J., Renton, J., & Cunliffe, S. 2021. A second independent audit of ECT in England, 2019: Usage, demographics, consent, and adherence to guidelines and legislation. Psychology and Psychotherapy: Theory, Research and Practice. https://doi.org/10.1111/papt.12335)NICE 2003 recommended that since many people are unaware of their rights and may be subject to both explicit and implicit coercion, '…..mechanisms to monitor and prevent this from occurring must be developed and implemented'. No such mechanisms have been put in place, and therefore this possibility remains a risk, and one that is reported by many patients who subsequently regret having ECT.NICE 2003 made a strong call for	

						more research into efficacy and safety of ECT, as did NICE 2009 and 2014, but this has not been followed up. 'Further research is urgently required to examine the long-term efficacy and safety of ECT… Of particular concern (was) the lack of long-term evidence regarding adverse effects on cognitive function….In addition to the use of appropriately validated psychometric scales, outcome measures should include user perspectives on the impact of ECT, the incidence and impact of important side effects such as cognitive functioning, and mortality….'(NICE 2003)' The Draft Guideline has not included recent research reviews and independent audits finding little evidence of efficacy, significant potential harms, and serious problems with monitoring practice and outcomes (Read, J., Kirsch, I., McGrath, L. 2020. Electroconvulsive Therapy for depression: A Review of the quality of ECT vs sham ECT trials and meta-analyses. Ethical Human Psychology and Psychiatry, doi:10.1891/EHPP-D-19-00014; Read, J., Harrop, C., Geekie, J., Renton, J., & Cunliffe, S. 2021. A second independent audit of ECT in England, 2019: Usage, demographics, consent, and adherence to guidelines and legislation. Psychology and Psychotherapy: Theory, Research and Practice. https://doi.org/10.1111/papt.12335) I am concerned that this intervention is still being used	

						on approximately 2,500 people a year in the continuing absence of this research. We believe the Draft Guideline fails to address NICE 2003's statement that 'RCTs….did not adequately capture the experience of service users'. While some people report finding ECT helpful, others say that they have suffered lifelong impairment. NICE 2018 noted that there is a significant gap between most professional views and most patient experiences, as NICE 2018 noted, with 'many others, including some patient groups, consider(ing) it to be an outdated and potentially damaging treatment (Rose et al., 2003) (p. 197).' Patient experiences are not adequately represented in this Draft Guideline.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

301	SH	Janssen	Guideline	019-21	General	We note the expansion of the recommendation on the use of lithium and we welcome increased clarity around the appropriate use and management of lithium in the guideline from previous versions. This is specifically important in a primary care setting where safety monitoring required for lithium from our experience is not always necessarily adequately managed.	Thank you for your comment and support of these recommendations.
302	SH	Janssen	Guideline	049-051	General	It is good to see further clarity provided in the provision of electroconvulsive therapy (ECT) within the guideline to help support the safe and effective treatment of an invasive treatment option that has the risk of serious adverse events. We would suggest that this section most logically follows Section 1.9 Further line treatment, as this is a continuation of the pathway from the treatment options mentioned in Section 1.9 to ECT, as usually ECT is considered as a last line option for those patients that have previously failed further line treatments. This will ensure that these recommendations on ECT are not missed within the guideline given they are useful in outlining the appropriate use of ECT.	Thank you for your comment and support of the ECT recommendations. The committee discussed if the ECT recommendations would fit better at the end of the section on further-line treatment but agreed that as ECT may be used for some people earlier in the treatment pathway, it should remain as a stand-alone section of the guideline.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

303	SH	The Association of Clinical Psychologists UK	Guideline	047 - 048	General	The ACP-UK contests the construct of 'Personality Disorder' in line with The Consensus Statement for People with Complex Mental Health Difficulties who are diagnosed with a Personality Disorder (2018) consensus-statement-final.pdf (mind.org.uk).	Thank you for your comment. The depression guideline is not able to make recommendations about the diagnosis of personality disorders. However, the recommendations were intended to address historical exclusion of people with personality disorder from receiving treatment for their depression, and to emphasise access to psychological interventions. In response to stakeholder comments, a new recommendation has been added that diagnosis of personality disorder should not be used to exclude people from treatment.
304	SH	Janssen	Guideline	010-11	General	We are supportive of this section 1.3 on the Choice of treatments. We strongly believe that encouraging patient engagement in treatment choice is beneficial to the treatment alliance and treatment outcomes. This will also ensure that the most appropriate treatment option is identified for the person with depression to meet their needs throughout their treatment course and will ultimately lead to better outcomes over time for all people with depression.	Thank you for your comment and support of these recommendations.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

305	SH	Janssen	Guideline	013-014	General	Overall, we are supportive of the appropriate discussion taking place with people with depression ahead of starting antidepressant medication, so that they are aware of the risks and benefits of antidepressant treatments and to how to take them appropriately. This is important in building a therapeutic alliance and to ensure that best outcomes can be achieved for the person with depression. This is especially important when medications are being initiated that have been started before (and discontinued due to a lack of efficacy or tolerability). This can be a huge frustration to people with depression when being referred from primary to secondary care and they are often started again on the same medication and go through months of treatments that they have tried before. This is linked to our other points around the lack of clinical outcomes being collected in both primary and secondary care and unfortunately the person with depression suffers as a result from cycling ineffectual treatment options. To these points, we believe that strong rationales and evidence should be recorded in previously tried therapy (or of the same class) is re-commenced and that agreement from the person with depression with this approach is recorded. Accordingly, we ask the guideline committee to consider making a recommendation on this point.	Thank you for your comment. The recommendations on choice already advise that people's previous experience of prior treatments for depression are discussed, the section on the delivery of all treatments already advises routine outcome monitoring, and discussing and agreeing a treatment plan is also now included in the section on starting antidepressants, so further additions in response to your comment have not been made.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

307	SH	Janssen	Guideline	021-22	General	We welcome the expansion of the recommendation on the use of antipsychotics and also the increased clarity around the appropriate use and management of antipsychotics, especially given that virtually all antipsychotics that are used do not have market authorisations in depression. We are especially supportive of physical health monitoring of side effects given the known burden of antipsychotic medication.	Thank you for your comment and support for these recommendations.
308	SH	Mind	Guideline	026-027	Table 1	We support the inclusion of exercise as a treatment option for less severe depression.We are concerned about the delivery section for group exercise for those with less severe depression, recommending these sessions to usually be “60 minute sessions, usually 3 times a week for 10 weeks.” We feel that these are unrealistic frequencies and lengths of exercise sessions for people with depression, given symptoms including low motivation and fatigue, and that people will have different starting points for their physical fitness. A randomised control trial of the Movement for Mind programme (2021) demonstrated that clinically meaningful improvements to mental wellbeing can be gained in two 30-minute sessions a week - www.asics.com/gb/en-gb/mk/movement-for-mind-results. Setting and realising achievable targets for people with depression will foster self-esteem and build motivation. Setting these too	Thank you for your comment. The committee noted that the evidence was for a structured formal exercise programme, with exercise of moderate to high intensity, but recognise there may be challenges to implement this. The committee has now removed the suggested duration of exercise sessions and modified the recommended frequency to allow more flexibility in the delivery of exercise programmes. In response to stakeholder comments, the committee also supported less intense 'move more' exercise for general wellbeing (although not as a treatment for depression) and made a new recommendation to reflect this.

						high could further impact on the symptoms of mental ill health.We think it is vital that the recommendations for intensity and frequency of physical activity must be tailored to the individual's needs. We would also recommend that physical activity options are broadened from just 'group exercise' given we know that there are a wide range of barriers to people with mental health problems becoming more active, these might include self-led exercise and community based interventions open to the whole community (such as parkrun, our parks and similar).	
309	Individual	Individual 7	Guideline	032-033	Table 2	Section on antidepressant medication: There is a recommendation that antidepressants should 'Usually taken for at least 6 months (and for some time after symptoms remit)' This should be strengthened to emphasise the crucial importance of a minimum 6-month period of treatment. Perhaps: 'Should be taken for a minimum of 6 months after remission of symptoms.'	Thank you for your comment. The recommended duration of antidepressant therapy is, as the recommendations state, usually 6 months after the remission of symptoms and this is included in the sections on starting antidepressant therapy and in the tables of treatment options. However, some people may wish to discontinue medication earlier, particularly if it is not effective, so this recommendation has not been strengthened.

310	SH	Janssen	Guideline	pg.12	026-028	We welcome the acknowledgement of routine outcome monitoring (using appropriate validated sessional outcome measures) and follow up being conducted. We are concerned, however, that this is only to be 'considered' currently. We believe this recommendation is not strong enough and that all people with depression should have routine outcome monitoring (using appropriate validated sessional outcome measures) and follow up. In addition, a threshold defining what success looks like should be incorporated. Without this being strengthened, people with depression run the risk being kept on ineffectual treatments for significantly longer than required and their depressive episode is likely to continue longer, leading to a risk of more severe and resistant depression. In any physical health condition, the appropriate follow up and monitoring with a validated instrument would be standard practice. In addition, we believe that NICE should be stronger in proposing a validated measure to ensure continuity of outcome measurement through primary to secondary care and to facilitate consistent and appropriate decision making on treatment effectiveness. Internal market research data available at Janssen suggest that only about 20-25% of psychiatrists are using outcome scales currently. A scale like the PHQ-9 would be appropriate given the relative ease in	Thank you for your comment. The committee noted that routine outcome monitoring was used more in psychological therapy practice including in IAPT, than in primary care or specialist mental health services. The committee agreed that the evidence on whether routine outcome monitoring improves outcomes was equivocal, but noted that it may be valued by people with depression. On this basis, the committee agreed to keep this recommendation as a 'consider'. In response to stakeholder comments the committee agreed to include the PHQ-9 as an example of a scale that might be used to measure depression symptoms, given that it is the scale most widely used in UK clinical practice.

						administration and burden and applicable to being used in primary and secondary care. Overall, the guideline committee and NICE should be stronger in the recommendation around routine outcome monitoring to ensure this is conducted routinely in clinical practice and leads to the effective and efficient treatment and management of depression. This is one of the main factors leading to ineffectual outcomes and inefficiency in the depression pathway and we hope the guideline committee are able to consider this further and incorporate within the final guideline.	
311	Individual	Individual 7	Guideline	Question 1		Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. The areas likely to have the biggest impact on practice and be most challenging to implement are those related to psychological and other non-pharmacological therapies. The problems are most likely to be related to availability, with a lack of qualified therapists and insufficient provision generally. This has the effect of limiting patient choice: imagine telling a patient,	Thank you for your comment. The committee are aware that there may be waiting times for psychological therapies and will pass your views on this challenge to implementation to be considered by NICE where relevant support activity is being planned

						you can have psychological therapy if you wait 6 months or you can have an antidepressant today. To a patient living with the misery of depression, this is no choice at all.	
312	SH	Practice Plus Group	Guideline	Table 1	General	It is not clear why CBT and BA have been split up when CBT often involves BA	Thank you for your comment. The committee considered behavioural activation to be a distinct intervention as it is sometimes used without cognitive components.
313	SH	British Psychological Society	Guideline	2	2	It is stated that these guidelines were mainly drawn up before Covid. We advise that if the guideline team has been unable to address this momentous worldwide issue, there should be acknowledgment of the evidence of increased mental distress in the context of Covid and that this reinforces the need not only for understanding the social determinants of depression but social solutions.	Thank you for your comment. The committee decided not to make Covid-specific recommendations as these may become outdated, but, as you suggest, the emphasis in the guideline on assessing the person, the possible factors contributing to their depression and their needs and preferences has been increased.
314	Individual	Individual 7	Guideline	Question 2	General	Would implementation of any of the draft recommendations have significant cost implications? In the short-term, yes. There will be setting up costs for psychological and associated therapies plus the on-going need for funding for premises and staff. However, if making these therapies available leads to better outcomes for people with depression, significant savings are likely to accrue. Similarly, if patients were better	Thank you for your comment. The committee agreed with your remarks and, after assessing the available evidence, recommended interventions that may have higher initial costs for set up and monitoring, but were shown to be clinically and cost-effective, so that their benefits are expected to outweigh set up costs, and their provision overall ensures efficient use of resources.

						supported in taking antidepressants in the longer term, drug costs would rise, but savings arising from better outcomes would more than outweigh them. When considering costs, the cost of the outcome (particularly poor outcomes) is more important than the cost of the intervention.	
315	SH	We Are With You	Guideline	Table 2	General	'Self-help with support' is recommended to be offered as an initial 30 minute session followed by eight 15 minute sessions over 16 weeks. This is a significant change from current models of delivering guided self-help in IAPT services and practitioners have raised concerns that a 15 minute appointment is insufficient for safe, effective practice accommodating agenda setting, risk review (and risk management, as needed), progress review (including review of clinical questionnaire responses) and collaborative working to explain concepts and overcome treatment barriers or challenges. This recommended way of working is significantly different to IAPT current practice and would require a substantial overhaul of Psychological Wellbeing Practitioner training and course curricula as well as practice in service. Practice changes in service could have a significant and unsettling impact on the existing Psychological	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions. No need for additional training, change in the course curriculum or practice in service is anticipated in relation to the recommendations around guided self-help.

						Wellbeing Practitioner workforce, where retention is already a challenge.	
316	Individual	Individual 7	Guideline	Question 3	General	What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)I'm not aware of existing resources or examples of particularly good practice. What would really help would be better and more easily accessible information for patients and carers, and training and resources for practitioners in how to help patients to make informed choices.	Thank you for your comment. Your comments about information needs will be considered by NICE where relevant support activity is being planned
317	Individual	Individual 7	Guideline	Question 4	General	Please tell us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication. None over and above the actions that are already being implemented in practice generally.	Thank you for your comment and letting us know there is nothing else you think should be added in relation to Covid-19.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

318	SH	Independent Age	Guideline	5	11	Rec 1.1.1 - We welcome the additional bullet point to highlight that symptoms of depression and stigma can be barriers to accessing support. Our 2020 report, Minds that matter[i], found that stigma is a barrier to seeking support for common mental health issues for some people in later life. The reasons for this vary but for some people it may stem from mental health issues being less well-understood or openly discussed in previous decades. There can also be stigma among some older people specifically around being prescribed medications such as antidepressants.Research has found that only a third of people aged 65+ with symptoms of depression serious enough to warrant intervention discuss it with their GP, and only half of those get treatment, primarily medication.[ii] Our research has found that many older people, and some health professionals, view common mental health issues like anxiety and depression as a normal part of ageing. In addition, some older people have lower mental health literacy and often use euphemistic language when speaking about their mental health, e.g. 'feeling blue', 'my bad days'. These are important issues to recognise when considering strategies to engage with people in later life and when offering different support options. As such, we expect to see associated guidance around efforts to tackle common misunderstandings, such as informing	Thank you for your comment and sharing your work with us. The recommendations on access include specific advice to improve access for people who may face stigma and discrimination and this includes older people.

						older people that poor mental health is not an inevitable part of getting older and that treatment can and does make a real difference for this cohort.	
319	SH	British Psychological Society	Guideline	5	011-015	We support the recommendation to "ensure steps are taken to reduce stigma…..". It would be helpful to have some examples of good practice for achieving this.	Thank you for your comment. Some examples of methods to reduce stigma have been added to this recommendation
320	Individual	Individual 11	Guideline	6	8	Rec 1.1.4 – I am concerned that advance statements may result in people refusing treatment that may be lifesaving and that advance statements may be made when people with chroonic depression are not fully weel ……..	Thank you for your comment. Advance statements are can only be made by people who have capacity and are not legally binding, but serve as a guide for healthcare professionals to follow (compared to advance decisions which are legally binding). Advance statements are therefore unlikely to lead to life-saving treatment being withheld.

321	SH	Independent Age	Guideline	6	20	Rec 1.1.6 - We are a little unclear if this refers primarily to supporting carers' mental health. We assume it does and so welcome this recommendation. Our Minds that matter research showed that many older people provide informal care for partners, relatives or friends, and that this can increase the risk of depression, and that many do not receive the assessment or support they need.	Thank you for your comment. Yes, this recommendation is intended as a reminder that informal carers need support too.
322	SH	Institute of Health Visiting	Guideline	6	General	To add preconception care plans for women who have had previous perinatal depression and are considering planning for another baby, see:https://www.tommys.org/pregnancy-information/search?keys=preconception+care+plan	Thank you for your comment. Women with antenatal or postnatal depression were not included in the scope of this guideline and the committee agreed that prescribing to women who had previous perinatal depression would always need an individualised approach and the level of detail you suggest would not be appropriate to include in this guideline. However, a link to the NICE guideline on antenatal and postnatal mental health has been included in the section of the guideline on the delivery of treatments, to remind healthcare professionals to consider the care of these women separately.
323	SH	Royal College of Speech and Language Therapists'	Guideline	7	19	The RCSLT recommend repeating the information on supporting communication in the sections on assessment and care and treatment planning.We welcome this section on supporting people with communication needs. Accurate assessments and decisions directly affect patient recovery and	Thank you for your comment and for your support for the recommendations on supporting communication. The committee agreed that the principles of adapting communication outlined at the start of this section applied throughout the

						safety. Unsupported communication leads to compromised patient care which affects patient safety.	section and so it was not necessary to repeat them.
324	SH	Psychological Professions Network	Guideline	7	019-027	The communication methods are in the wrong order. Attempts should be made to communicate with the person directly and then their family member or carer.	Thank you for your comment. The order of these 2 bullet points has been switched as you suggest.
325	SH	Association for Dance Movement Psychotherapy UK, British Association of Art Therapists, British Association of Music Therapists and the British Association of Dramatherapists	Guideline	7	019-030	The guideline states under Recognition and Assessment:1.2.5 If a person has language or communication difficulties (for example, people with sensory or cognitive impairments or autism), to help identify possible depression consider: asking a family member or carer about the person's symptomsasking the person about their symptoms directly, using the appropriate method of communication depending on the person's needs (for example, using a British Sign Language interpreter, English interpreter, or augmentative and alternative communication).Although the guideline acknowledges that depression can be relevant not only for those with verbal capacities but also to people with language or communication difficulties, it stresses verbal therapies as the main psychological treatment options. The role of creative arts psychotherapies has been largely ignored as interventions that allow for non-verbal communication at diagnosis,	Thank you for your comment. Insufficient evidence for creative arts psychotherapies were identified to allow the committee to recommend them. You are correct that talking therapies are suggested as the main type of psychological therapies offered. However, it is a legal requirement for providers to make reasonable adaptations for people with disabilities, and this would include adapting talking therapies for people with communication difficulties. This is covered in more detail in the NICE guideline on mental health problems in people with learning disabilities which has now been cross-referenced from the section on the delivery of psychological treatments

						initial assessment stage and/or as a treatment option.	
326	SH	Royal College of Speech and Language Therapists'	Guideline	8	2	Section 1.2.6. The RCSLT recommend adding a statement on the importance of supporting communication during the initial assessment. People with communication difficulties will be disadvantaged. Whilst the initial assessment will take this into account impairments and disabilities, not all people with communication difficulties will have a disability. Therefore they will lose any support and protection under this section. There is a risk of compromised patient safety and an inaccurate assessment when communication is not supported.	Thank you for your comment . The committee agreed that the principles of adapting communication outlined at the start of this section applied throughout the section and so it was not necessary to repeat them.
327	SH	British Society of Lifestyle Medicine	Guideline	8	7	Rec 1.2.7 - Include here an assessment of current lifestyle factors including dietary habits, physical activity, smoking, alcohol and substance use, sleeping patterns, psychosocial stressors and social connection and support.	Thank you for your comment. The committee added a separate bullet relating to lifestyle (diet, physical activity and sleep). They were not aware of any link between smoking and depression. Stressors, social connections and alcohol and

							substance use are already included in the list of possible contributory factors.
328	SH	British Psychological Society	Guideline	8	012-018	We support the recommendation to ask about debt and employment. An amendment has been made clarifying about difficulties with interpersonal relationships, which seems helpful. However, if the responses are only about changing the individual person, which may allow systemic and institutional problems that maintain depression to go unchallenged, they will be ineffective. Clinicians need to be more aware of the social determinants of mental well-being and trained to intervene with systemic factors. Systemic therapeutic interventions such as couple and family therapy which are already available in NHS psychological therapy services may be one way to address them although by no means the only way.	Thank you for your comment. This section of the guideline relates to the initial assessment of people with depression, and although other agencies are signposted from here, specific interventions (such as couples therapy) is included in the sections of the guideline relating to treatment.
329	SH	Psychological Professions Network	Guideline	8	16	This only focuses on deficits. It should also focus on supportive relationships – present and past to enable identification of protective factors	Thank you for your comment. The consideration of positives, including supportive relationships has been added to this recommendation,

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

330	SH	EMDRIA	Guideline	8	17	In assessment, 1.2.7, the guideline recommends discussing factors that might have contributed to the development of the patient's depression, including "living conditions, drug and alcohol use, debt, employment situation and social isolation. [2009, amended 2021] ". However, it makes no mention of asking about any traumatic, stressful, or adverse life events that may have contributed to the development of their depression. We feel this is significant omission. It goes to the heart of conducting assessments in a way which help develop destigmatising formulations around "what has happened to you" rather than "what is wrong with you". We suggest adding to the bullet-point list of factors to ask about in 1.2.7 the following additional sentence: "recent and historical experiences of stressful, aversive or traumatic life events that have contributed to their depression symptoms: including discreet events (e.g. redundancy, divorce, bereavement, acute illness, trauma) and chronic stressors (workplace bullying, harassment, disability, discrimination, ongoing legal issues)."	Thank you for your comment. Some examples of stressful or traumatic events have been added to the list of examples in this recommendation as you suggest.
331	SH	We Are With You	Guideline	8	17	Specific reference to 'drug and alcohol' use as part of assessing for depression is helpful but a more helpful prompt would be 'illicit substance use, use or misuse of prescribed medications and alcohol use' to ensure that use or misuse of prescription medications is routinely considered	Thank you for your comment. The wording has been amended to include prescribed medications.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

332	SH	Royal College of Speech and Language Therapists'	Guideline	8	020 - 021	Section 1.2.8. The RCSLT recommend that every step must be taken to support effective communication with the person. It might be difficult for a practitioner to ascertain if a person with communication problems is at risk of suicide. People with communication problems might not understand or self-report this intent. Every step must be taken to support the person.	Thank you for your comment . The committee agreed that the principles of adapting communication outlined at the start of this section applied throughout the section and so it was not necessary to repeat them.
333	SH	Institute of Health Visiting	Guideline	8	Gener al	Risk Assessment should also include 999 and emergency services as options if a person with depression presents with considerable immediate risk to themselves or others.	Thank you for your comment. The recommendations state that people at immediate risk should be referred urgently to specialist services, as this would provide more specific help than dialling 999.
334	SH	EFT International	Guideline	9	001-002	1.2.10. (and similarly 1.2.11) We suggest insertion of wording to clarify that increased risk of agitation applies to commencement of treatment involving pharmaceutical agents, as many patients with less severe depression according to this guidance would be likely to commence talk therapy only, which does not carry the same risk for agitation and suicide	Thank you for your comment. The committee agreed that this may apply to some psychological treatments too, such as short-term psychodynamic psychotherapy, so have not amended this text.

335	SH	Royal College of Speech and Language Therapists'	Guideline	9	7	Section 1.2.11 The RCSLT recommends adding that the family and carer should also be vigilant for changes in language and communication. Literature reveals that associations between psychiatric illness and abnormalities of language and communication are common.In depression, published findings have included, for example, increased latency of response, decreased length of utterance, poor concentration, slow speech rate and monotonous pitch (1,2) and impairments in other aspects of verbal and non-verbal communication (2) which lead to reduction in communicative effectiveness.References1. Bryan K, Roach J. Assessment of speech and language in mental health. In: France J, Kramer S (eds). Communication and mental illness. London: Jessica Kingsley, 2001: 110-22.2. France J. Depression and other mood disorders. In: France J, Kramer S (eds). Communication and mental illness. London: Jessica Kingsley, 2001: 65-80.Furthermore, people who are depressed are reported to exhibit unwillingness to communicate and changes in voice. Reference Bozikas et al. (2007) Impaired perception for affective prosody and facial emotion perception in remitted patients with bipolar disorder. The Journal of Neuropsychiatry and Clinical Neurosciences, Vol. 19, No. 4, pp. 436-440.Jonathan Fine (2006) Language in Psychiatry. A handbook of Clinical Practice. EquinoxGlahn et al.	Thank you for your comment. As specified in the scope, the recognition, assessment and initial management section from the 2009 guideline was not included in this update. In line with NICE processes, the 2009 content has been carried across to this updated guideline. However, the evidence on recognition, assessment and initial management has not been reviewed, and recommendations could not be made about changes in language and communication in the context of diagnosis.

						(2007) study – 75% of asymptomatic patients had difficulties on at least four cognitive measures, and lithium had a negative effect on memory and speed of information processing (Glahn, 2007, Psychiatric Times, Vol. 24, no. 6).	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

336	SH	Parkinson's UK	Guideline	9	7	The proposed guideline encourages family members and carers of those with depression to be vigilant for "mood changes, agitation, negativity and hopelessness, and suicidal ideation." This is a considerable responsibility, especially given the high burden and risk of carer strain that family members and unpaid carers of people with Parkinson's face.We know that family members and unpaid carers of people with Parkinson's support their loved ones in managing a wide range of mental health symptoms, from depression to hallucinations and delusions.This can be distressing for family members and unpaid carers, taking a toll on their own mental health. In a recent survey of unpaid carers, we found that 65% experience anxiety and 62% depression (Parkinson's UK. 'Nobody really knows us: The state of health and social care for people with Parkinson's-related dementia', 2021, p. 4). This burden has been further heightened by the COVID-19 pandemic, with 70% of unpaid carers in the UK picking up even more care for older, sick, or disabled relatives (Carers UK. 'Research: The forgotten families in lockdown: unpaid carers close to burnout during Covid-19 crisis', https://bit.ly/31KCKA8, accessed 4 January 2022). We recommend the guideline states that health professionals should support unpaid carers and family members of those with depression in addressing their own mental health	Thank you for your comment. There is existing NICE guidance on supporting adult carers (identifying, assessing and meeting the caring, physical and mental health needs of families and carers), and a recommendation in the 'Supporting families and carers' section of the guideline cross-refers to this guidance.

						concerns, and signpost to relevant support services.	
337	SH	Psychological Professions Network	Guideline	9	19	Should include a wider range of methods of contact such as video calls	Thank you for your comment. Video calls has been added to the recommendation as another option.
338	SH	Royal College of Speech and Language Therapists'	Guideline	10	4	Section 1.2.14. People with cognitive and communication difficulties need to be supported by a speech and language therapist. The RCSLT recommend that this is added to the guideline. At present the mention of a "specialist" could deny this support for communication.	Thank you for your comment. The committee agreed that the term specialist may relate to the person's communication difficulties or to their specific condition, or to a communication specialist such as a speech and language therapist, and so agreed not to specify the role in this recommendation.
339	SH	Royal College of Speech and Language Therapists'	Guideline	10	10	Section 1.2.15 The RCSLT recommend adding that interventions should be tailored to the communication ability of the individual.	Thank you for your comment. The words 'ability to communicate' have been added to this recommendation.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

340	SH	Janssen	Guideline	10	013-020	We suggest that an additional bullet point is added regarding how the clinician intends to monitor progress of the patient and evaluate outcomes of treatment. This is an important consideration for the patient in terms of understanding how quickly they may respond to treatment and how this will be evaluated. This applies throughout the patient pathway and would help to ensure that there are no delays in progressing treatment across the pathway of care. We note reference is made in the Delivery of treatments section of the guidelines (Section 1.4) regarding individual treatments but suggest that it is also worth adding here, as a general point to ensure that this is considered at a higher level in discussing treatment options with patients.	Thank you for your comment. In response to stakeholder comments the committee agreed to include the PHQ-9 as an example of a scale that might be used to measure depression symptoms, given that it is the scale most widely used in UK clinical practice.
341	SH	British Psychological Society	Guideline	10	14	Rec 1.3.1 We welcome this point about what people think might contribute to the development of the depression and suggest that the guidelines advise that enquiries are also made about people's views regarding what helps/alleviates their depression. Suggested wording:What, if anything, they think might be contributing to the development of their depression and what they have noticed helps/alleviates their depression.	Thank you for your comment. This recommendation has been amended to include treatments that people have previously found helpful.
342	SH	Tavistock Relationships	Guideline	10	14	Rec 1.3.1 We welcome this point about what people think might contribute to the development of the depression and suggest that the guidelines advise also that enquiries are also made about	Thank you for your comment. This recommendation has been amended to include treatments that people have previously found helpful.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

						people's views regarding what helps/alleviates their depression.Suggested wording:what, if anything, they think might be contributing to the development of their depression and what they have noticed helps/alleviates their depression.	
343	SH	Royal College of General Practitioners	Guideline	10	21	Can the committee consider changing this recommendation to ensure that involvement of family members, carers or other supporters is offered by the health care professional, rather than only considered if the person asks for this. Many patients, particularly those who are struggling may not think to ask for this support which is often required and very helpful for both the person and the health care professional.	Thank you for your comment. This recommendation has been amended to make it more pro-active so not to rely on the person with depression to think of this themselves.
344	SH	Oxford Health NHS Foundation Trust	Guideline	10	21	Reduction in suggested time for assessment (30 minutes) does not fit with description of 'adequate' time to discuss treatment options	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective assessment of clients and delivery of low intensity interventions.
345	SH	Royal College of Speech and Language Therapists'	Guideline	10	21	The RCSLT supports the statement highlighting allowing extra time for initial discussions. This is critical to people and their families with communication needs to be able to understand different options and make their choices. It is important that this built into the proposal.	Thank you for your comment and support of this recommendation.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

346	SH	Psychological Professions Network	Guideline	10	21	Reduction in suggested time for assessment (30 minutes) does not fit with description of 'adequate' time to discuss treatment options. The adequate time needs to be longer to accommodate this	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective assessment of clients and delivery of low intensity interventions.
347	SH	British Psychological Society	Guideline	10	22	Rec 1.3.2 Involving family members, carers or other supporters is important and welcomed by many people. It can help the assessment and intervention but is not often even offered. This should not be limited to occasions when asked for by the person with depression as suggested in the guideline. Some people would find making this request too challenging and many people do not realise it is an option. Involving family members, carers or other supporters should be offered routinely. We suggest changing the wording to:Allow adequate time for the initial discussion about treatment options, and routinely offer to involve family members, carers or other supporters in contact with the person with depression.	Thank you for your comment. This recommendation has been amended to make it more pro-active so not to rely on the person with depression to think of this themselves.

348	SH	Tavistock Relationships	Guideline	10	22	Rec 1.3.2 Involving family members, carers or other supporters is important and welcomed by many people. It can aid the assessment and intervention yet is rarely offered or done. This should not be limited to occasions when requested by the person with depression as suggested in the guideline. Making such a request can be too challenging for some and many do not realise it is an option. Involving family members, carers or other supporters should be offered routinely. We suggest changing the wording to:Allow adequate time for the initial discussion about treatment options, and routinely offer to involve family members, carers or other supporters in contact with the person with depression.	Thank you for your comment. This recommendation has been amended to make it more pro-active so not to rely on the person with depression to think of this themselves.
349	SH	Independent Age	Guideline	10	24	Rec 1.3.3 - We welcome the additional guidance around recording people's views and preferences for other practitioners to see. Older people often have multiple interactions with health and care professionals for a range of issues. However, treatment preferences and views are not always recorded for different professionals to view. We hope that consistent recording and use of this information will mean older people receive more holistic and tailored support across the health and care pathway. This should include clear communication between health professionals and patients about what is being recorded, who else will be able to view it and the value of shared	Thank you for your comment and support for this recommendation.

						records for more tailored and accurate healthcare. In research for our 2020 report Minds that matter, many people in later life discussed the importance of continuity of care for building trusted relationships with GPs and enabling GPs to have a holistic and consistent view of their mental health. A greater degree of continuity of care from the same GP is the ideal, but we welcome this inclusion.	
350	SH	NHS Sheffield CCG	Guideline	10	026-027	We are concerned that this recommendation may be challenging to implement in practice.	Thank you for your comment. The recommendation to see the same healthcare professional includes the caveat 'wherever possible' as the committee recognised this would not always be possible.

351	SH	EFT International	Guideline	10	General	1.3 Patient Choice Many patients would choose the Combined Somatic and Cognitive Therapy, Emotional Freedom Techniques (EFT) if this were available to them, but it is not widely available within NHS services. It is lamentable that in the evidence reviews NICE has not even considered or analysed the substantial evidence that is available for EFT for Depression. We can supply a longer list of peer-reviewed published literature to NICE separately on request, but as an example from the top of the hierarchy of evidence, https://pubmed.ncbi.nlm.nih.gov/27843054/ "A Systematic Review and Meta-Analysis of Randomized and Nonrandomized Trials of Clinical Emotional Freedom Techniques (EFT) for the Treatment of Depression" Nelms & Castel, 2016, concluded, ****"The results show that Clinical EFT were highly effective in reducing depressive symptoms in a variety of populations and settings. EFT were equal or superior to TAU and other active treatment controls. The post-test effect size for EFT (d = 1.31) was larger than that measured in meta-analyses of antidepressant drug trials and psychotherapy studies. EFT produced large treatment effects whether delivered in group or individual format, and participants maintained their gains over time." (our emphasis)This was 2016 and there has been further evidence for EFT published since, in particular a pilot study directly	Thank you for your comment. The committee did not consider emotional freedom technique (EFT) to be an intervention that was in regular clinical use for the treatment of depression. Therefore these interventions were not specified in any of the review protocols and consequently the studies that you cite would not have met the inclusion criteria for the reviews. As such the evidence on emotional freedom technique (EFT) has not been appraised and the committee were not able to make any recommendations for the use of EFT.

						comparing EFT for Depression with CBT for Depression https://pubmed.ncbi.nlm.nih.gov/27330487/ "The Effectiveness of Cognitive Behavioral Therapy and Emotional Freedom Techniques in Reducing Depression and Anxiety Among Adults: A Pilot Study" Chatwin et al, 2016:"Findings revealed that both treatment approaches produced significant reductions in depressive symptoms, with the CBT group reporting a significant reduction post-intervention, which was not maintained with time. The EFT group reported a delayed effect involving a significant reduction in symptoms at the 3- and 6-mo follow-ups only." (Our emphasis)Results from this study were that symptom reduction in the CBT group were not maintained with time whereas reductions in symptoms in the EFT group improved with time. There are clear implications for relapse prevention.Given the immense impact that NICE Guidance has upon availability of patient choice, and in the light of the abundance of evidence for EFT for Depression that has not even been considered within this review process*, this omission could be considered negligent of NICE. It is likely that this negligence would have significant cost implications as well as implications on patient choice, because where research and analysis has compared the cost of EFT treatment with the cost of other therapies, including CBT, for example for	

						PTSD (within the 2018 review of the NICE guidance for PTSD, the NICE NMA, and elsewhere – details available on request), EFT has been shown to be highly cost effective. It is generally known to be effective in fewer sessions than needed for comparably effective therapies such as CBT.(*Searches were conducted in the Evidence Review documents using the term “Emotional Freedom Techniques”, for which no matches were found and “EFT”, which was only found in relation to emotional-focussed therapy – another therapy altogether -, the word ‘left’ and the name, “Hefting”.)We have not had the opportunity to contribute earlier in this process and therefore ask that evidence for EFT is now thoroughly considered and, at the very least, inclusion made of a research recommendation for EFT for Depression**, with a view to enhancing patient choice and making EFT more available within the NHS. **A precedent for this would be the NICE Guideline for PTSD 2018.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

352	SH	Parkinson's UK	Guideline	11	3	We welcome the guideline's emphasis on patient choice so that people can access the support they need, in a way that works for them. From our community, we know that many people with Parkinson's are not offered a choice in their treatment and the way they receive it. This is compounded by a persistent attitude among health professionals that mental health problems, including depression, are "just part of Parkinson's." This prevents people from receiving proper support, and sometimes referrals are not accepted for this reason (Parkinson's UK. 'Mental health matters too', 2018, p. 19). We are pleased to see the guideline's recommendation that health professionals should deliver remote appointments for those who need and choose them. For people with Parkinson's, the motor symptoms of the condition, together with inaccessible healthcare settings and regional variation of services, can make physically getting to appointments difficult. It is important that their mobility is considered when looking at the distance away and regularity of their treatment for depression. The significant waiting times for, under-resourcing of, and complex referral processes into, mental health services will prove a significant challenge to the implementation of this guidance. 1.6 million people are waiting for mental health support or treatment, and a further eight million people are	Thank you for your comment. People with depression and a chronic physical health problem, such as Parkinson's, are not within the scope of this guideline. Therefore it is not possible to make recommendations for people with Parkinson's in this guideline. CG91 on 'Depression in adults with a chronic physical health problem' covers identifying, treating and managing depression in people aged 18 and over who also have a chronic physical health problem such as cancer, heart disease or diabetes. Your feedback will be passed on to the NICE surveillance team so that people with Parkinson's who are experiencing depression can be considered for inclusion in future updates of CG91.

						unable to get on the waiting list because they are not deemed unwell enough to access care. (Mind. 'Mind responds to NICE draft guidelines for treatment of depression', https://bit.ly/336O7To, accessed 6 January 2022). Many people with Parkinson's report excessive waiting times for treatment after referral to mental health services by their GP. We have heard in many cases people waiting months rather than weeks, and in some cases over a year. One person waited 18 months to see a neuropsychologist and another was told the waiting list for a psychologist was over two years. In responses to a Parkinson's UK survey, many people with Parkinson's reported difficulty in receiving a referral to mental health services from their Parkinson's nurse or other members of their multidisciplinary team. (Parkinson's UK. 'Mental health matters too', 2018, p. 20). And this is likely to be further exacerbated by the pandemic.	
353	SH	British Psychological Society	Guideline	11	5	Rec 1.3.4 Suggest amend 'providing information on what treatments are available' to 'providing information on all treatments available' or practitioners may default to those with which they are most familiar.	Thank you for your comment. The following (second) bullet point states that the choice should be from all treatments recommended in the guideline, so we have not amended the first bullet point.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

354	SH	Tavistock Relationships	Guideline	11	5	Rec 1.3.4 Suggest amend 'providing information on what treatments are available' to 'providing information on all treatments available' or practitioners will likely default to those with which they are most familiar.	Thank you for your comment. The following (second) bullet point states that the choice should be from all treatments recommended in the guideline, so we have not amended the first bullet point.
355	SH	Sussex Partnership NHS Foundation Trust	Guideline	11	5	What info to be provided – link to NICE recommended info on benefits and harms	Thank you for your comment. A link has been added to take the reader to the 2 tables on treatment options which provides this information.
356	Individual	Individual 7	Guideline	11	005-007	Section 1.3.4If information is to be offered to patients about treatments and their expected outcomes, then practitioners need to have this information readily to hand. For example, in more severe depression, is CBT likely to be more beneficial than exercise? What is the effect of combining treatments? It would be useful to have this information available, perhaps on-line, where it can easily be accessed during a consultation.	Thank you for your comment. A link has been added to take the reader to the 2 tables on treatment options which provides this information.
357	SH	Janssen	Guideline	11	008-012	It is also important to note the timing of treatments being delivered to patients, in addition, to how the treatment will be delivered and where they will be delivered. When a treatment is likely to be delivered is an important consideration for a person with depression, especially if the person feels that they need immediate treatment options. We note that this is indirectly referred to in line 6 with the reference to waiting times but suggest that it would be clearer to call this out when	Thank you for your comment. Discussion of waiting times and how this may impact on choice of treatments is covered both in the recommendations on choice, and in more detail in the section of the delivery of psychological interventions, so we have not added more detail about waiting times.

						considering the choice of treatment in lines 8-12 as well.	
358	Individual	Individual 10	Guideline	11	10	1.3.4 Please could couple-based interventions be included in the choice of treatment options, i.e. amend this line to read 'individual, couple or group'	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA). The committee did not consider it appropriate to include couple in the recommendation referred to in your comment as the evidence and recommendation for behavioural couples therapy was for a subgroup of people with depression, unlike the other interventions covered by this recommendation. There are recommendations in the choice of treatment section of the guideline that people with depression should be given the option to include family members or carers in the discussion of treatment options, and to attend (some or all of) treatment with a family member or friend.

359	Individual	Individual 10	Guideline	11	10	1.3.4 Please could couple-based interventions be included in the choice of treatment options, i.e. amend this line to read 'individual, couple or group'	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA). The committee did not consider it appropriate to include couple in the recommendation referred to in your comment as the evidence and recommendation for behavioural couples therapy was for a subgroup of people with depression, unlike the other interventions covered by this recommendation. There are recommendations in the choice of treatment section of the guideline that people with depression should be given the option to include family members or carers in the discussion of treatment options, and to attend (some or all of) treatment with a family member or friend.

360	SH	British Psychological Society	Guideline	11	10	Rec 1.3.4 The phrase: - how they will be delivered (for example individual or group, face to-face or remotely) needs to include the option of couple therapy e.g. - how they will be delivered (for example individual, couple or group, face to-face or remotely)	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA). The committee did not consider it appropriate to include couple in the recommendation referred to in your comment as the evidence and recommendation for behavioural couples therapy was for a subgroup of people with depression, unlike the other interventions covered by this recommendation. There are recommendations in the choice of treatment section of the guideline that people with depression should be given the option to include family members or carers in the discussion of treatment options, and to attend (some or all of) treatment with a family member or friend.

361	SH	Tavistock Relationships	Guideline	11	10	Rec 1.3.4 The phrase: - how they will be delivered (for example individual or group, face to-face or remotely) needs to include the option of couple therapy e.g. - how they will be delivered (for example individual, couple or group, face to-face or remotely)	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA). The committee did not consider it appropriate to include couple in the recommendation referred to in your comment as the evidence and recommendation for behavioural couples therapy was for a subgroup of people with depression, unlike the other interventions covered by this recommendation. There are recommendations in the choice of treatment section of the guideline that people with depression should be given the option to include family members or carers in the discussion of treatment options, and to attend (some or all of) treatment with a family member or friend.
362	SH	British Psychological Society	Guideline	11	12	Rec 1.3.4 There should also be a clear choice to attend with a family member if preferred.	Thank you for your comment. The option to involve family members in discussions is already covered in an earlier recommendation in this section.

363	SH	Tavistock Relationships	Guideline	11	12	Rec 1.3.4 There should also be a clear choice to attend with a family member if preferred.	Thank you for your comment. The option to involve family members in discussions is already covered in an earlier recommendation in this section.
364	SH	Royal College of General Practitioners	Guideline	11	13	Whilst the RCGP agree that patients should be able to express their preference for the gender of the healthcare professional and the professional they know, it is essential that this is not promised, especially when emergency situations arise necessitating the health care professional who is available to work with the person at short notice, when preferences may not be realised. If patients are aware that their requests may not always be fulfilled, depending on staff availability, it will ensure expectations are managed more appropriately and that patients do not refuse help because their choice is not available, which may be detrimental to their care in an urgent situation. We would therefore request the addition of an additional recommendation highlighting that preferences will always be taken into account, but cannot always be realised, depending upon the clinical urgency and available staffing within the service at that time.	Thank you for your comment.The recommendation states that people have the option to express a preference for the gender of the healthcare professional, not that it must always be provided, so the committee agreed it was not necessary to add another recommendation stating this cannot always be realised.
365	SH	Psychological Professions Network	Guideline	11	13	The option does not imply that any response will be forthcoming from the service. It should offer something more such as 'where possible, the service should facilitate the meeting of preferences such as…'	Thank you for your comment.The recommendation states that people have the option to express a preference for the gender of the healthcare professional, but the committee agreed it would not always be possible to

							achieve this so the committee agreed not to make a stronger recommendation about this.
366	SH	NHS Sheffield CCG	Guideline	11	013-016	Although we agree with the potential benefit of this recommendation, we strongly think having it in the guidance is unnecessary. Patients may make demands which can't be met in practice.	Thank you for your comment.The recommendation states that people have the option to express a preference for the gender of the healthcare professional, but the committee agreed it would not always be possible to achieve this so the committee agreed not to make a stronger recommendation about this.
367	SH	British Psychological Society	Guideline	11	019-022	We support the recommendation for monitoring access to therapies.	Thank you for your comment and support of this recommendation.
368	SH	NICE quality standards & indicators team	Guideline	11	21	Is it possible to define 'a timely manner'?	Thank you for your comment. The committee agreed it was not possible or appropriate to include specific waiting time targets for psychological therapies in the guideline, but did add a reminder that the NHS constitution advises a maximum wait of 18 weeks to start treatment to the recommendations on waiting times for psychological treatments.
369	SH	Royal College of Speech and Language Therapists'	Guideline	12	003-011	Section 1.4.1 The RCSLT recommends adding consideration of communication needs. Approximately 60% of people accessing mental health services have communication difficulties. Therefore, before considering treatments,	Thank you for your comment. Consideration of the need to address any communication needs when delivering treatments has been added to this recommendation.

						consideration of communication needs must be taken into account. Reference: Walsh, I., Regan, J., Sowman, R., Parsons, B. and McKay, A.P., 2007. A needs analysis for the provision of a speech and language therapy service to adults with mental health disorders. Irish journal of psychological medicine, 24(3), pp.89-93	
370	SH	Voyage Care	Guideline	12	11	1.4.1 We agree with the list of things to consider when looking at treatment options but would like to add consideration of any social problems and consideration of any emotional problems as we know there is a correlation between depression and suicide and life events, poverty, isolation, domestic abuse, socioeconomic factors such as unemployment and debt.	Thank you for your comment. This section of the guideline is about delivery of treatments, but the consideration of contributors to depression are already covered in the earlier section of the guideline on initial assessment.
371	SH	We Are With You	Guideline	12	11	Specific reference to illicit substance use, use or misuse of prescribed medications and alcohol use should be prompted again as part of the treatment decision and not just at the assessment stage.	Thank you for your comment. The committee agreed that it was not necessary to repeat the consideration of the use of drugs (prescribed or illicit) and alcohol at multiple locations in the guideline.
372	SH	The Mindfulness Initiative	Guideline	12	13	We are concerned that there is separate guidance for people with learning disabilities which is from 2016 and does not include evidence-based treatments that may now be suitable for this population. In particular, there are more studies coming out of the US on the evidence of mindfulness-based interventions (MBIs) for people with learning disabilities, and autistic people. We hope that the emphasis on choice here will be	Thank you for your comment. People with learning disabilities were not included in the scope of this guideline as there is separate guidance relating to them. However, as you have informed us about new evidence relating to this group, this will be passed on to the NICE surveillance team who are responsible for ensuring guidelines are up to date.

						extended to those people currently in excluded categories covered by other guidelines. We note too that mindfulness and neurodiversity is a growing field within the UK.	
373	SH	The Mindfulness Initiative	Guideline	12	13	We note that the guidelines carve out postnatal depression and that there has been a significant increase in postnatal depression as a result of the Covid-19 pandemic[47]. The NICE clinical guidelines on antenatal and postnatal mental health precede the Covid-19 pandemic, so we ask that the treatment choices given throughout these new guidelines are also considered for women experiencing antenatal or postnatal depression.	Thank you for your comment. Women with antenatal or postnatal depression were not included in the scope of this guideline and so the evidence reviewed did not include these women. It is therefore not possible to suggest that the treatments suggested in the depression guideline can be extrapolated to postnatal depression. However, a link to the NICE guideline on antenatal and postnatal mental health has been included in the section of the guideline on the delivery of treatments, to remind healthcare professionals to consider the care of these women separately.
374	SH	Practice Plus Group	Guideline	12	19	I agree that a review is needed between 2 and 4 weeks after starting treatment but the wording “review how well the treatment is working” suggests there should be some improvement when this may not be the case and the purpose of this review is really to check for side effects or issues with psychotherapy rather than check it is working.	Thank you for your comment. The review is to check for improvement, if there is any. It is also to check for side-effects and concordance or other issues and these points are covered in the subsequent bullet points in this recommendation.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

375	SH	Janssen	Guideline	12	019-020	We are supportive of the inclusion of early assessment of whether a treatment is working between 2 and 4 weeks after starting treatment. This will ensure appropriate monitoring early on after treatment initiation and that adjustments or changes to treatment happen in a timely manner.	Thank you for your comment and support for this recommendation.
376	SH	Wellmind Health	Guideline	12	26	Rec 1.4.2 Routine outcome monitoring is recommended for consideration, however the use of clinical-grade digital therapeutics (DTx) for the treatment of depression, which have built-in outcome monitoring using validated outcome measures, is not mentioned in the guidelines for consideration as a treatment option.	Thank you for your comment. The committee were aware that the digital therapeutic tool you are referring to (Be Mindful) has been evaluated by NICE as part of the digital therapies it assessed for inclusion in the IAPT programme, and has not been recommended for further practice evaluation, so the committee did not refer to it in the guideline.
377	SH	Institute of Health Visiting	Guideline	12	General	Delivery of treatments should also include:Data sharing between agencies to support child safeguarding where applicableAssessment of risk to themselves and others (including consideration of the needs of dependent children where applicable using the 'Think Family' approach: https://www.myguideapps.com/projects/safeguarding/default/s2/context-of-NHS-safeguarding/s2-05.htmlRegular liaison with health and social care professionalsNICE Perinatal guidance (2014) https://www.nice.org.uk/guidance/cg192	Thank you for your comment. A link to the NICE guideline on antenatal and postnatal mental health has been included in the guideline to ensure that the management of depression in the perinatal period is not excluded, and this includes recommendations on integration between agencies.

378	SH	Institute of Health Visiting	Guideline	12	General	For all treatments for people with depression, it should include:If the depressed person is pregnant – consideration of safest treatment options and monitoring of the unborn baby.Considerations for the infant and impact on parenting if in the perinatal period	Thank you for your comment. Women with antenatal or postnatal depression were not included in the scope of this guideline and the committee agreed that prescribing to pregnant women or those who are breastfeeding would always need an individualised approach and the level of detail you suggest would not be appropriate to include in this guideline. However, a link to the NICE guideline on antenatal and postnatal mental health has been included in the section of the guideline on the delivery of treatments, to remind healthcare professionals to consider the care of these women separately.
379	SH	Voyage Care	Guideline	13	2	1.4.3 We agree people should be informed and kept informed about waiting lists and feel it is important this is communicated in writing, in a way that meets the communication needs of the person, and specific details provided on how to escalate their concerns and who to contact.	Thank you for your comment. The recommendation already includes advice on how to escalate concerns. The committee did not agree that this information could always be provided in writing, and communicating in a way appropriate to a person's needs is covered in the over-arching recommendation on providing information, so this recommendation has not been amended.
380	SH	NICE quality standards & indicators team	Guideline	13	2	Given that there may be waiting lists it would be helpful to confirm if there should be any reviews for people who are not taking antidepressant medication while they are waiting for psychological or psychosocial interventions to start.	Thank you for your comment. The committee have amended this recommendation to included more details of the support and information that should be provided to people who are waiting for psychological treatment, but agreed that it

							was not possible to specify exactly how often these reviews should occur.
381	SH	Oxford Health NHS Foundation Trust	Guideline	13	2	Waiting times should not exceed national targets e.g., IAPT 6 & 18 week targets	Thank you for your comment. The committee agreed not to include specific waiting times here as these may vary for different treatments, but did include the 18 week wait as per the NHS constitution in the recommendations on the waiting times for psychological treatments.
382	SH	Psychological Professions Network	Guideline	13	2	This is disappointing in a guideline on treatment – should be caveated that waiting lists should not exceed national targets i.e. IAPT and/or 18 week RTT.	Thank you for your comment. The committee agreed not to include specific waiting times here as these may vary for different treatments, but did include the 18 week wait as per the NHS constitution in the recommendations on the waiting times for psychological treatments.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

383	SH	Independent Age	Guideline	13	2	Rec 1.4.3 - We welcome this recommendation. In our 2020 report, Minds that matter, some older people spoke about experiencing long waits for treatment, particularly for talking therapies. Many of those who had to wait many weeks or months found that the wait further negatively impacted on their mental health. Our 2021 report Patiently Waiting, about the experience of long waits for elective healthcare, also found that people struggled with not knowing how long they would have to wait for treatment.[iii] Many older people highlighted that having an indication of when treatment might be, as well as receiving regular updates about their place on the waiting list, would make a positive difference to managing anxiety, preparing for treatment and coping with the wait.For some, long waiting times forced people to pay to have health treatment privately. However, this was limited to those who could afford it. Those who could afford private mental health support felt fortunate, but some also found they had to finish talking therapy prematurely because of the cost, potentially limiting progress or improvements. We believe that informing people about the wait time for treatment from the point of referral, and offering interim support such as self-help, could help limit further negative impact on people's mental health. We also welcome the provision of information on how to access help if a	Thank you for your comment and support for these recommendations. The committee have amended this recommendation to included more details of the support and information that should be provided to people who are waiting for psychological treatment, but agreed that it was not possible to specify exactly how often these reviews should occur. The committee have added a new recommendation to the end of this section of the guideline to advise that a discussion with people approaching the end of a course of psychological treatment may help them maintain their wellness beyond the end of the treatment.

						condition worsens while waiting for treatment. Such information should be provided in a range of formats, including non-digital versions. Similarly, some people may benefit from information or signposting at the end of a course of treatment like talking therapy. Some people told us about feeling unsupported, at a loss or even abandoned at the end of a set number of therapy sessions.	
384	SH	Janssen	Guideline	13	002-005	This is an important recommendation given that traditionally there have been long waiting times to access psychological and psychosocial interventions in some parts of the country. We are supportive of people with depression being kept informed, made aware of how to access help if their condition worsens and providing self-help material in the interim. We also believe that people with depression should also be offered more timely treatment options if their selected options are not available. Untreated depression can have significant consequences, especially with	Thank you for your comment. A separate recommendation for commissioners in the section of the guideline on choice, covers the timely delivery of treatments. If people do not wish to wait or their condition deteriorates then the recommendations already advise how to access additional help.

						people with more severe or worrisome depressive symptoms. We strongly urge the guideline committee to have a stronger recommendation around timely access to the patients' preferred treatments. If that timeline is not possible or unable to be met then we suggest that patients are offered alternative available options, like other types of psychological treatment or pharmacological treatments.	
385	SH	Greater Manchester Mental Health Services	Guideline	13	4	Negative side effects of psychological therapies should be part of discussion	Thank you for your comment. More detail on the features of different psychological therapies is included in Table 1 and Table 2 of the guideline so it has not been covered in this over-arching section on the delivery of psychological treatments.

386	SH	Wellmind Health	Guideline	13	4	Rec 1.4.3 The provision of self-help material is recommended for consideration in the interim for patients on waiting lists, but through the inclusion of digital therapeutic (DTx) CBT/MBCT courses in treatment options, the issue of waiting times for suitable patients to access treatment would be eliminated as access to digital therapeutic courses is immediate.	Thank you for your comment. The guideline recommends that people with depression are offered a choice about how all interventions will be delivered including options of face-to-face or remote delivery, and computerised CBT is included under self-help or self-help with support treatment options. However, the committee also discussed the importance of patient choice and problems associated with digital exclusion or digital poverty: some people may prefer a face-to-face intervention either because they are not comfortable using technology, because they lack the appropriate device or internet connection, lack a private and confidential space, or because of wider issues associated with difficulties in accessing services. The committee therefore recommended interventions be available via a range of different methods, and the methods of delivery should be guided by patient choice. The committee were aware that the digital therapeutic tool you are referring to (Be Mindful) has been evaluated by NICE as part of the digital therapies it assessed for inclusion in the IAPT programme, and has not been recommended for further practice evaluation, so the committee did not refer to it in the guideline.

387	SH	EFT International	Guideline	13	4	1.4.3 Wait times and self-help material. It is common knowledge that demand/need for therapy significantly exceeds supply and in this less than ideal situation, self-help material can be of some use. This is particularly the case with Emotional Freedom Techniques (EFT). Self-help material, lay support and peer support is extremely easily accessed and can be very effective. EFT can readily be taught to groups, empowering group members quickly and easily to access the self-help element of EFT. Anecdotally, where EFTi members have run EFT-based groups within NHS settings there has been a high group retention rate (which in the service concerned, was not the case with other group therapies). Practitioner training can also take place quite quickly.This has been mentioned within other comments, but we are asked that each comment stand alone without cross-references. NICE has, conceivably negligently, failed to consider EFT for Depression in spite of the existence of a significant body of evidence. We ask that it be considered now, in the light of the advantages of its availability for self-help. A list of references to peer-reviewed research on EFT for Depression can be supplied on request.	Thank you for your comment. The committee did not consider emotional freedom technique (EFT) to be an intervention that was in regular clinical use for the treatment of depression. Therefore these interventions were not specified in any of the review protocols and consequently the studies that you cite would not have met the inclusion criteria for the reviews. As such the evidence on emotional freedom technique (EFT) has not been appraised and the committee were not able to make any recommendations for the use of EFT.
388	SH	Sussex Partnership NHS	Guideline	13	13	Specify ‘Clinical supervision’	Thank you for your comment. This has been added.

		Foundation Trust					
389	SH	APPG for Prescribed Drug Dependence	Guideline	13	017-027	The new Safe Prescribing and Withdrawal Guideline recommends that a 'Management Plan' be created when prescribing drugs associated with dependence (P7, L19) – this should be included / referred to in this Guideline as part of 1.4.7 or 8 for consistency.	Thank you for your comment. This recommendation now includes the use of a management plan to ensure consistency with the safe prescribing guideline.
390	SH	The Association of Clinical Psychologists UK	Guideline	13	017-027	The new Safe Prescribing and Withdrawal Guideline recommends that a 'Management Plan' be created when prescribing drugs associated with dependence (P7, L19) – this should be included / referred to in this Guideline as part of 1.4.7 or 8 for consistency.	Thank you for your comment. This recommendation now includes the use of a management plan to ensure consistency with the safe prescribing guideline.
391	SH	Royal College of Speech and Language Therapists'	Guideline	13	019-028	Section 1.4.7. The RCSLT recommend adding Offer accessible written information, including easy-read, to all people.Gaining timely access to healthcare services often requires a high level of health literacy. People with communication difficulties are likely to have problems accessing and understanding information. As a result they are less likely to understand and access information about risks, harm and benefits.	Thank you for your comment. The provision of accessible written information is covered in the recommendations on the provision of information and support and in more detail in the NICE guideline on patient experience which is cross-referenced from here.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

392	SH	Sussex Partnership NHS Foundation Trust	Guideline	13	23	Evidence based guidance on harms	Thank you for your comment. The 'harms' in this recommendation is already further clarified to relate to side-effects and withdrawal effects. The side-effects would be specific to each drug or class of drug, and the withdrawal effects are explained in the subsequent section on stopping antidepressants.
393	SH	British Psychological Society	Guideline	13	023-025	We support the recommendation to advise people about both risks and benefits of medication. The possibility of loss of libido could also be mentioned as a potential side effect.	Thank you for your comment. A warning about the possible effects on sexual function has been added to this recommendation.
394	SH	Greater Manchester Mental Health Services	Guideline	13	24	Withdrawal effects as harm – symantic they are 'potential' and 'possible' and also modifiable and can be minimised with adherence to dosing regime – needs to be included	Thank you for your comment. The fact that withdrawal effects can be modified (the guideline uses the term 'minimised') and the importance of adhering to the medication are included in the following recommendation. The likelihood of withdrawal effects and the fact they are 'possible' are included in this recommendation.
395	SH	Practice Plus Group	Guideline	13	25	Need to include sexual side effects specifically here not just weight gain and sedation as they are more common and need to be more explicitly discussed.	Thank you for your comment. The possible effects on sexual function have been added to this recommendation

396	SH	Institute of Health Visiting	Guideline	13	General	Starting with antidepressant medicationTo include:HCP discussing individualising the risk (for pregnant women who are depressed especially) who are not wanting to take medication for the fear of the impact on their unborn baby. The risk of not taking medication (i.e., risk of suicide or risk of poor infant mental health with respect to both the parent and unborn baby/developing baby) NICE (2014) states the following information about risks and benefits should also be provided:A description of any uncertainty around any estimate of risk, harm or benefit. To use absolute values based on a common denominator (risk out of 100 or 1000 etc).Provide records of the consultation, in a variety of visual, verbal or audio formats and decision aids in a variety of formats which focus on personalised views of risks and benefits. Discuss the risks of becoming ill if a woman does not take medication.It is important that these are all considered in the decision-making process for the prescriber, the woman, the infant and her family.https://www.nice.org.uk/guidance/cg192When offering a person medication for the treatment of depression, consider whether they are pregnant or breastfeeding (for example fluoxetine) is present in breast milk at relatively high levels).https://cks.nice.org.uk/topics/depression-antenatal-postnatal/management/pregnant-on-an-antidepressant/	Thank you for your comment. Women with antenatal or postnatal depression were not included in the scope of this guideline and the committee did not make detailed recommendations on the use of antidepressants in pregnant or breastfeeding women because, as you have pointed out, this is already covered in the NICE guideline on antenatal and postnatal mental health.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

397	SH	Practice Plus Group	Guideline	14	1	Written information is often not practical – often more appropriate to signpost to a website with it rather than print it off for them	Thank you for your comment. This recommendation relates to written information about medication, and could include the patient information leaflet which is widely available, and so this recommendation has not been amended.
398	SH	Practice Plus Group	Guideline	14	7	Should specify if it is going to work “at that dose” as if there is no effect at e.g. 50mg sertraline it is reasonable to increase the dose	Thank you for your comment. The subsequent bullet point describes the process to check if the antidepressant is working and so the detail on dose has not been added to this recommendation.
399	SH	Janssen	Guideline	14	008-009	As noted in comment 6, there should be a stronger recommendation made around making routine clinical monitoring a requirement and how this is conducted with validated depression outcomes and a threshold of success is used. This will aid the appropriate use of all treatments (not just pharmacological options) and this will aid patient awareness of how their symptoms are evaluated and how the benefit of treatment is being assessed.	Thank you for your comment. The committee agreed that routine outcome monitoring was used more in psychological therapy practice including in IAPT, than in primary care or specialist mental health services. The committee agreed that the evidence on whether routine outcome monitoring improves outcomes was equivocal, but noted that it may be valued by people with depression. On this basis, the committee agreed to keep this recommendation as a 'consider'. In response to stakeholder comments the committee agreed to include the PHQ-9 as an example of a scale that might be used to measure depression symptoms, given that it is the scale most widely used in UK clinical practice.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

400	Individual	Individual 11	Guideline	14	13	As a carer of someone who gets wildly suicidal when starting a new antidepressant I think it needs to be stressed how potentially dangerous and sudden it can be. Also for my person the danger period is 2-6 weeks when the guidelines assume that issues with suicidality have settled. My person is also 28 and still when it happens can't perceive increased suicidality as an issue as for her it seems a sensible thing to do……. I would like to see more emphasis on the suicide risks in certain people and acknowledgement that when people are suicidal they need 24 hour care.	Thank you for your comment. The section of the guideline on risk assessment and management already includes advice on the topics you have described, so a cross-reference to this has been added from the section on antidepressant medication for people at risk of suicide.
401	SH	Voyage Care	Guideline	14	17	1.4.8. We are concerned there is no reference on what actions to take if the person takes more tablets than prescribed for example overdose that is intentional or unintentional.	Thank you for your comment. The section of the guideline on risk assessment and management already includes advice on considering the risk of overdose and so this information is not repeated here. The guideline does not provide specific detail on immediate action to be taken in the event of an overdose as this would be as per local standard clinical practice (for example, call an ambulance)
402	SH	NICE quality standards & indicators team	Guideline	14	18	Is it possible to define 'regular monitoring' to improve measurability? CG90 indicated this should be at intervals of 2 to 4 weeks in the first 3 months and longer intervals after that.	Thank you for your comment. The committee agreed that initially people should be monitored after 2 weeks and this is included in the recommendation (in a higher bullet point). Ongoing monitoring is more flexible and would depend on the person with depression so the committee agreed not to specify a minimal interval here.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

403	SH	Voyage Care	Guideline	14	20	1.4.8 We agree self- monitoring is important it should be recognised people would need further guidance and advice on how this can be achieved for example resources such as recording sheets, digital recording.	Thank you for your comment. The method of self-monitoring symptoms would depend on the person's preference and the committee had not reviewed evidence to show if any method was more effective than another, and so chose not to define or recommend a particular method.
404	Individual	Individual 7	Guideline	14	022-023	Section 1.4.8The wording suggests that it is not essential to continue treatment for at least 6 months. The recommendation should be stronger, to emphasise the crucial importance of a minimum 6-month period of treatment, perhaps: treatment should continue for at least 6 months after the remission of symptoms, and in some cases, longer. During this time, the treatment should be reviewed regularly.	Thank you for your comment. The recommended duration of antidepressant therapy is, as the recommendations state, usually 6 months after the remission of symptoms and this is included in the sections on starting antidepressant therapy and in the tables of treatment options. However, some people may wish to discontinue medication earlier, particularly if it is not effective, so this recommendation has not been strengthened. The need for regular review is already included in an earlier bullet point in this recommendation.
405	SH	Janssen	Guideline	14	022-024	We believe this is an important recommendation for a couple of reasons; this ensures that a patient has the correct expectation that they will need to continue treatment beyond remission to ensure that remission can be maintained indefinitely, and they are able to recover. We believe that 6 months is also an appropriate timeline for most people in remission to be considered as to whether they need to continue treatment with antidepressant medication or they are able to stop treatment based on available evidence and the majority of	Thank you for your comment and support of this recommendation.

						summary of product characteristics for oral antidepressants.	
406	SH	Institute of Health Visiting	Guideline	14	General	The guideline needs to highlight consideration for how taking antidepressant medication may impact on:PregnancyThe birthThe unborn babyThe parent and infant relationshipBreastfeedingThis will ensure that people have information on how taking antidepressant medication may affect their pregnancy or impact their unborn baby.The guideline should include 'safety-netting' advice i.e. when to seek urgent medical treatment for 'red flags'	Thank you for your comment. Women with antenatal or postnatal depression were not included in the scope of this guideline and the committee agreed that prescribing to pregnant women would always need an individualised approach and the level of detail you suggest would not be appropriate to include in this guideline. However, a link to the NICE guideline on antenatal and postnatal mental health has been included in the section of the guideline on the delivery of treatments, to remind healthcare professionals to consider the care of these women separately.
407	SH	British Psychological Society	Guideline	15	001-019	We support the provision of information about potential withdrawal effects of medication.	Thank you for your comment and support of these recommendations.
408	SH	Royal College of General Practitioners	Guideline	15	3	Rather than GP, can we request that the wording is changed to "primary care health care professional". Increasingly, non GP members of the team are prescribing for patients in primary care and it is essential that the whole team is recognised in national clinical guidance.	Thank you for your comment. GP has been amended to 'primary healthcare professional'.

409	SH	Voyage Care	Guideline	15	6	1.4.10 We feel self- monitoring should be recommended.	Thank you for your comment. Self-monitoring symptoms is included in the recommendations on starting antidepressant medication, and person-led withdrawal is included in subsequent recommendations on stopping antidepressants so no addition about self-monitoring has been added to this recommendation.
410	Individual	Individual 7	Guideline	15	007-019	Section 1.4.11It's not helpful simply to give a list like this. There needs to be context, with information on which symptoms are most common and most unpleasant and which are unlikely to occur.	Thank you for your comment. The evidence the committee reviewed to develop this list was based on a mixed methods review conducted as part of the development of the NICE guideline on safe prescribing. The quantitative part of this review compared withdrawal effects with antidepressants compared to placebo or continuing on medication, and so did not allow for an overall ranking by frequency to be constructed. The unpleasantness of symptoms is subjective and so it would not be possible to rank them by unpleasantness. However, the committee made some adjustments to the order so that the 'most likely' withdrawal effects (based on their expertise) were at the top of the list.
411	Individual	Individual 7	Guideline	15	020-024	Section 1.4.12Patients should be informed that withdrawal symptoms are not signs of addiction.	Thank you for your comment. As antidepressants are not addictive (tolerance or cravings do not occur), and the recommendations focus on withdrawal, the committee agreed it was not necessary to state that they are not addictive.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

412	SH	Mind	Guideline	15	020-024	Rec 1.4.12 - We welcome that this recommendation highlights that withdrawal symptoms from anti-depressants can last “several weeks, occasionally several months”. We are however concerned that this paragraph does not fully reflect the draft guidelines for Medicines associated with dependence or withdrawal symptoms: safe prescribing and withdrawal management for adults which states that “withdrawal can be difficult, and may take several months or more.” Instead these guidelines currently emphasise that usual withdrawal period is within one to two weeks, and that it can “occasionally” take several months. We recommend that this paragraph on withdrawal from anti-depressants reflects the draft guidelines for Medicines associated with dependence or withdrawal symptoms: safe prescribing and withdrawal management for adults and state:Explain that while withdrawal symptoms can be mild, appear within a few days of reducing or stopping antidepressant medication, and go away within 1 to 2 weeks, withdrawal can be difficult and take several months or more. Explain that symptoms can be severe, particularly if the antidepressant medication is stopped suddenly.	Thank you for your comment.The committee have amended the wording of this recommendation to bring it in-line with the NICE guideline on Safe prescribing.

413	SH	APPG for Prescribed Drug Dependence	Guideline	15	020-024	1.4.12: This is an out-of-date definition. Whilst the 2009 version of the guideline originally stated that "[withdrawal] symptoms are usually mild and self-limiting over about 1 week", following representations in 2019 (and the revelation that the '1 week' claim was not evidence based), the guideline was updated to reflect current evidence that such symptoms can last for much longer. The updated wording, which was supported by the Royal College of Psychiatrists, Public Health England, and other stakeholders, was: "1.9.2.2 Explain that whilst the withdrawal symptoms which arise when stopping or reducing antidepressants can be mild and self-limiting, there is substantial variation in people's experience, with symptoms lasting much longer (sometimes months or more) and being more severe for some patients [2019]" A summary of some of the evidence upon which this update was based was published in the BMJ in May 2019: https://www.bmj.com/content/365/bmj.l2238/rrThe BMJ also reported on the 2019 update here: https://www.bmj.com/content/367/bmj.l6103In this latest proposed version, however, similar wording to the 2009 version has re-appeared, and the information that symptoms can last for months or more, has been lost. This is at variance with the growing evidence base for protracted withdrawal (just two examples being cited below):	Thank you for your comment. The information that withdrawal symptoms can last for months or more has not been lost, but this recommendation has now been amended to ensure this is made even more clear, and to ensure it is in-line with the Safe prescribing guideline, as you suggest.

						http://prescribeddrug.org/wp-content/uploads/2018/10/APPG-PDD-Survey-of-antidepressant-withdrawal-experiences.pdfhttps://journals.sagepub.com/doi/full/10.1177/2045125320980573The proposed reversal of the 2019 update will, if realised, effectively remove all acknowledgement of protracted (>6 months) withdrawal, and will, contrary to the evidence, deny the experiences of a very large and international prescribed-harm patient campaigning community.Please revert to the 2019 wording and ideally, ensure consistency with the Safe Prescribing and Withdrawal Guideline to avoid confusion.	
414	SH	The Association of Clinical Psychologists UK	Guideline	15	020-024	1.4.12: This is an out-of-date definition. Again for consistency it should be based on the one to be used in the new draft guideline on Safe Prescribing and Withdrawal (P14, Section 1.5.9, L18 onwards) e.g.Explain that withdrawal can be difficult and may take several months or more. Withdrawal symptoms do not affect everyone, and it is not possible to predict who will be affected. They vary	Thank you for your comment.The committee have amended the wording of the recommendations to bring them in-line with the NICE guideline on Safe prescribing, and to include the variability in type and duration of symptoms that may be experienced

						widely in both type and severity, can be physical or psychological, vary in intensity, change over time and can last for months or longer.	
415	SH	Institute of Health Visiting	Guideline	15	General	Stopping antidepressant medicationFor pregnant women/ people, to include:Treatment options which support breastfeeding and the health and wellbeing of the unborn baby Before starting, stopping or switching antidepressant treatment during pregnancy, seek advice, ideally from a specialist perinatal mental health team, where available; or from a secondary mental health service. Ensure an individualised approach to care and risk management are taken. Consider risk of relapse/ deterioration and ability to cope with pregnancy or parenting and their own emotional health.	Thank you for your comment. Women with antenatal or postnatal depression were not included in the scope of this guideline and the committee agreed that prescribing to pregnant women would always need an individualised approach and the level of detail you suggest would not be appropriate to include in this guideline. However, a link to the NICE guideline on antenatal and postnatal mental health has been included in the section of the guideline on the delivery of treatments, to remind healthcare professionals to consider the care of these women separately.
416	SH	The Mindfulness Initiative	Guideline	16	3	We welcome the guidance on supporting people who wish to stop taking antidepressant medication, but this section read in isolation does not seem to recommend other treatment alternatives (such as Mindfulness-Based Cognitive Therapy (MBCT)) which would provide additional support with tapering off the medication, and an alternative for the person to prevent relapse of their symptoms. Given MBCT is recommended as a treatment to prevent the relapse of depression by NICE, we recommend that is made clear in this	Thank you for your comment. The committee recognised that there is some evidence that psychological interventions might help people taper antidepressants but the evidence base is limited and trials were designed to measure relapse prevention, not withdrawal from medication. On this basis the committee did not feel able to recommend MBCT to support stopping antidepressant medication, but MBCT remains an option for preventing relapse in those assessed as being at higher risk of relapse.

						section that the options for supporting people withdrawing from medication include offering MBCT and other evidence-based prevention treatments. This strengthens a person's decision making around their continued management options for depression, rather than only focussing support on their withdrawal from medication.	
417	SH	British Psychological Society	Guideline	16	004-021	We support the recommendations about support for paced withdrawal of medication.	Thank you for your comment and support of this recommendation.
418	SH	Royal College of General Practitioners	Guideline	16	11	It is important to note that liquid preparations are not able to be prescribed in primary care in many instances due to the prohibitive costs and this is restricted by CCG/ICS prescribing teams. This approach may therefore require patients to be refered back into mental health services to enable this approach to be taken.	Thank you for your comment. The committee discussed that liquid preparations were available for a number of antidepressants and should be used where possible as this was a more accurate method of reducing doses than splitting tablets. The committee were also aware that these preparations are more expensive but agreed that including them in the guideline would encourage their wide availability to prescribers. However, they have modified their recommendations to now state that they should be prescribed where slow tapering cannot be achieved with tablets or capsules.

419	SH	NHS Nottingham and Nottinghamshire CCG	Guideline	16	11	1.4.14 – This recommendation will be challenging in practice because many antidepressants aren't available in licensed liquid preparations. Concerned this may increase prescribing of expensive and unlicensed specials.	Thank you for your comment. The committee discussed that liquid preparations were available for a number of antidepressants and should be used where possible as this was a more accurate method of reducing doses than splitting tablets. The committee were also aware that these preparations are more expensive but agreed that including them in the guideline would encourage their wide availability to prescribers. However, they have modified their recommendations to now state that they should be prescribed where slow tapering cannot be achieved with tablets or capsules.
420	SH	Voyage Care	Guideline	16	24	1.4.15 We feel self-monitoring should be recommended.	Thank you for your comment. Self-monitoring symptoms is included in the recommendations on starting antidepressant medication, and person-led withdrawal is included in subsequent recommendations on stopping antidepressants so no addition about self-monitoring has been added to this recommendation.
421	SH	British Psychological Society	Guideline	17	012-014	We support reassuring people about withdrawing medication.	Thank you for your comment and support of this recommendation.
422	SH	Royal College of General Practitioners	Guideline	17	27	Rather than GP, can we request that the wording is changed to "primary care health care professional". Increasingly, non GP members of the team are prescribing for patients in primary care and it is essential that the whole team is recognised in national clinical guidance.	Thank you for your comment. GP has been amended to 'primary healthcare professional'.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

423	SH	British Psychological Society	Guideline	18	005-022	We support the modified recommendation about monitoring for potential suicide risk when starting antidepressants in younger people.	Thank you for your comment and support of this recommendation.
424	Individual	Individual 11	Guideline	18	11	As a carer of someone who gets wildly suicidal when starting a new antidepressant I think it needs to be stressed how potentially dangerous and sudden it can be. Also for my person the danger period is 2-6 weeks when the guidelines assume that issues with suicidality have settled. My person is also 28 and still when it happens can't perceive increased suicidality as an issue as for her it seems a sensible thing to do……. I would like to see more emphasis on the suicide risks in certain people and acknowledgement that when people are suicidal they need 24 hour care.	Thank you for your comment. The section of the guideline on risk assessment and management already includes advice on the topics you have described, so a cross-reference to this has been added from the section on antidepressant medication for people at risk of suicide.
425	SH	University of Nottingham Health Service	Guideline	18	11	I work in a university health service and start countless patients on SSRI medication. Whilst I understand there is a small risk of an increase in suicidal ideation in patients under 25 years, mandating that they are all reviewed within 7 days anecdotally feels like a huge waste of precious clinical time and resource.Why not restructure the guidance to state that patients should be carefully counselled about the risk of increased suicidal ideation and safetynetted to see a medical professional if suicidal ideation increases shortly after starting an SSRI?What is the cost-effectiveness analysis of this recommendation as it stands? I am concerned that the cost of GP time in	Thank you for your comment. The committee did not remove the requirement for a review after 1 week when starting antidepressants for people at risk of suicide as they agreed this was a part of the important safety-netting you suggest for these people. The recommendation has however, been amended to include a cross-reference to the section of the guideline on risk assessment and management as this includes more details on strategies to reduce risk.

						this recommendation is not properly accounted for.	
426	SH	University of Nottingham Health Service	Guideline	18	12	Again mandating all patients to be reviewed within 7 days of a dose change is simply not practical in general practice given the current demands. I cannot believe that this is a cost effective recommendation. This recommendation is again setting GP up to fail. Please remove this requirement from the guidance.I would recommend NICE remove 'ideally in-person' given there is a global pandemic at present.	Thank you for your comment. The committee did not remove the requirement for a review after 1 week when increasing the dose of antidepressants for people at risk of suicide as they agreed this was a part of risk management for these people. The recommendation states 'ideally in-person' but alternative options are given as well so this has not been changed.
427	SH	British Psychological Society	Guideline	19	007-011	We support taking the risk of medication to older people more seriously.	Thank you for your comment and support of this recommendation.
428	SH	British Psychological Society	Guideline	19	014-017	We support taking the risk of lithium more seriously for older people.	Thank you for your comment and support for these recommendations.

429	SH	Institute of Health Visiting	Guideline	19	General	Lithium – to include:If a woman is planning a pregnancy or is of reproductive age – a discussion about lithium and the increased risk this carries should be discussed. The risks and benefits of all the options should be considered alongside the need for additional monitoring during pregnancy, during birth and postnatally (to include monitoring of the baby) Preconception planning is very important – women should have a care plan in place (see guidance below):https://www.nice.org.uk/guidance/ng201https://www.nice.org.uk/guidance/ng194https://www.tommys.org/pregnancy-information/planning-a-pregnancy/are-you-ready-to-conceive/bipolar-disorder-and-planning-pregnancy	Thank you for your comment. An additional recommendation has been added to highlight the need for caution in women of reproductive age, preconception planning and additional monitoring.
430	SH	NHS Sheffield CCG	Guideline	19	General	Additional monitoring: we suggest that after line 27, another line is added to state 'significant change in person's sodium or fluid intake'.	Thank you for your comment. Consideration of a person's hydration status is already included in the following recommendation so the committee have not repeated it here, and this also ensures the recommendations in the depression guideline are consistent with those in the NICE bipolar guideline.
431	SH	NHS Nottingham and Nottinghamshire CCG	Guideline	20	22	Rec 1.4.27 – This recommendation will be challenging in practice because not every Area Prescribing Committee has classified lithium as a shared care medicine.	Thank you for your comment. The committee agreed that shared care prescribing of lithium was best practice and so have not changed this recommendation.

432	SH	Parkinson's UK	Guideline	20	54	The guideline's emphasis on collaborative care, and specifically consideration of a person's mental and physical health, represents a welcome step forward. However, we recommend that NICE expand this section to ensure this consideration includes the specific ways in which mental and physical symptoms interplay among those with neurological conditions such as Parkinson's. This is especially important given the high prevalence of depression among these populations. Depression can be part of, or contribute to, Parkinson's motor and non-motor related symptoms. They are complicated and intertwining, making recognising and diagnosing Parkinson's symptoms difficult for health professionals. A physical symptom, such as loss of facial expression, may appear as depression in someone who is not depressed. Conversely, a person with Parkinson's experiencing verbal communication issues may have this attributed to a physical symptom because of their Parkinson's, as opposed to being caused by anxiety or depression. As such, the provision of integrated, multidisciplinary care is especially important for people with Parkinson's experiencing depression.	Thank you for your comment. People with depression and a chronic physical health problem, such as Parkinson's, are not within the scope of this guideline. Therefore it is not possible to make recommendations for people with Parkinson's in this guideline. CG91 on 'Depression in adults with a chronic physical health problem' covers identifying, treating and managing depression in people aged 18 and over who also have a chronic physical health problem such as cancer, heart disease or diabetes. Your feedback will be passed on to the NICE surveillance team so that people with Parkinson's who are experiencing depression can be considered for inclusion in future updates of CG91.
433	SH	NHS Nottingham and Nottinghamshire CCG	Guideline	21	1	1.4.30 – Concerned that this recommendation may imply that lithium can't be withdrawn in primary care with specialist advice. If a specialist is supervising withdrawal that suggests the patient	Thank you for your comment. This recommendation has been clarified to state that stopping lithium should be done with the advice of a specialist, so this does not preclude it from being stopped in primary care.

						must be re referred which presents service and capacity challenges.	
434	SH	NHS Sheffield CCG	Guideline	21	001 - 002 - 003	Rather than 'under' their supervision, could we add 'under' their advice? This allows for more a flexible approach in primary care.	Thank you for your comment. This recommendation has been clarified to state that starting and stopping lithium should be done with the advice of a specialist.
435	Individual	Individual 7	Guideline	21	4	Use of antipsychoticsFirst-generation antipsychotics should be avoided as they are associated with a high incidence of extrapyramidal side effects when used in the treatment of affective disorders.Some antipsychotics, particularly olanzapine, have a high risk of weight gain and cardiometabolic effects. The drugs that are likely to cause these problems should be identified in order of risk. Similarly, some drugs are more likely to prolong the cardiac QT interval and are contraindicated with antidepressants that also cause QT prolongation. A table identifying these drugs and risks would be very useful.	Thank you for your comment. The recommendations provide advice on how often to monitor weight and cardiometabolic markers, and the potential interaction with other drugs likely to prolong the QT interval is also covered by the recommendations. The choice of antipsychotic for an individual patient is a clinical decision and the relevant information on drugs and risks is already included in the BNF and so has not been repeated in the guideline.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

436	SH	British Psychological Society	Guideline	21	004-026	Regarding off-label antipsychotics: We are concerned that the absence of advice against prescribing antipsychotics for depression may encourage it, especially in light of the (justified) caution about prescribing antidepressants. Although both types of medication pose risks, antipsychotics are potentially the more harmful, and therefore it is important that these guidelines (a) advise against starting them, and (b) provide a hierarchy if medication is to be prescribed, starting with those that have lower risks. Clinicians should be aware of any psychological and social therapies available in their locality and offer the maximum choice of treatment options.	Thank you for your comment. This section of the guideline covers the practical aspects of prescribing, monitoring and stopping antipsychotics. More detail on the indications for antipsychotics are included in the later sections of the guideline on treatment for different types and severity of depression and there is no suggestion they should be prescribed in preference to psychological and social therapies where these would be more appropriate. The choice of antipsychotic for an individual patient is a clinical decision and the relevant information on drugs and relative risks is already included in the BNF and so has not been repeated in the guideline.
437	SH	Janssen	Guideline	21	005-006	This statement should be clarified, as all antipsychotics do not have market authorisations for the use of depression apart from quetiapine.	Thank you for your comment. The statement makes it clear that this is '…an off-label use for some antipsychotics.'
438	SH	NHS Nottingham and Nottinghamshire CCG	Guideline	21	7	1.4.31 – Concerned that this recommendation implies that physical health monitoring may not be necessary for patients prescribed antipsychotics for depression. I think this needs to be more explicit.	Thank you for your comment. This recommendation has been strengthened to clarify that this monitoring is recommended and not optional.
439	SH	NHS Sheffield CCG	Guideline	21	012-013	Why use 'consider' if the SPC states to undertake the following monitoring?	Thank you for your comment. This recommendation has been strengthened to clarify that this monitoring is recommended and not optional.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

440	SH	Greater Manchester Mental Health Services	Guideline	21	18	Baseline ECG recording is a requirement for all patients started on antipsychotics irrespective of cardiac risk.	Thank you for your comment. The committee agreed that ECGs would not be carried out on all patients before starting an antipsychotic as this would depend on the actual drug used, and would not be feasible in all situations, so they did not amend this recommendation.
441	SH	NHS Sheffield CCG	Guideline	21	09-011	Kindly add more detail as to when this is needed	Thank you for your comment. This recommendation has been strengthened to clarify that this monitoring is recommended and not optional.
442	SH	Institute of Health Visiting	Guideline	21	General	Use of antipsychoticsConsideration should be given to whether the person is pregnant or is responsible for the care of infants and young children.	Thank you for your comment. Women with antenatal or postnatal depression were not included in the scope of this guideline and the committee agreed that prescribing to pregnant women would always need an individualised approach and the level of detail you suggest would not be appropriate to include in this guideline. However, a link to the NICE guideline on antenatal and postnatal mental health has been included in the section of the guideline on the delivery of treatments, to remind healthcare professionals to consider the care of these women separately.
443	SH	NHS Sheffield CCG	Guideline	21	General	We acknowledge the usefulness of not specifying who does the monitoring. That is quite helpful for primary care.	Thank you for your comment and support for these recommendations.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

444	SH	NHS Nottingham and Nottinghamshire CCG	Guideline	22	6	1.4.32 – Concerned that this recommendation implies that antipsychotics must be managed under shared care. This then implies that any patient prescribed antipsychotics can never be discharged from the specialist which presents huge capacity and service issues for specialist mental health services.	Thank you for your comment. The committee agreed that managing antipsychotic prescribing under shared care arrangements was best practice and so they have not amended this recommendation. However, this does not preclude primary care services from starting or stopping antipsychotics with specialist advice.
445	Individual	Individual 7	Guideline	22	6	Section 1.4.32This recommendation is vague. More clarity is needed. Antipsychotics should be co-prescribed with an antidepressant only in consultation with a consultant psychiatrist or a specialist mental health pharmacist.	Thank you for your comment. The committee agreed that managing antipsychotic prescribing under shared care arrangements was best practice and so they have not amended this recommendation. However, the detail of the shared care arrangement and whose advice should be sought, would be decided by local implementation of shared care arrangements
446	SH	NHS Nottingham and Nottinghamshire CCG	Guideline	22	11	1.4.34 - Concerned that this recommendation may imply that antipsychotics can't be withdrawn in primary care. We know that some patients wouldn't wish to be referred to specialist mental health services if there has been a sustained period of stability. This also presents huge capacity issues for specialist services if every patient on an antipsychotic must be referred back to them to have it withdrawn.	Thank you for your comment. The committee agreed that managing antipsychotic prescribing under shared care arrangements was best practice and so they have not amended this recommendation. However, this does not preclude primary care services from starting or stopping antipsychotics with specialist advice.
447	SH	NHS Sheffield CCG	Guideline	22	011 – 012 - 013	Rather than 'under' their supervision, could we add 'under' their advice? This allows for more a flexible approach in primary care.	Thank you for your comment. This recommendation has been clarified to state that stopping antipsychotics should be done with the advice of a specialist.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

448	SH	Practice Plus Group	Guideline	22	18	Can add but the evidence for exercise outdoors is stronger and the evidence for outdoor light is strong for improving sleep which may improve depression	Thank you for your comment. In response to stakeholder comments, the committee supported less intense 'move more' exercise for general wellbeing (although not as a treatment for depression) and made a new recommendation to reflect this. The recommendation also emphasised the benefits of outdoors activities. The committee also recognised that people with depression may benefit from general activities to promote wellbeing, and added a new recommendation to advise people that maintaining a healthy lifestyle (for example, eating a healthy diet, not over using alcohol, getting enough sleep) may improve their mood.

449	SH	The Mindfulness Initiative	Guideline	22	020-021	We recommend that the term 'less severe depression' includes subthreshold symptoms, mild and moderate depression (emphasis added). Evidence from psychological therapy trials maps onto subthreshold/mild/moderate depression, and so these levels of depression should be categorised together, with 'severe depression' then being a category in its own right. We strongly urge for the mindfulness-based treatments within this section to be extended to people experiencing moderate as well as mild depression. To take moderate depression out of the definition of less severe depression could restrict people's access to treatments such as MBCT that are effective and non-stigmatising.	Thank you for your comment. The committee considered the distinction between less severe (subthreshold/mild) and more severe (moderate/severe) depression to be clinically meaningful in terms of supporting effective clinical decision making and being aligned with how clinicians conceptualize depression (in particular, GPs and other primary care staff, given that the majority of people with depression and almost all first line presentations of depression are managed in primary care). Based on this distinction, an anchor point of 16 on the PHQ-9 was selected as the cut-off between less severe and more severe depression, on the basis of alignment with the clinical judgement of the committee and eligibility criteria in the included studies. Published standardization of depression measurement crosswalk tables (Carmody 2006; Rush 2003; Uher 2008; Wahl 2014) were used in order to 'read-across' different symptom severity scales that were used in different studies. The committee did not consider it appropriate to recommend a mindfulness/meditation group intervention for those with more severe depression (the traditional categories of moderate and severe depression) as there was

							only evidence from 15 participants randomised to mindfulness/meditation group included in the NMA for more severe depression. This intervention could also not be included in the economic model as it had been tested on less than 50 participants, and the committee decided to look only at treatments tested on at least 50 participants across RCTs included in each NMA, after looking at the total size of the evidence base in this area (treatment of a new episode of depression) and noticing that there were several treatment classes with larger volume of evidence.
450	SH	University of Nottingham Health Service	Guideline	23	7	What is the evidence for suggesting a review of these patients 'normally within 2 weeks'. This is not achievable in most general practices – especially given the pressure primary care is under at the moment. For patients with less severe	Thank you for your comment. The committee agreed that 2 weeks would be an appropriate time, but have added the caveat 'normally' to allow some flexibility.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

						patients reviewing them within 4 weeks is perfectly reasonable.	
451	SH	UK Mindfulness Centres Collaboration	Guideline	23	18	We support the inclusion of a range of treatment options as first-line treatments for less severe depression.	Thank you for your comment and support of these recommendations.
452	SH	UK Mindfulness Centres Collaboration	Guideline	23	18	The inclusion of Mindfulness Based Cognitive Therapy in this section is welcome and rightly recognises the evidence that MBCT is effective for people experiencing a current episode of depression.	Thank you for your comment and support of these recommendations.
453	SH	British Society of Lifestyle Medicine	Guideline	23	21	Rec 1.5.3 - We welcome this recommendation and the recommended first-line treatment options, but recognise that availability may be lacking or incur very long waiting lists	Thank you for your comment. The committee were keen to ensure that the evidence-based treatments they recommended were available, as you suggest, and so have added a new recommendation in the section on choice about the timely availability of treatment.

454	SH	Independent Age	Guideline	23	21	Rec 1.5.3 - We strongly welcome this recommendation. There is a wealth of evidence that older people are often prescribed antidepressants or other medication as a first-line response to depression, without the offer of alternative forms of treatment, when often this is not their preference. NHS research has found that among people with depression, older people are six times more likely than younger people to be on medication.[iv] This is despite evidence that people in later life generally report a preference for talking therapy over medication, particularly for low-level mental health symptoms.[v] The same study found that some health professionals make assumptions around older people's treatment preferences - assuming that many older people will not engage with talking therapy or be able or willing to engage with remote/online support options. Findings from our Minds that matter report highlighted a belief among some older people that there is no point going to the GP for their mental health as they would only be offered medication. Several of the older people interviewed spoke about their reluctance to take medication to improve their mental health. Reasons included the fact that some were already taking a large amount of medication for other health issues, concerns about side effects and interactions with other medications, a preference for other support options such as	Thank you for your comment. The recommendations relate to all people with depression, including older people, who should be offered the same choice of treatments as younger people, and this would include combination therapy. In addition, the committee recognised there may be issues with accessing treatment for older people and so have included separate recommendations in the section on access, with the aim of reducing stigma and discrimination and improving access for certain groups, including older people.

						talking therapy, and the stigma around taking certain medications like antidepressants. We further recommend that the guidance explicitly emphasise the importance of offering choice of different forms of support to patients, including referrals or signposting to talking therapy but also other forms of support where appropriate, such as social prescribing and bereavement counselling. This should specify the importance of avoiding assumptions around older people's treatment delivery preferences, such as remote therapy and other digital support options. In addition, some people benefit from a chosen combination of interventions – such as medication and talking therapy – so ideally a range of options would be embedded in patient offers.	
455	SH	British Psychological Society	Guideline	23	021-022	We support the recommendation not to routinely start people on antidepressants as a first line treatment for mild depression.	Thank you for your comment and support of these recommendations.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

456	SH	Janssen	Guideline	23	021-022	We are concerned by this statement and although acknowledging the ambition, we worry that this could lead to poorer patient outcomes given the limited capacity and the current limited availability of psychological and psychosocial treatment options. We worry that not routinely offering antidepressant medication as a first line treatment will mean that in reality people with depression get no treatment while they wait to access talking therapies. We also note that this recommendation is not necessarily backed up by the evidence in Evidence Review B,C and D, where the evidence for the majority of psychological treatment options is not consistent with the level or amount of antidepressant evidence. For example, as seen in page 82-85 of Evidence Review B. Given the general uncertainty in the evidence base and therefore cost effectiveness, we do not believe the evidence is strong enough to exclude the use of antidepressants as a first line treatment option here for people with a new episode of less severe depression. At the very least people with depression should be offered both talking therapies and antidepressants and then presented with the risks, benefits and availability of all treatment options.	Thank you for your comment. Based on their overall review of the clinical evidence the committee agreed that some treatment classes and interventions appeared to be more effective than others, but there was otherwise little to choose between treatments. The committee therefore reviewed the results of the health economic modelling which determined which treatments appeared to be cost-effective, and used this to develop a suggested prioritisation of which treatments should be offered to people with depression, or considered for use. Based on the clinical and cost-effectiveness evidence, the potential for side effects, and the knowledge and experience of the committee, it was agreed that antidepressants should not be routinely offered as a first-line treatment for less severe depression. However, the recommendation includes the exception that antidepressants can be offered if that is the person's preference, and SSRIs are included in the treatment options in Table 1 although they appear relatively low in the suggested order in which they should be considered based on the committee's interpretation of their clinical and cost effectiveness. The guideline also includes a recommendation that people should be informed if there is a waiting list, how long the

							wait is likely to be, and that the offer of self-help materials in the interim should be considered.
457	SH	NHS Sheffield CCG	Guideline	23	22	Is there new evidence now to suggest that the risk of starting antidepressants in less severe depression outweighs the benefit? Current NICE guidance suggests that risk-benefit ratio is poor but it sets criteria for exemption.	Thank you for your comment. The committee agreed that there was some evidence for the effectiveness and cost-effectiveness of antidepressants and that they should be included as a treatment option for people who preferred them, but that there was evidence that some psychological interventions were more effective and more cost-effective, and

							given the potential for side effects and/or withdrawal symptoms with antidepressants, psychological interventions were recommended to be considered first.
458	Individual	Individual 10	Guideline	23	23	Table 2: Couple therapy for depression should be included in the list of treatment options for less severe depression. It seems as if the decision to leave it out was based on the incorrect assumption that is it only appropriate and effective for people who are in a distressed relationship, but this is not the case (e.g. Barbato, A. & D'Avanzo, B. (2020). The findings of a Cochrane Meta-Analysis of couple therapy in adult depression: Implications for research and clinical practice. Family Process, 59 (2), 1-15.)	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA).
459	Individual	Individual 10	Guideline	23	23	Table 2: Couple therapy for depression should be included in the list of treatment options for less severe depression. It seems as if the decision to leave it out was based on the incorrect assumption that is it only appropriate and effective for people who are in a distressed relationship, but this is not the case (e.g. Barbato, A. & D'Avanzo, B. (2020). The findings of a Cochrane Meta-Analysis of couple therapy in adult depression: Implications for	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in

						research and clinical practice. Family Process, 59 (2), 1-15.)	pairwise comparisons (and not included in the NMA).
460	SH	EMDRIA	Guideline	23	23	We liked the tables and visual guides that are presented (e.g. Tables 1, p23; and Table 2, p31; supporting documentation visual guides) comparing the pros and cons of different treatment options, we felt this could be a really helpful clinical tool for supporting patient choice and decision making. We thought it would be good to also provide a visual guide for further-line treatment options, similar to those for less/more severe depression first-line treatment, as this will be a very common choice point for patients.	Thank you for your comment. The committee have now also developed a visual summary for relapse prevention and further-line treatment

461	SH	British Society of Lifestyle Medicine	Guideline	23	23	Table 1 - We suggest that wider Lifestyle Medicine evidence is represented here to broaden discussions and improve health outcomes. We would like to highlight the following for consideration:Dietary Intervention & Depression Firth J, Marx W, Dash S, et al. The Effects of Dietary Improvement on Symptoms of Depression and Anxiety: A Meta-Analysis of Randomized Controlled Trials [published correction appears in Psychosom Med. 2020 Jun;82(5):536]. Psychosom Med. 2019;81(3):265-280This is the only meta-analysis of 16 RCTs (45,826 individuals) regarding the effect of dietary improvements on depression or depressive symptoms. Dietary interventions reduced depressive symptoms significantly (g = 0.275, 95% CI = 0.10 to 0.45, p = 0.02). Effects were similar for RCTs primarily aiming for weight loss, reducing fat intake, and aiming to improve nutritional intake. Studies that involved dieticians / nutritionists were more likely to find significant improvement of depressive symptoms (g = 0.329, 95% Ci = 0.12 to 0.54, p = 0.02). The eight studies with predominantly female participants (defined as >75%) all observed significant improvements in depressive symptoms. Only one RCT (The SMILES Trial, Jacka et al. 2017 – see below) treated clinical depression as opposed to depressive symptoms. The dietary interventions generally reduced intake of junk foods (High Fat /	Thank you for your comments. The committee did not consider dietary interventions to be interventions that were in regular clinical use for the treatment of depression. Therefore these interventions were not specified in any of the review protocols and consequently the studies that you cite would not have met the inclusion criteria for the reviews. The committee noted that the evidence reviewed for exercise was for a structured formal exercise programme. However, in response to stakeholder comments, the committee also supported less intense 'move more' exercise for general wellbeing (although not as a treatment for depression) and made a new recommendation to reflect this. The committee also recognised that people with depression, like everyone, might benefit from a healthy lifestyle but recognised that people with depression might find this harder to achieve. On this basis, a new recommendation was added to advise people with depression that maintaining a healthy lifestyle may help improve their sense of wellbeing. A link to the NHS advice on mental wellbeing was also added, which lists 5 steps to mental

						Salt / Sugar, and takeaways) and increased high fibre nutrient-dense foods such as fruit and vegetables.Jacka FN, O'Neil A, Opie R, et al. A randomised controlled trial of dietary improvement for adults with major depression (the 'SMILES' trial) [published correction appears in BMC Med. 2018 Dec 28;16(1):236]. BMC Med. 2017;15(1):23. Published 2017 Jan 30. doi:10.1186/s12916-017-0791-yThe SMILES Trial is the RCT of dietary intervention in 67 individuals with diagnoses of moderate to severe depression over 12 weeks as measured on MADRS and remission rates. The dietary intervention group (n = 33) received seven individual nutritional consulting sessions by a dietician. The ModiMedDiet based on Australian and Greek dietary guidelines encourage consumption of 12 key food groups: whole grains (5-8 servings/d), Vegetables (6/d), fruit (3/d), Legumes (3-4/w), Low-fat unsweetened dairy (2-3/d), Nuts raw unsalted (1/d), Fish (2/w), lean red meat (3-4/w), Chicken (2-3/w), Eggs (<7/w), and Olive oil (3 tablespoons/d). The intervention group had significantly greater reductions in MADRS (t = 4.38, p < 0.001) and remission (MADRS < 10) achieved in 32.3% compared with 8% of controls, given a NNT to achieve remission of 4.1.Opie RS, Itsiopoulos C, Parletta N, et al. Dietary recommendations for the prevention of depression. Nutr Neurosci.	wellbeing: connect with other people; be physically active; learn new skills; give to others; pay attention to the present moment (mindfulness).

						2017;20(3):161-171. doi:10.1179/1476830515Y.0000000043The group responsible for 1 & 2 above made five key dietary recommendations for the prevention of depression: 1) Follow traditional dietary patterns; 2) Increase fruit, vegetables, legumes, wholegrain, nuts and seeds; 3) Include food rich in omega-3; 4) Replace unhealthy foods with wholesome nutritious foods; and 5) Limit intake of processed foods, fast foods, commercial baking, and sweets.Opie RS, O'Neil A, Itsiopoulos C, Jacka FN. The impact of whole-of-diet interventions on depression and anxiety: a systematic review of randomised controlled trials. Public Health Nutr. 2015;18(11):2074-2093. doi:10.1017/S1368980014002614An earlier review by the same group included 17 RCTs of whole diet interventions on depression and anxiety. 47% (8/17) of RCTs found significant dietary intervention effects on depression scores and 20% (2/10) on anxiety. Of successful interventions all utilised a single mode of delivery and 85% used a dietician, while 75%recommended a diet high in fibre and / or fruit and vegetables.Beezhold BL, Johnston CS. Restriction of meat, fish, and poultry in omnivores improves mood: a pilot randomized controlled trial. Nutr J. 2012;11:9. Published 2012 Feb 14. doi:10.1186/1475-2891-11-9A pilot RCT randomised 39 adults following an omnivorous diet	

						to omnivorous (daily meat, fish and poultry), fish (fish 3-4 times/w, but no meat or poultry) and vegetarian arms. The vegetarian group showed greater improvements in DASS & POMS scores.Parletta N, Zarnowiecki D, Cho J, Wilson A, Bogomolova S, Villani A, Itsiopoulos C, Niyonsenga T, Blunden S, Meyer B, Segal L, Baune BT, O'Dea K. A Mediterranean-style dietary intervention supplemented with fish oil improves diet quality and mental health in people with depression: A randomized controlled trial (HELFIMED). Nutr Neurosci. 2019 Jul;22(7):474-487. doi: 10.1080/1028415X.2017.1411320. Epub 2017 Dec 7. PMID: 29215971.The HELFIMED Study is another RCT investigating whether a Mediterranean-style diet supplemented with fish oils can improve depressive disorder. The results were statistically significant showing remission from depression sustained at 6 months in the dietary intervention arm, as well as improved Quality of Life scores.Diet Quality & Depression RiskLi Y, Lv MR, Wei YJ, et al. Dietary patterns and depression risk: A meta-analysis. Psychiatry Res. 2017;253:373-382. doi:10.1016/j.psychres.2017.04.020A Meta-analysis included 21 studies from 10 countries. A healthy dietary pattern with high intakes of vegetables, fruits, whole-grains, olive oil, fish, soya, poultry and low-fat dairy was 36% less likely to be associated with depression (OR = 0.64, 95% CI =	

						0.57 to 0.72, p < 0.00001). In contrast a Western dietary pattern with high intakes of processed / red meats, refined grain, sweets, high-fat dairy, potatoes and high-fat gravy as well as low fruit and vegetable intake increased risk of depression by 18% (OR = 1.18, 85% CI = 1.05 to 1.34, p = 0.006).Quirk SE, Williams LJ, O'Neil A, et al. The association between diet quality, dietary patterns and depression in adults: a systematic review. BMC Psychiatry. 2013;13:175. Published 2013 Jun 27. doi:10.1186/1471-244X-13-175 A systematic review 25 studies from nine countries mostly published since 2009 synthesised findings to conclude: 1) Traditional Mediterranean, Norwegian and Japanese diets were associated with lower risk of depression; 2) Inconsistent evidence for healthy diet being associated with lower risk of depression; 3) Inconsistent evidence that Western diets increase risk of depression; and 4) Inconsistent evidence that depression predicts poor diet quality. There was a high level of heterogeneity between studies.Lifestyle & Diet & DepressionNull G, Pennesi L. Diet and lifestyle intervention on chronic moderate to severe depression and anxiety and other chronic conditions. Complement Ther Clin Pract. 2017;29:189-193. doi:10.1016/j.ctcp.2017.09.007Mixed diet, lifestyle and behavioural modification (plant-based diet, daily exercise and mindfulness) was tried in 500	

						adults with chronic moderate to severe depression and anxiety as well as other conditions over 12 weeks. There were improvements in self-reported depression, anxiety, fatigue, pain and insomnia with the majority reporting substantial benefits. These benefits persisted after six months.Lopresti AL, Hood SD, Drummond PD. A review of lifestyle factors that contribute to important pathways associated with major depression: diet, sleep and exercise. J Affect Disord. 2013;148(1):12-27. doi:10.1016/j.jad.2013.01.014A broad review of the impact of lifestyle factors including diet, sleep and exercise on depression as well as potential mechanisms underlying depression (inflammation, neurotransmitters, oxidative stress, HPA-axis and mitochondrial function).Sarris J, O'Neil A, Coulson CE, Schweitzer I, Berk M. Lifestyle medicine for depression. BMC Psychiatry. 2014;14:107. Published 2014 Apr 10. doi:10.1186/1471-244X-14-107Narrative discussion of aspects of lifestyle medicine applied to depression, including diet, exercise, mindfulness, management of substance use, sleep, and more.Gut MicrobiomeDash S, Clarke G, Berk M, Jacka FN. The gut microbiome and diet in psychiatry: focus on depression. Curr Opin Psychiatry. 2015;28(1):1-6. doi:10.1097/YCO.0000000000000117Narrative review of emerging evidence of the bidirectional links between diet, microbiome, inflammation,	

						neurotransmitters and mental health.Koopman M, El Aidy S; MIDtrauma consortium. Depressed gut? The microbiota-diet-inflammation trialogue in depression. Curr Opin Psychiatry. 2017;30(5):369-377. doi:10.1097/YCO.0000000000000350Narrative review of emerging evidence of the bidirectional links between diet, microbiome, inflammation, neurotransmitters and depression.Physical activityWe are pleased to see the recommendations for physical activity programmes. We would like to add the following for consideration by NICE:Schuch FB, Stubbs B. The Role of Exercise in Preventing and Treating Depression. Curr Sports Med Rep. 2019;18(8):299-304. doi:10.1249/JSR.0000000000000620People who are more physically active have at least 30% lower rates of depression across age groups and countries. People with depression were 50% more likely not to meet recommended 150 minutes of moderate exercise per week. People with depression can respond to even a single 20 minutes of exercise and seem to benefit from any intensity of exercise. Meta-analyses show significant treatment effects in favour of exercise (SMD = 0.98, 95% CI = 0.68 to 1.28, p = 0.001), a response rate of 40% and a remission rate of 28%. Neurobiological mediators are discussed.Morres ID, Hatzigeorgiadis A, Stathi A, et al. Aerobic	

						exercise for adult patients with major depressive disorder in mental health services: A systematic review and meta-analysis. Depress Anxiety. 2019;36(1):39-53. doi:10.1002/da.22842Meta-analysis of 11 RCTs involving 455 patients, aerobic exercise (45 min, at moderate intensity, three times/week, for 9.2 weeks) had a large antidepressant effect (g = -0.79, 95% CI = -1.01, -0.57, p < 0.001).Kvam S, Kleppe CL, Nordhus IH, Hovland A. Exercise as a treatment for depression: A meta-analysis. J Affect Disord. 2016;202:67-86. doi:10.1016/j.jad.2016.03.063Meta-analysis of 23 RCTs with 977 participants confirmed a large effect size for exercise versus no intervention (g = -1.24), a moderate effect size compared to usual care (g = -0.48), and small effect sizes compared to antidepressants (g = -0.22) as well as psychotherapy (g = -0.08). Exercise as an adjunct to antidepressants had a moderate effect size (g = -0.50).Schuch FB, Vancampfort D, Richards J, Rosenbaum S, Ward PB, Stubbs B. Exercise as a treatment for depression: A meta-analysis adjusting for publication bias. J Psychiatr Res. 2016;77:42-51. doi:10.1016/j.jpsychires.2016.02.023Meta-analysis of 25 RCTs controlling for publication bias identified a large effect size for exercise in depression (SMD = 1.11, 95% CI = 0.79 top 1.43. There were highly significant reductions in scores	

						on HAMD (-4.52, 95% CI 2.03 to 7.01, p < 0.001) and BDI (-6.46, 95% nCI 4.18 to 8.41, p < 0.001) in the exercise groups.Wegner M, Helmich I, Machado S, Nardi AE, Arias-Carrion O, Budde H. Effects of exercise on anxiety and depression disorders: review of meta- analyses and neurobiological mechanisms. CNS Neurol Disord Drug Targets. 2014;13(6):1002-1014. doi:10.2174/1871527313666140612102841Meta-analysis of 37 studies including 42,264 adults with anxiety and 48,207 with depression. While the average effect size for anxiety was small (0.34) the effect of exercise on depression was moderate (0.56). Exercise was more beneficial in clinical populations.Knapen J, Vancampfort D, Moriën Y, Marchal Y. Exercise therapy improves both mental and physical health in patients with major depression. Disabil Rehabil. 2015;37(16):1490-1495. doi:10.3109/09638288.2014.972579Analysed four meta-analyses. The effect of exercise was comparable to medication and psychotherapy for mild to moderate depression and moderately reduced depression scores. Exercise is extremely potent at treating common comorbidities in depression including cardiovascular disease, type 2 diabetes and metabolic syndrome. Attendance rates for exercise treatments ranged from 50% to 100%.Paolucci EM, Loukov D, Bowdish DME, Heisz	

						JJ. Exercise reduces depression and inflammation but intensity matters. Biol Psychol. 2018;133:79-84. doi:10.1016/j.biopsycho.2018.01.015Exercise reduced depression and inflammation in sixty-one university students over six weeks, with moderate intensity exercise being more effective than high intensity interval training.****Psychological therapiesWe would like to include Acceptance and Commitment Therapy and Compassion Focused Therapy, for their focus on client autonomy, mindfulness and self-compassion.SleepRecommendations about sleep hygiene, sleep restriction and CBT for insomnia (CBTi) are currently missing from the draft guidelines but sleep is invariably affected in depression. We would like to see these recommendations added.CBTi has evidence in depression:Cunningham, J.E.A., Shapiro, C.M., 2018. Cognitive Behavioural Therapy for Insomnia (CBT-I) to treat depression: A systematic review. J Psychosom Res 106, 1–12. https://doi.org/10.1016/j.jpsychores.2017.12.012 Fang, H., Tu, S., Sheng, J., Shao, A., 2019. Depression in sleep disturbance: A review on a bidirectional relationship, mechanisms and treatment. J Cell Mol Med 23, 2324–2332. https://doi.org/10.1111/jcmm.14170	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

462	SH	Newham Talking Therapies	Guideline	23	23	After reading the proposed guidelines for treating depression, we have some concerns about the proposal for self help with support. It appears that the evidence comes from trials on Computerised CBT programmes rather individual self help sessions that are occurring every day in IAPT services. Have you been able to trial it in IAPT services or do you have plans to trial it in IAPT services before rolling it out?	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The self-help with support section has been relabelled as guided self-help, placed earlier in the treatment pathway, and the description of guided self-help has been amended to recommend that printed or digital materials that follow the principles of guided self-help are used including structured CBT, structured BA, problem solving or psychoeducation materials, delivered face-to-face or by telephone or online.

463	SH	Tavistock Relationships	Guideline	23	23	Table 1 Please include behavioural couples therapy in this table and the visual summary since it appears the decision to leave it out was in part based on an incorrect assumption that it is more or only appropriate for a subgroup of people with depression and studies were excluded from the research evaluation on this basis. This intervention is in the guidelines but, if excluded from the tables and visual summaries, is very unlikely to be considered as an option. Options such as counselling and STPP were included as the committee recognised that these treatments, although with less evidence of effectiveness, may be helpful for some people. This argument also applies to behavioural couples therapy. The committee agreed this treatment was available through the Improving Access to Psychological Therapy (IAPT) services and should be included as an option in the guideline but if listed in isolation and not in the table and visual summary there is a real risk it will be overlooked by commissioners and providers. Behavioural couples therapy is the only family-inclusive therapy option listed and may be of particular value to some minority ethnic and cultural groups who may find it harder to engage with services and do not all share individualistic Western values. Couple therapy by definition involves the partner of the person with depression. Carers often feel ignored by healthcare	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA). The committee did not consider it appropriate to include behavioural couples therapy in the tables or visual summaries of treatment options in the guideline as the evidence and recommendation for behavioural couples therapy was for a subgroup of people with depression, unlike the other interventions listed in these tables/visual summaries. There is a recommendation in the access section of the guideline for commissioners and providers of mental health services to ensure that pathways have a number of components in place in order to promote access and increased uptake of services and these include: services delivered in culturally appropriate or culturally adapted language and formats; and procedures to support active involvement of families, partners, and carers.

						professionals in decisions about their loved ones and want to be involved in discussions about treatment options (Healthwatch, 2020). Couples therapy for depression should be more widely available to depressed people to help reduce the burden on partners and potentially prevent relationship breakdown (Priestley, J and McPherson, SJ and Davies, F (2018) Couples Disease: The Experience of Living with a Partner with Chronic Depression. Journal of Couple and Relationship Therapy, 17 (2). 128 - 145. ISSN 1533-2683).If couples therapy is not included in the tables and visual summaries, it will be much less likely to be considered as an option for people with depression, and people from black, Asian and minority ethnic communities, and carers, will be negatively impacted in particular. It is very important that the choice of couples therapy alongside individual and group interventions is made more widely available within NHS services. The NHS constitution states that services should work in partnership with patients their families and carers.	There are also recommendations in the choice of treatment section of the guideline that people with depression should be given the option to include family members or carers in the discussion of treatment options, and to attend (some or all of) treatment with a family member or friend.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

464	SH	Association for Dance Movement Psychotherapy UK, British Association of Art Therapists, British Association of Music Therapists and the British Association of Dramatherapists	Guideline	23	023-025	Treatment for people with a new episode of less severe depression The guideline includes treatment options for less severe depression in table 1. We are concerned this table makes no reference to any form of arts therapies.In the associated evidence reviews, music therapy and art therapy are the only two disciplines mentioned without references to dance movement psychotherapy and dramatherapyIn all cases and with few exceptions, associated evidence from systematic reviews, meta-analyses (including Cochrane Reviews) and randomised controlled trials are omittedThese clear omissions ignoring the HCPC and UKCP recognised forms of psychotherapy and reported preferences of patients for arts therapies, for example as evidenced Millard, E., Medlicott, E., Cardona, J., Priebe, S., & Carr, C. (2021). Preferences for group arts therapies: a cross-sectional survey of mental health patients and the general population. BMJ Open 2021;11: e051173. doi: 10.1136/bmjopen-2021-051173.Typically, studies that have been omitted include treatments from one of the arts therapies. However, as a joint response from the four arts therapies professional associations, we would like to highlight the evidence across these four disciplines (dance movement psychotherapy, art therapy, music therapy and dramatherapy) in studies with joint and discipline specific	Thank you for your comment and for drawing our attention to Millard et al. (2021), which is not eligible for inclusion as the study design does not meet eligibility criteria. Aalbers 2017, Zhao 2016, and Dunphy 2019 were identified by the searches and have been checked for additional eligible studies and are listed in the excluded studies list (as not appropriate to include in their entirety due to different review questions) of Supplement B1. Maratos et al. (2008) was not assessed for eligibility as Aalbers 2017 updates it. Meekums et al. (2015), Karkou et al. (2019), and Tang et al. (2020) had not been identified by the searches but, in response to your comment, these systematic reviews have been checked for additional relevant studies and no new eligible studies were identified. These systematic reviews (and any associated studies included within them for which full text was checked to assess eligibility) have been added to the excluded studies list of Supplement B1. Cohen and Maxwell (2020), de Witte et al. (2021), Parsons et al. (2019), Zubala et al. (2013), and Fachner et al. (2013) were not assessed for eligibility as they do not meet study design

						provision.Preliminary findings from a scoping review of systematic reviews published between 2000-2021 that was submitted to WHO clinical guideline group for depression resulted in 45 publications representing 616 studies with varied methodologies. Twenty-five of the included reviews also included meta-analyses. The quality of the studies varied with three Cochrane Reviews included in this scoping exercise (Aalbers et al 2017; Maratos et al 2008; Meekums et al 2015), but none of these reviews and associated RCTs relating to mild to moderate depression have been included in this NICE draft guideline. The results of our review indicate that arts therapies can reduce depressive scores for people with depression. When studies of high risk of bias were excluded, changes with moderate (Aalbers et al 2017) to high effect sizes (Karkou et al 2019) were calculated in some of these reviews. Significant changes were also reported by several others (Maratos et al 2008; Meekums et al 2015; Tang et al 2020; Cohen and Maxwell 2020). The severity of depression, the duration of the intervention, the approach and techniques used, and the presence or absence of a qualified arts therapist are also reported in these studies alongside studies on therapeutic approaches and factors (de Witte et al 2021; Parsons et al 2019; Zubala et al 2013). Although most of the reviews considered studies	inclusion criteria. Hyvönen et al. (2020) was not identified by the searches but, in response to your comment, it has been assessed for eligibility. This study does not meet inclusion criteria for the first-line treatment review as less than 80% of participants were receiving first-line treatment for depression (56% receiving antidepressants at baseline). This study has been added to the excluded studies list of Supplement B1. Pylvänäinen et al. (2015), Punkanen et al. (2014), and Margrove et al. (2013) do not meet inclusion criteria as they are not randomised controlled trials. These studies have been added to the excluded studies list of Supplement B1. Federman et al. (2019) was not identified by the searches but, in response to your comment, it has been assessed for eligibility. This study does not meet inclusion criteria as details of group assignment were not sufficient to categorise as an RCT ('Division of the subjects into the control and experimental groups was randomly made by arbitrarily assigning subjects from the list of participants to one group or the other'). This study has been added to the excluded studies list of Supplement B1.

						with working age adults, several reviews also included and/or specifically referred to older people. For example, there were reviews on changes on depression scores for older people (Zhao et al 2016). Reasons for these results have been explored by Dunphy et al (2018) who, through a review of 75 studies, argued that when creative arts therapies are used with older people with depression the following areas are activated supporting therapeutic change: physical (e.g., increased muscle strength; neurochemical effects, such as endorphin release), intra-personal (e.g., enhanced self-concept, strengthened agency and mastery; processing and communication of emotions), cultural (e.g., creative expression, aesthetic pleasure), cognitive (e.g., stimulation of memory), and social (e.g., increased social skills and connection). In all cases, arts therapies are perceived as acceptable interventions and, in most cases, they are associated with improvements on depression scores as evidenced here:Dance movement psychotherapy A systematic review of the evidence for dance movement psychotherapy for depression (Karkou et al, 2019) analysed the most recent evidence in light of a previous Cochrane review (Meekums et al, 2015) that was inconclusive. Karkou et al (2019) included the following studies with adults with mild to moderate depression all with significant reduction	The Leubener & Hinterberger 2017 citation could not be identified. Erkkilä 2011 was identified by the searches but did not meet criteria for inclusion in the first-line treatment of depression review as less than 80% of participants were receiving first-line treatment for depression (72% on antidepressant medication at baseline). This study is in the excluded studies list of Supplement B1. Erkkila et al. (2021) was not identified by the searches but, in response to your comment, it has been assessed for eligibility. This study does not meet criteria for inclusion in the first-line treatment of depression review as less than 80% of participants were receiving first-line treatment for depression (50% receiving medication at baseline). This study has been added to the excluded studies list of Supplement B1. Thyme 2007 was identified by the searches but is not included in the first-line treatment review as less than 80% of partipants had non-chronic depression (64% diagnosed with dysthymic disorder). This study is listed under excluded

						in depression scores post intervention:Hyvönen, K., Pylvänäinen, P., Muotka, J., & Lappalainen, R. (2020) The Effects of Dance Movement Therapy in the Treatment of Depression: A Multicenter, Randomized Controlled Trial in Finland. Frontiers in Psychology. Available at: https://doi.org/10.3389/fpsyg.2020.01687This is a multi-centred RCT funded by the Finish insurance system with medium risk of bias that demonstrated significant reduction in depression scores in the dance movement therapy groups compared with groups receiving treatment as usual only. In total, 109 persons participated in the study in various locations in Finland. The participants were 39 years old, on average (range = 18–64 years), and most were female (96%). All participants received treatment as usual (TAU). They were randomized into DMT + TAU (n = 52) or TAU only (n = 57). The participants in the DMT + TAU group were offered 20 DMT sessions twice a week for 10 weeks in addition to standard care. The measurement points included pretreatment measurement at the baseline, posttreatment measurement at the end of the intervention, and a follow-up measurement 3 months afterward. The observed effects of the intervention among participants in the DMT+TAU group were a greater reduction in depression and in indicators of physical and psychological distress in comparison	studies in Supplement B1. Blomdahl 2018 was identified by the searches but is not included as baseline severity could not be categorised (outcome measure outside protocol MADRS-self-report).This study is listed under excluded studies in Supplement B1. Choi et al. (2020) was not identified by the searches. However, in response to your comment the study has been assessed for eligibility for the further-line treatment review (as all participants receiving pharmacological treatment). However, it does not meet inclusion criteria as participants were not randomised at the point of non-response. This study has now been added to the excluded studies list of Supplement D. Ciasca 2018 was identified by the searches but is not included as the outcome measure is outside protocol (GDS-15). This study is listed under excluded studies in Supplement D. Nan 2017 is included in the further-line treatment review. However, this was the only included study for art therapy, and the committee considered the evidence too limited to make a recommendation.

						to the participants who received TAU-only. At the 3-month follow-up, the corrected between-group effect sizes (ESs) were medium and in favor of the DMT + TAU group (d = 0.60–0.72). These results are in line with the increasing number of research studies showing the benefits of DMT intervention among participants with depression, and these results indicate that DMT may improve the effectiveness of standard care.Pylvänäinen, P. M., Muotka, J. S., & Lappalainen, R. (2015). A dance movement therapy group for depressed adult patients in a psychiatric outpatient clinic: effects of the treatment. Frontiers in psychology, 6, 980. https://doi.org/10.3389/fpsyg.2015.00980 Pylvänäinen et al (2015) is a control trial that demonstrated statistically significant reduction in symptoms in the dance movement therapy group compared to TAU only. All adult patients (n = 33) included in the study received treatment as usual (TAU). Twenty-one patients participated in a 12-session DMT group intervention, and the remaining 12 patients chose to take TAU only. The majority of the patients suffered from moderate or severe depression, recurrent and/or chronic type. The effects of the interventions were investigated after the intervention, and at 3-month follow-up. Compared to the TAU, adding DMT seemed to improve the effect of the treatment. The effect of the DMT was observable whether the patient was	Gussak (2007) was not assessed for eligibility as it includes prison populations, and (as outlined in the review protocols) trials of adults in contact with the criminal justice system (not solely as a result of being a witness or victim) were excluded. There is separate NICE guidance on Mental health of adults in contact with the criminal justice system (NG66). The Arts on prescription: All Party Parliamentary Group on Arts, Health and Wellbeing (2017) citation was not considered by the committee as it does not meet study design eligibility criteria.

						taking antidepressant medication or not. At follow-up, between group effect sizes (ES) were medium in favor for the DMT group (d = 0.60-0.79). In the DMT group, the within ES at the 3 months follow-up varied from 0.62 to 0.82 as compared to TAU 0.15-0.37. The results indicated that DMT is beneficial in the treatment of depressed patients.Punkanen, M., Saarikallio, S., and Luck, G. (2014). Emotions in motion: short-term group form dance/movement therapy in the treatment of depression: a pilot study. Arts in Psychotherapy, 41, 493–497. doi: 10.1016/j.aip.2014.07.001.Punkanen et al (2014) a pilot study that demonstrated significant reduction in depression scores and increase in satisfaction of life and secure attachments post treatment. The main research question was whether a short-term group form of DMT intervention could decrease the symptoms of depression and anxiety. Depressed participants (N = 21, aged 18–60 years) received 20 sessions of group DMT, and measurements, including psychometric questionnaires, were taken before and after the intervention. The mean score of the primary outcome measure, the BDI, decreased significantly from the pre- (M = 21.67, SD = 5.26) to post-measurement (M = 10.50, SD = 5.50), t(17) = 10.40, p < .001. Thus, the shortterm, group form of DMT intervention had a positive effect on patients with	

						depression. However, further research using a control group, follow-up measurements and a larger sample size is needed to acquire more evidence supporting the efficacy of the intervention model described in this pilot study. Federman, D., Shimoni, S., & Turjeman, N. (2019) 'Attentive movement' as a method for treating depression, Body, Movement and Dance in Psychotherapy, 14:1, 14-25, DOI: 10.1080/17432979.2019.1586773 A further RCT (Federman et al, 2019) has been published that demonstrates significant reduction in depression scores compared to the control, all included in the Cochrane Review currently being updated by Karkou et al. The objective of this study was to examine whether 'attentive movement', is an effective method for treating depression. A quantitative research methodology design was used. Fifty participants took part in attentive movement group therapy sessions once a week for 12 weeks. All completed the Beck Depression Inventory (BDI) and a demographic questionnaire. A mixed-design ANOVA was performed; the between-group variables included the study groups (control/experimental) and the within-test group comparison examined measurement time (time1/time2). Results revealed a significant effect for measurement time ($F(1,44) = 27.78$, $p < .001$), which indicated a significant reduction in the	

						symptoms of depression from the first measurement (M = .98, SD = .39) to the second measurement (M = .72, SD = .50). The level of depression following treatment in the experimental group was significantly lower than in the control group. The research hypothesis was confirmed.Music therapyModerate to high effect sizes are reported in the Cochrane Reviews in music therapy(Aalbers et al 2017; Maratos et al 2008) and other systematic reviews in the field (e.g. Tang et al 2020' Cohen and Maxwell 2020; Leubener & Hinterberger 2017). The 2017 Cochrane review included a two-armed RCT (Erkiklla et al 2011) with 79 participants and a sub-study investigating changes on brain biomarkers of depression and anxiety (Fachner et al 2013). The most recent Music Therapy RCT study (2021) included 70 participants and focused on two potential music therapy enhancers: Erkkila, J., Brabant, O., Hartmann, M., Mavrolampados, A., Ala-Ruona, E., Snape, N., . . . Gold, C. (2021). Music Therapy for Depression Enhanced With Listening Homework and Slow Paced Breathing: A Randomised Controlled Trial. Front Psychol, 12, 613821. doi:10.3389/fpsyg.2021.613821In a 2 x 2 factorial randomised controlled trial, working-age individuals (70 eligible participants (74% female), their age ranging from 19 to 57 years (M = 39)) with depression were allocated into groups based	

						on four conditions derived from either the presence or absence of two enhancers (slow paced breathing and listening homework). All received music therapy over 6 weeks. Outcomes were observed at 6 weeks and 6 months. The primary outcome was the Montgomery Asberg Depression Rating Scale (MADRS) score. Results: There was a significant overall effect of treatment for the primary outcome favouring the breathing group (d = 0.50, 95% CI 0.07 to 0.93, p = 0.02). The effect was larger after adjustment for potential confounders (d = 0.62, 95% CI 0.16 to 1.08, p = 0.009). Treatment effects for secondary outcomes, including anxiety (anxiety scale of Hospital Anxiety and Depression Scale) and quality of life (RAND-36), were also significant, favouring the breathing group. The homework enhancer did not reach significant treatment effects.Erkkilä , J., Punkanen, M., Fachner, J., Ala-Ruona, E., Pöntiö, I., Tervaniemi, M., . . . Gold, C. (2011). Individual music therapy for depression - Randomised Controlled Trial. Br J Psychiatry, 199(2), 132–139. doi:10.1192/bjp.bp.110.085431Participants (n= 79) with an ICD–10 diagnosis of depression were randomised to receive individual music therapy plus standard care (20 bi-weekly sessions) or standard care only, and followed up at baseline, at 3 months (after intervention) and at 6 months. The primary outcome was the Montgomery Asberg	

						Depression Rating Scale (MADRS) score. Participants receiving music therapy plus standard care showed greater improvement than those receiving standard care only in depression symptoms (mean difference 4.65, 95% CI 0.59 to 8.70), anxiety symptoms (1.82, 95% CI 0.09 to 3.55) and general functioning (74.58, 95% CI 78.93 to 70.24) at 3-month follow-up. The response rate was significantly higher for the music therapy plus standard care group than for the standard care only group (odds ratio 2.96, 95% CI 1.01 to 9.02).The results of this study indicated that music therapy with its specific qualities is a valuable enhancement to established treatment practices.Fachner, J., Gold, C., & Erkkilä, J. (2013). Music therapy modulates fronto-temporal activity in the rest-EEG in depressed clients. Brain Topography, 26(2), 338-354. doi:10.1007/s10548-012-0254-x(N=79) Fronto-temporal areas process shared elements of speech and music. Improvisational psychodynamic music therapy (MT) utilizes verbal and musical reflection on emotions and images arising from clinical improvisation. Music listening is shifting frontal alpha asymmetries (FAA) in depression, and increases frontal midline theta (FMT). In a two-armed randomized controlled trial (RCT) with 79 depressed clients (with comorbid anxiety), we compared standard care (SC) versus MT added to	

						SC at intake and after 3 months . We found that MT significantly reduced depression and anxiety symptoms (Erkkila et al 2011).The purpose of this EEG biomarker study was to test whether or not music therapy has an impact on anterior fronto-temporal depression (FAA) and anxiety (FMT) resting state biomarkers. Correlations between anterior EEG, Montgomery–Asberg Depression Rating Scale (MADRS) and the Hospital Anxiety and Depression Scale—Anxiety Subscale (HADS-A), power spectral analysis (topography, means, asymmetry) and normative EEG database comparisons (neurometric z-score mapping) were explored. After 3 month of MT, lasting changes in resting EEG were observed, i.e., significant absolute power increases at left fronto-temporal alpha, but most distinct for theta (also at left fronto-central and right temporoparietal leads). MT differed to SC at F7–F8 (z scored FAA, $p < .03$) and T3–T4 (theta, $p < .005$) asymmetry scores, pointing towards decreased relative left- sided brain activity after MT; pre/post increased FMT and decreased HADS-A scores ($r = .42$, $p < .05$) indicate reduced anxiety after MT. Verbal reflection and improvising on emotions in MT may induce neural reorganization in fronto-temporal areas. Alpha and theta changes in fronto-temporal and temporoparietal areas indicate MT action and treatment effects on cortical activity in depres-	

						sion, suggesting an impact of MT on anxiety reduction.Art therapyThyme et al. (2007). The outcome of short-term psychodynamic art therapy compared to short-term psychodynamic verbal therapy for depressed women. Psychoanalytic Psychotherapy. Vol.21(3), 250-264.The primary aim of this randomized controlled clinical trial was to compare the outcome from two types of short-term psychodynamic psychotherapy. The participants were thirty-nine women with depression. Half of the participants (n = 18) received art psychotherapy and the other half received verbal psychotherapy (n = 21). Data was collected before and after psychotherapy, and at a 3-month follow-up using self-rating scales and interviewer-based ratings. Results showed that art and verbal psychotherapies were comparable, and at follow-up, the average participant in both groups had few depressive symptoms and stress-related symptoms. The conclusion was that short-term psychodynamic art therapy could be a valuable treatment for depressed women.Blomdahl et al. (2018). A manual-based phenomenological art therapy for individuals diagnosed with moderate to severe depression (PATd): A randomized controlled study. Psychiatric Rehabilitation Journal, 41(3), 169-182;N=79. Multicentre randomised controlled trial. Art Therapy + treatment as usual versus treatment as	

						usual alone. 43 AT, 36 TAU.Significantly reduced depression in art therapy, and more return to work compared to treatment as usual alone. Choi et al. (2020). The effects of combining art psychotherapy with pharmacotherapy in treating major depressive disorder: Randomized control study. The Arts in Psychotherapy, 70, ArtID 101689 N = 46. Randomised controlled trial. 16 had antidepressants versus 19 having antidepressants and art psychotherapy. Widely used measures of depression, anxiety, self-esteem, relationships and other indicatorsArt psychotherapy and antidepressants were better than antidepressants alone for depression, anxiety, interpersonal relationships and self-esteem. No difference in dropout, remission, or treatment satisfaction. Ciasca et al. (2018). Art therapy as an adjuvant treatment for depression in elderly women: A randomized controlled trial. Brazilian Journal of Psychiatry, 40(3), 256-263;N = 56 women over 60 years old with major depression and on antidepressants. 31 had art therapy, 25 no art therapy. Randomised. Standardised depression and anxiety scales.Significant improvement in depression and anxiety in art therapy compared to control Nan & Ho (2017). Effects of clay art therapy on adults outpatients with major depressive disorder: A randomized controlled trial. Journal of Affective Disorders, 217, 237-245;	

						Method: One-hundred and six adults with depression were randomized into a CAT group or visual art (VA) control group for six 2.5-h weekly sessions. Intervention effects were measured using the Beck Depression Inventory, 12-Item General Health Questionnaire (Chinese version), Body-Mind-Spirit Well-Being Inventory, and 20-Item Toronto Alexithymia Scale (Chinese version) at baseline, immediately postintervention (T1), and 3-weeks postintervention (T2).Result: Multivariate analysis of covariance results indicated a more significant time × group effect for CAT than for VA on depressive signs, general health, and body-mind-spirit well-being (all p<0.05). Significant within-groups changes were observed in these three aspects after treatment and at T2 (all p<0.001) and in alexithymia at T2 (p<0.01) in the CAT group, but the change was nonsignificant in the VA group at T1 and T2.Limitations: The homogeneity of the participants affected the generalizability of the study findings. The short-term postintervention follow-up (3 weeks) presented difficulties in demonstrating the long-term effects of CAT.Conclusions: CAT can aid emotion regulation and benefit various aspects of mental health in adults. The short duration of the intervention suggests additional application value in treating depression. Further investigation is warranted regarding the potential effect of CAT on	

						alleviating physical symptoms and improving social functionGussak, D. (2007). The effectiveness of art therapy in reducing depression in prison populations. International Journal of Offender therapy and comparative Criminology, 51(4), 444-460.Two quantitative studies were initiated in a North Florida prison to measure the effectiveness of art therapy with inmates, specifically in decreasing depressive symptoms. This article will present a pilot and follow-up study. The methods, including the Formal Elements Art Therapy Scale (FEATS) and the Beck Depression Inventory–Short Form, will be delineated. What was revealed was that although the FEATS proved more effective as a measurement tool for the pilot than for the follow-up study, ultimately, the results reflected a significant decrease in depressive symptoms in those inmates who participated in the program.References - Generic Arts Therapies:de Witte M, Orkibi H, Zarate R, Karkou V, Sajnani N, Malhotra B, Ho RTH, Kaimal G, Baker FA, Koch SC. From Therapeutic Factors to Mechanisms of Change in the Creative Arts Therapies: A Scoping Review. Front Psychol. 2021 Jul 15;12:678397. doi: 10.3389/fpsyg.2021.678397. PMID: 34366998; PMCID: PMC8336579.Dunphy K, Baker FA, Dumaresq E, Carroll-Haskins K, Eickholt J, Ercole M, Kaimal G, Meyer K, Sajnani N, Shamir OY, Wosch T. Creative Arts Interventions to Address Depression	

						in Older Adults: A Systematic Review of Outcomes, Processes, and Mechanisms. Front Psychol. 2019 Jan 8;9:2655. doi: 10.3389/fpsyg.2018.02655. PMID: 30671000; PMCID: PMC6331422Parsons, A., Omylinska-Thurston, J., Karkou, V., Harlow, J., Haslam, S., Hobson, J., ... & Griffin, J. (2020). Arts for the blues–a new creative psychological therapy for depression. British Journal of Guidance & Counselling, 48(1), 5-20.Zubala A, MacIntyre D J, Gleeson N, Karkou V (2013) Description of arts therapies practice with adults suffering from depression in the UK: Quantitative results from the nationwide survey, The Arts in Psychotherapy, Volume 40, Issue 5, Pages 458-464.Aalbers, S., Fusar-Poli, L., Freeman, R. E., Spreen, M., Ket, J. C., Vink, A. C., . . . Gold, C. (2017). Music therapy for depression. Cochrane Database Syst Rev, 11, CD004517. doi:10.1002/14651858.CD004517.pub3Maratos, A. S., Gold, C., Wang, X., & Crawford, M. J. (2008). Music Therapy for Depression (Review). In The Cochrane Database of Systematic Reviews (Issue 1. Art. No.: CD004517. DOI: 004510.001002/14651858.CD14004517.pub14651852.)Tang, Q., Huang, Z., Zhou, H., & Ye, P. (2020). Effects of music therapy on depression: A meta-analysis of randomized controlled trials. PLOS ONE, 15(11), e0240862. doi:10.1371/journal.pone.0240862Cohen, Donna;	

						Maxwell, Elizabeth (2020) Music Therapy for Depression. American Family Physician 2020;101(5):273-274Zhao k; Bai ZG, Bo A and Chi I (2016) A systematic review and meta-analysis of music therapy for older adults with depression, International journal of geriatric psychiatry, 31(11):1188-1198Erkkila, J., Brabant, O., Hartmann, M., Mavrolampados, A., Ala-Ruona, E., Snape, N., . . . Gold, C. (2021). Music Therapy for Depression Enhanced With Listening Homework and Slow Paced Breathing: A Randomised Controlled Trial. Front Psychol, 12, 613821. doi:10.3389/fpsyg.2021.613821Karkou, V., Aithal, S., Zubala, A., & Meekums, B. (2019). Effectiveness of dance movement therapy in the treatment of adults with depression: a systematic review with meta-analyses. Frontiers in psychology, 10, 936 https://doi.org/10.3389/fpsyg.2019.00936Meekums, B., Karkou, V., & Nelson, E. A. (2015). Dance movement therapy for depression. Cochrane Database of Systematic Reviews, (2). https://doi.org/10.1002/14651858.CD009895.pub2Arts on prescription - review: All Party Parliamentary Group on Arts, Health and Wellbeing (2017) Creative health: The arts for health and wellbeing, https://www.culturehealthandwellbeing.org.uk/appg-inquiry/Publications/Creative_Health_Inquiry_Rep	

						ort_2017_-_Second_Edition.pdfSpecific study: Margrove, KL, SE-SURG, Heydenrych K & Secker J (2013) Waiting list-controlled evaluation of a participatory arts course for people experiencing mental health problems. Perspectives in Public Health, 133(1):28-35. https://doi.org/10.1177/1757913912461587	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

465	SH	Institute of Health Visiting	Guideline	23	General	Column 4, titled 'other things to think about' To add:If a parent is in the perinatal period – an additional barrier to accessing help and treatment may be due to childcare reasons. There is also an additional layer of stigma that new parents feel if they become depressed in the perinatal period and access to care can be more problematic for these reasons. For the 'treatment' sectionFor SSRI – to add - consider if the women is pregnant or breastfeeding. Group physical activity – Individual physical activity should be an option	Thank you for your comment. The committee agreed that there could be many barriers to treatment for many different sections of the population and the tables of treatment options cannot cover all of these in detail. Prescribing to pregnant women would always need an individualised approach and the level of detail you suggest would not be appropriate to include in this guideline. The evidence for exercise related specifically to group exercise and not individual exercise so this is what the committee recommended.

466	SH	APPG for Prescribed Drug Dependence	GuidelineAnd Evidence Review B	23031	Table 1Table 2Visual summary 1 & 2	The results of the NMAs and cost analysis for individuals with first episode of depression showed that the treatments included were all found to be similarly clinically effective, and all included interventions have been found to be cost effective. Surely this means that options should be offered in a non-ranked way (e.g., alphabetically), not as currently presented in the visual summary & text. Specifically, the evidence in this review does not support antidepressants being offered before counselling or short term psychodynamic therapy which are currently placed further round the cycle of options. Given the text advice to not routinely offer antidepressants as a first line treatment, they should be the last intervention in the list.	Thank you for your comment. Although NMA and economic results were characterised by uncertainty, they did not suggest that all treatments were similarly clinically and cost-effective. For example, in less severe depression, the effect of individual CT/CBT class vs TAU (based on an evidence base of N=481) was -0.73 (95%CrI -1.78 to 0.36), whereas the respective effect of counselling (based on a narrower evidence base of N=55) was -0.20 (95%CrI -2.82 to 2.50) – see bias-adjusted results in Table 9, evidence report B. Moreover, as seen in Table 10, results for interventions within individual CT/CBT class showed evidence of effect vs TAU, which was not the case for non-directive counselling at the intervention level. Regarding clinical effectiveness derived from the NMAs, the committee considered not only the mean effects of treatment classes vs the reference treatment, but the uncertainty around them (as expressed in 95%CrI), the volume of the evidence base for each treatment, and the evidence of effect or the lack of it (as shown by 95%CrI crossing or not the no effect line) of the classes but also of the individual interventions within each class, versus the reference treatment. They also considered the results of pairwise meta-analysis of follow-up data, functioning nad quality of life data. Regarding cost-effectiveness, it is not true that

							all interventions were found to be cost-effective: in less severe depression, non-directive counselling and short-term psychodynamic psychotherapy were found to be less cost-effective than GP care. In more severe depression, IPT and short-term psychodynamic psychotherapy were found to be less cost-effective than GP care. Highly ranked interventions in economic analysis were more cost-effective than interventions lower in ranking, although there was uncertainty in the results and differences might be small in some cases. Interventions are arranged in Tables 1 and 2 of the guideline in the suggested order in which options should be considered, based on the committee's interpretation of their clinical and cost effectiveness, and consideration of other issues such as the availability of treatments (individual problem solving) and the structure of IAPT services. However, this is not a rigid hierarchy, all treatments included in Tables 1 and 2 can be used as first-line treatments, and it may be appropriate to recommend an intervention from lower down in the table where this best matches the person's preferences and clinical needs. The committee were aware of the need to provide a wide range of interventions to

							take into account individual needs and allow patient choice. Antidepressants were listed above counselling and short term psychodynamic therapy for less severe depression in Table 1 because these psychological interventions (unlike antidepressants) were found to be less cost-effective than GP care in the guideline economic analysis. However, the committee did make a recommendation to not routinely offer antidepressants as first-line treatment to this population unless that was the person's preference.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

467	SH	The Mindfulness Initiative	Guideline	23	Table 1	To improve a person's choice over their treatment we recommend that this table is not ranked in terms of effectiveness (which will differ with individuals) but instead that all the available evidence-based treatment options are presented (e.g. as menu options) to a person with less severe depression in a way that allows them to make an informed choice about their treatment. There is a direct correlation between an individual's choice over their treatment and its effectiveness. We are concerned that by ranking the treatments, assumptions are being made over what an individual's preference might be, and they are not truly being given choice over access to them. Because they are used by the general population and is not only linked to treatment of mental health, mindfulness-based treatments are a popular and non-stigmatising choice.It would be helpful for people to be given an accompanying patient leaflet setting out each of the treatment options, with a brief description of what they involve. We would be happy to provide assistance in drafting the relevant information on the mindfulness-based interventions.	Thank you for your comment. The committee listed the treatments in order of clinical and cost-effectiveness to guide treatment selection for people with depression and clinicians. The committee were aware that many people with depression express a preference for 'a talking therapy' but do not have a preference beyond that, so a certain degree of ordering will help in this situation. For people who do express a particular preference, the treatment of choice can be selected, without having to fail other treatments first.

468	SH	Institute of Psychoanalysis	Guideline	23031	Table 1Table 2Visual summary 1 & 2	It is very striking and of great concern that the treatments in these Tables and in the accompanying text throughout this document, including the two visual summaries provided separately, are hierarchically ordered even though not a single treatment included in these analyses have been proven more clinically effective or indeed more cost-effective. Additionally, some interventions are highlighted as “more effective” or “more cost effective” compared to other interventions in various places of the guideline documents and review evidence B. This is misleading given the findings reported and this should be amended. The NMA and economic cost analysis do not suggest a clear hierarchy of treatments and thus highlight the need to offer a menu (non-ranked) of treatment options for new episodes of depression to be made available. We suggest an ordering in alphabetical order in the Tables and Visual Summaries might perhaps be most appropriate.Additionally, we strongly advise that the hierarchy of treatment options for first-line and ‘more severe’ depression must be replaced with a menu (non-ranked) on the basis that (1) there is no evidence that the treatments are differentially effective in any clinically meaningful way on the basis of the NMA analyse; (2) the economic analyses are – by admission of the researchers who conducted the analyses -	Thank you for your comment. Although NMA and economic results were characterised by uncertainty, they did not suggest that all treatments were similarly clinically and cost-effective. For example, in less severe depression, the effect of group CT/CBT class vs TAU (based on an evidence base of N=480) was -1.01 (95%CrI -1.76 to -0.06), whereas the respective effect of counselling (based on a narrower evidence base of N=55) was -0.20 (95%CrI -2.82 to 2.50), i.e. one fifth of the effect of group CT/CBT class, although both treatments were recommended – see bias-adjusted results in Table 9, evidence report B. Similarly, in more severe depression, the effect of individual CT/CBT + AD class vs placebo (based on an evidence base of N=192) was -1.18 (95%CrI -2.07 to -0.44), whereas the respective effect of IPT (based on an evidence base of N=145) was -0.45 (95%CrI -1.36 to 0.47), i.e. almost a third of the effect of individual CT/CBT + AD class – see bias-adjusted results in Table 24, evidence report B. Regarding clinical effectiveness derived from the NMAs, the committee considered not only the mean effects of treatment classes vs the reference treatment, but the uncertainty around them (as expressed in 95%CrI), the volume of the evidence base for each treatment, and the evidence of effect or the lack of it (as shown by

						show high levels of uncertainty related to the relative effectiveness and cost effectiveness of all the interventions. This includes a high degree of uncertainty about the estimates of cost. Notwithstanding the serious critique highlighted above about the NMA, this is an important finding as it replicates and confirms what many other studies and systematic reviews have found, mostly recently Cuijpers and colleagues in two systematic reviews (2020, 2021a).	95%CrI crossing or not the no effect line) of the classes but also of individual interventions within each class, versus the reference treatment. They also considered the results of pairwise meta-analysis of follow-up data, as well as data on functioning and quality of life. Regarding cost-effectiveness, highly ranked interventions in the guideline economic analysis were more cost-effective than interventions lower in ranking, although there was uncertainty in the results and differences might be small in some cases (especially for interventions in close ranking places). Some interventions were found to be less cost-effective than GP care in less or more severe depression (or both). Interventions are arranged in Tables 1 and 2 of the guideline in the suggested order in which options should be considered, based on the committee's interpretation of their clinical and cost effectiveness, and consideration of other issues such as side effects (antidepressants), applicability of the evidence (e.g. individual problem solving), and structure of IAPT services. However, this is not a rigid hierarchy, all treatments included in Tables 1 and 2 can be used as first-line treatments, and it may be appropriate to recommend an intervention from lower down in the table where this best matches

							the person's preferences and clinical needs. The committee were aware of the need to provide a wide range of interventions to take into account individual needs and allow patient choice. Listing interventions in a non-ranked menu would not reflect the evidence base nor serve as a guide to choice for those who do not have pre-existing preferences. Statements that one intervention was found to be 'more effective' or 'more cost-effective' than another intervention referred to results and conclusions of published economic studies included in the systematic review of economic evidence, described under 'Summary of studies included in the economic evidence review'. Such statements were not made for the results of the NMA or the guideline economic analysis, where treatments may have been described as 'ranking more highly' than another in terms of clinical or cost-effectiveness. The committee were aware of the Cuijpers et al. (2021) NMA papers. They considered that this study also supported their recommendations made based on their systematic review of the evidence, that all psychological treatments will provide some benefit, so offering a wide choice of treatments is appropriate, but that

							counselling may not provide the same level of treatment response - hence counselling was ranked in lower places in the recommendation tables.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

469	SH	Leeds Community Healthcare NHS trust	Guideline	23	Table 2	This recommendation will be an extremely challenging change, as current waiting lists for step 3 therapies are over 12 months and for more severe depression. It would result in huge changes to screenings and evidence based algorithms we currently use to determine which step is appropriate.	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive and least resource intensive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice.
470	SH	Leeds Community Healthcare NHS trust	Guideline	23	Table 2	12-16 bi-weekly sessions of cognitive behavioural therapy 60 minutes each would decrease capacity as currently we are offering 50 minute weekly appointments and have extremely long waiting list for CBT.	Thank you for your comment. The frequency and duration of sessions of psychological therapies has now been removed from the recommendations, to allow more flexibility in the delivery of interventions.
471	SH	Leeds Community Healthcare NHS trust	Guideline	23	Table 2	Self help for severe depression: Suggests initial session of 30 mins with further 7 sessions of up to 15 minutes. Is not clear whether initial 30 mins include telephone assessment?	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective assessment of clients and delivery of low intensity interventions.

472	SH	Leeds Community Healthcare NHS trust	Guideline	23	Table 2	Is very difficult to assess risk and do treatment in 15 minutes.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective assessment of clients and delivery of low intensity interventions.
473	SH	Leeds Community Healthcare NHS trust	Guideline	23	Table 2	Will potentially impact engagement as patients may feel rushed in 15 minute appointments.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions and patient engagement.
474	SH	Leeds Community Healthcare NHS trust	Guideline	23	Table 2	What if someone is late to their self help appointment? 15 minute appointments do not allow for patients being slightly late to their appointment. We currently call the patient 3 times in 5 minute intervals and if more than 15 minutes late, we rearrange the appointment.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

475	SH	Leeds Community Healthcare NHS trust	Guideline	23	Table 2	Will potentially affect Job retention as psychological wellbeing practitioners will feel even more burnout and pressure and will potentially have to retrain.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.
476	SH	Leeds Community Healthcare NHS trust	Guideline	23	Table 2	For a 15 minute appointment to be effective, they would need to be motivated and engaged, however low motivation is a symptom of depression.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions and patient engagement.

477	SH	Leeds Community Healthcare NHS trust	Guideline	23	Table 2	No Step 2 groups mentioned for less severe depression.	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive and least resource intensive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. Psychoeducation groups are not included in the recommendations for less severe depression as evidence from the network meta-analysis shows neither a clinically important nor statistically significant benefit of a psychoeducation group intervention relative to TAU on depression symptomatology for adults with less severe depression.

478	Individual	Individual 1	Guideline	24	General	The section on individual CBT suggesting 8 sessions goes against the recommendation that depression requires 16-20 sessions, 12 is often not enough and in fact this restriction will lead to higher costs in the long run as people re-refer rather than reduce costs as this document clearly suggests is the priority. Recommend that clients are offered up to 20, 90-minute sessions.	Thank you for your comment. For individual CBT in less severe depression, the guideline economic analysis, which informed guideline recommendations, considered individual CBT<15 sessions as an exemplar from the individual CBT class, because it had a very similar effect to CBT≥15 sessions and a somewhat larger evidence base across RCTs on the SMD outcome (see Table 10, results of bias-adjusted analysis for less severe depression, in evidence review B). The recommended resource use for all recommended interventions was based on relevant information reported in the RCTs that informed the guideline NMA and economic analysis of treatments for a new episode of depression, supplemented by the committee's clinical experience on optimal delivery of interventions within the NHS. This information has now been added in evidence review B, under Appendix N. It shows that all RCTs on individual CBT for less severe depression report 7-8 sessions, with the exception of 1 small study reporting 10 sessions. 'Usually' 8 sessions were recommended for individual CBT for less severe depression based on this information, supported by the committee's opinion that 8 sessions of a high intensity intervention are usually adequate for a population with less severe depression. The recommended number of 'usual' sessions serves

							only as guidance and can be modified depending on individual needs. This has now been clarified in the recommendation. Suggested duration of sessions has now been removed from the recommendations to allow flexibility in the delivery of interventions.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

479	SH	We Are With You	Guideline	24	General	IAPT services, commissioned to provide brief interventions for mild depression, currently offer practitioner-delivered low intensity guided self-help (CBT-based), where individual treatment appointments generally last for 30 minutes (not 60 minutes) with an average of four to six appointments (not 8). Low intensity treatments, as currently delivered in IAPT services, are clinically effective with good move to recovery rates. Changing treatments to 60 minutes for people presenting with mild depression will have significant impacts on service capacity, wait times and access rates and it is not clear if clinical outcomes can be expected to be significantly better than they are now.	Thank you for your comment. The duration of sessions has now been removed from recommendations to allow flexibility in the delivery of interventions. Furthermore, the recommendations have now been updated to clarify the role of low intensity interventions in the treatment pathway.
480	Individual	Individual 2	Guideline	24	Table 1	Individual CBT as first choice treatment, the stepped model of IAPT which is based on evidence, states guided self-help should be offered first – i.e. 8 bi-weekly sessions of half an hour rather than 8 weekly sessions of 60 minutes. I am concerned that this will increase the waiting lists for CBT therapists and increase the wait times for patients unnecessarily when working at PWP level (step 2) would be effective in the first instance. Evidence suggests the least intrusive option should be offered first.	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive, least resource intensive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The self-help with support section has been relabelled as guided self-help, and placed earlier in the treatment pathway. The frequency and duration of sessions of psychological therapies has also now been removed from the

							recommendations, to allow more flexibility in the delivery of interventions.
481	SH	Sport England	Guideline	24	Table 1	There is opportunity within the behavioural activation and self-help approaches to promote free national resources that support people living with mental health conditions to be more active. We recommend referencing and signposting patients to our We Are Undefeatable support tools. We recommend clinicians utilise the Moving Medicine programme. This is a free initiative by The Faculty of Sport and Exercise Medicine which supports healthcare professionals integrate physical activity conversations into routine clinical care. This includes evidence-based resources specifically for the treatment of depression.	Thank you for your comment. In response to stakeholder comments, the committee supported 'move more' exercise for general wellbeing (although not as a treatment for depression) and made a new recommendation to reflect this. Thank you for telling us about the existing physical activity programmes and campaigns. These will be passed on to the NICE shared learning team.

482	SH	Leeds Community Healthcare NHS trust	Guideline	24	Table 2	Step 3 groups consisting of only 8 participants will affect waiting times as current capacity is much greater.	Thank you for your comment. Presumably the comment refers to Table 1, as Table 2 includes only individual step 3 interventions (the only group intervention in Table 2 is group exercise). The recommended resource use was based on relevant information reported in the RCTs that informed the guideline NMA and economic analysis of treatments for a new episode of depression, supplemented by the committee's clinical experience on optimal delivery of interventions within the NHS. This information has now been added in evidence review B, under Appendix N. Few studies made specific reference to the number of participants per group. For group CBT and group BA in less severe depression this ranged between 4-8 participants per group. For group MBCT one study reported 8-15 participants per group. This reported use, combined with the committee's considerations on optimal delivery of group interventions have been reflected in the respective recommendations, which suggest the number of participants that groups should 'usually' have, which allows flexibility around the number of participants per group.

483	Individual	Individual 16	Guideline	25	General	This recommendation will have implications for NHS IAPT services who work within the stepped care model, effectively making step 2 redundant for the treatment of depression.	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive and least resource intensive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The self-help with support section has been relabelled as guided self-help, and placed earlier in the treatment pathway.

484	SH	We Are With You	Guideline	25	General	IAPT services, commissioned to provide brief interventions for mild depression, currently offer practitioner-delivered low intensity guided self-help (behavioural activation), where individual treatment appointments generally last for 30 minutes (not 60 minutes) with an average of four to six appointments (not 8). Low intensity treatments, as currently delivered in IAPT services, are clinically effective with good move to recovery rates. Changing behavioural activation treatments to 60 minutes for people presenting with mild depression will have significant impacts on service capacity, wait times and access rates and it is not clear if clinical outcomes can be expected to better.	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive and least resource intensive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The self-help with support section has been relabelled as guided self-help, placed earlier in the treatment pathway, and the description of guided self-help has been amended to recommend that printed or digital materials that follow the principles of guided self-help are used including structured CBT, structured BA, problem solving or psychoeducation materials, delivered face-to-face or by telephone or online. The frequency and duration of sessions of psychological therapies has also now been removed from the recommendations, to allow more flexibility in the delivery of interventions. The BA referred to in the recommendations is a high intensity intervention, and changes to recommendations for low intensity interventions are described above.

485	SH	Oxford Health NHS Foundation Trust	Guideline	25	Table 1	This suggests that self-help with support sessions are 15 mins – most telephone/digital sessions are at least 30 mins for guided self-help.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.
486	Individual	Individual 1	Guideline	26	General	The section on self-help with support will be difficult to implement as actual practice often requires longer than 30-minutes. It often takes 15-minutes to set up the session, complete measures and manage risk. Further limitations will only lead to unnecessary stepping up, re-referrals and increase burnout in staff as the reduced clinical time will result in staff having to see more people a week.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.
487	Individual	Individual 3	Guideline	26	General	The recommendation to complete self-help with support assessments in 30 minutes for both less severe and severe depression will be a challenging change to practice because quite a high number of assessments I have completed have taken 45 minutes and up to 1 hour. This does not consider those who need more time including older adults and those with health conditions.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective assessment of clients and delivery of low intensity interventions.

488	Individual	Individual 3	Guideline	26	General	The recommendation for 7 treatment sessions at 15 minutes each for self-help support is going to be a challenging change in practice because 15 minutes is in my opinion is not an adequate timeframe to explore an intervention.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective assessment of clients and delivery of low intensity interventions.
489	Individual	Individual 3	Guideline	26	General	I agree that considering the capacity of individual adaptions will be needed if offering 15 minutes for self-help support. This will be challenging to practice as 99% of my clients in 8 years of being a PWP have needed individual adaptations.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.
490	Individual	Individual 3	Guideline	26	General	The recommendation for shorter guided self-help sessions could lead to higher caseloads and burnout is highly prevalent within PWP field. This could cause further retention difficulties and implies that what PWP's do is insignificant.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.

491	Individual	Individual 14	Guideline	26	General	The recommendation is listed as 'Usually consists of 8 structured sessions (face-to-face or by telephone or online), with an initial session of up to 30 minutes and further sessions of up to 15 minutes • Usually takes place over 16 weeks'.Guided self-help in primary care IAPT services is usually delivered with a 45 minute assessment and a further 4-8 x 30 min sessions. Recommending less time than this would water down this treatment further which I feel would have a significant effect on its efficacy, due to a lack of adequate time to build an effective therapeutic relationship, and a lack of time to do everything that is needed in a follow-on session: complete a maintenance formulation diagram (usually in the first session), collect the minimum data set if needed, review compliance with meds if needed, check-in on how the week has been, review homework and discuss and problem solve any difficulties completing it/other difficulties that have cropped up, discuss the learning from the task and how to advance the use of techniques, set specific homework, book next appointment. As depression often brings cognitive impairment / poor concentration as a symptom, sessions sometimes need to be longer rather than shorter, to give a patient adequate time to process and respond to information. Shorter sessions would therefore be to the detriment of patients.The	Thank you for your comment. The usual number of sessions was informed by reported resource use in the RCTs that were included the NMA and the guideline economic analysis. This information is now reported in evidence review B, under Appendix N. The recommendation has now been amended to 'usually 6 to 8' sessions, which allows some flexibility. The suggested duration and frequency of sessions have now been removed from the recommendations to allow flexibility in the delivery of interventions, but it is indicated that regular sessions need to take place.

						recommendations here also suggest fortnightly sessions – whilst these can be helpful for some patients, the standard in IAPT services / clinical practice is often weekly sessions. Indeed even this higher frequency than made in the recommendation is often inadequate. Good practice when working with depressed clients is to offer more frequent contact where needed initially in treatment, to help capitalise on patient motivation and help break behavioural inertia. As behavioural activation is the main strategy used in guided self-help for depression it feels like recommending fortnightly sessions will be detrimental to the efficacy of the intervention. I would also expect it to be detrimental to the therapeutic relationship due to the longer gaps in contact. There is also a burden for the clinician, in that when seeing patients fortnightly their caseload is then twice as large (so rather than having a caseload of 30-50 patients, it would be 60-100). The cognitive burden of trying to hold so many patients in mind and the associated admin burden, potential need for risk management and emotional burden of hearing about so many patient's problems seems nightmarish. IAPT roles are well recognised to be busier than is healthy which is evidenced in staff turnover rates (see for example Koomson et al: https://www.rcpsych.ac.uk/docs/default-	

						source/events/faculties-and-sigs/general-adult-psychiatry-20/research-case-reports/abeku-koomson.pdf?sfvrsn=76850f44_2#:~:text=Amongst%20the%20IAPT%20workforce%2C%20PWPs,in%20the%20mental%20health%20field2.). This recommendation would be a step in the wrong direction in this regard, and to the detriment of both clinicians and therefore services.	

492	Individual	Individual 16	Guideline	26	General	We are concerned that this is not clear. It appears that the timings for this intervention have been taken from computerised cognitive behaviour therapy research, however the recommendation reads as though this would be for all or any step 2 intervention.	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive, least resource intensive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The self-help with support section has been relabelled as guided self-help and the description of guided self-help has been amended to clarify that this is not restricted to computerised CBT . In response to stakeholder comments, the committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.

493	SH	Department for Environment, Food & Rural Affairs	Guideline	26	General	Given group physical activities and group mindfulness and meditation are shown to be both effective and cost effective in this guidance, ensuring these physical activities are in green space could provide additional benefits, and should be considered in the recommendation.	Thank you for your comment. Nature-based interventions were not specified in any of the review protocols and thus specific benefits of these interventions as a treatment for depression have not been sought or reviewed. However, in response to stakeholder comments, the committee supported less intense 'move more' exercise for general wellbeing (although not as a treatment for depression) and made a new recommendation to reflect this. The recommendation also emphasised the benefits of outdoors activities.
494	SH	Herefordshire and Worcestershire Healthy Minds	Guideline	26	General	One of the factors that contribute towards successful treatment outcomes is the ability to build a therapeutic patient/therapist relationship. At present Psychological Wellbeing Practitioner's have to battle with the current time constraints to build a therapeutic relationship and deliver appropriate therapeutic interventions. Shortening sessions to 15 minutes will severely impact on the ability to do this and therefore impact negatively on patient outcomes.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions and development of a therapeutic patient/therapist relationship.
495	SH	Herefordshire and Worcestershire Healthy Minds	Guideline	26	General	Psychological Wellbeing Practitioner sessions usually involve routine practices which include a review of how the patient has been since the last session, checking for changes in medication, risk, reviewing MDS (questionnaires) which takes some considerable time and is important to the treatment session. Reducing sessions to 15 mins	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility

						will not allow adequate time for these reviews whilst also working on and intervention.	and ensure effective delivery of low intensity interventions.
496	SH	Herefordshire and Worcestershire Healthy Minds	Guideline	26	General	Some interventions at step 2 take longer than others. 15 minute sessions will reduce the opportunity for patients to ask questions, resolve concerns or any barriers, again impacting on the effectiveness of the treatment.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.
497	SH	Herefordshire and Worcestershire Healthy Minds	Guideline	26	General	Patient engagement: Patient may not feel important, considered, or listened to. Sessions may feel impersonal and patients may struggle to engage as they may feel rushed and not properly understood. It is not felt that the changes would benefit the client. Clients are often more complex than just 'low mood' which means there is no space to adapt sessions if we are only able to provide 15 minute sessions. These changes will impact all patients at step 2; including those with more severe symptoms and complexity.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions and patient engagement.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

498	SH	Herefordshire and Worcestershire Healthy Minds	Guideline	26	General	Many of our clients suffer with social isolation. I think it is important that we have the full 30 minutes with them to really ensure we can continue to build on our therapeutic relationship and show them the importance of connection. Ie. I have a client who always says how much better he feels after our session and this has encouraged him to go on and open up conversations with family and friends now he recognises the importance of this. This may have not been possible if we only had 15 minutes as we wouldn't have time to reflect on things like this.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions and patient engagement.
499	SH	Herefordshire and Worcestershire Healthy Minds	Guideline	26	General	Staff retention: Not allowing staff the adequate and appropriate time to implement the skills and competencies will lead to staff retention issues, burnout and stress; which will subsequently impact on patient care. The changes would place unrealistic expectations and demands on PSYCHOLOGICAL WELLBEING Practitioners which would be detrimental to their wellbeing and role.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

500	SH	Herefordshire and Worcestershire Healthy Minds	Guideline	26	General	The changes reflect a lack of respect or importance around the step 2 Psychological Wellbeing Practitioner role. The Psychological Wellbeing Practitioner role is pivotal in providing patients with the appropriate level of support in order to prevent further deterioration which would lead to a demand for further resources at step 3 and above.	Thank you for your comment. In response to stakeholder comments, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive, least resource intensive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The self-help with support section has been relabelled as guided self-help, moved to the beginning of Table 1, and the description of guided self-help has been amended. In response to stakeholder comments, the committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.
501	SH	Herefordshire and Worcestershire Healthy Minds	Guideline	26	General	Regarding the first session being 30 minutes: Most first sessions at step 2 last around 45 minutes as it allows enough time to establish expectations and rapport with a patient and also look into risk, MDS, and formulation properly. Some service users have never had CBT before, so making the first sessions shorter will take away an opportunity to properly socialise some patients to the CBT model.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility

							and ensure effective delivery of low intensity interventions.
502	SH	Herefordshire and Worcestershire Healthy Minds	Guideline	26	General	There is no clear rationale for offering shorter sessions over a longer period of time. Some patients struggle with motivation but are able to engage over 6 sessions/12 weeks- we may be likely to see more patients DNA from treatment if it is prolonged. Furthermore, with treatment stretched over 16weeks/4 months we are more likely to see cancellations and DNA's as a result.	Thank you for your comment. The suggested duration and frequency of sessions of psychological interventions have now been removed from the recommendations for all interventions, to allow flexibility in their delivery, but it is indicated that regular sessions need to take place.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

503	SH	Herefordshire and Worcestershire Healthy Minds	Guideline	26	General	Unless these changes are to be accompanied by changes to ensure that our service operates as intended (i.e. treating low-risk, low-scoring, motivated to get better, highly engaged and suffering no added life stresses or severe LTCs – those who are, in fact, already offered other suitable options such as cCBT and psychoeducation courses, but instead would prefer telephone work), these changes do not appear cohesive to our current working environment and challenges.	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive, least resource intensive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The self-help with support section has been relabelled as guided self-help, placed earlier in the treatment pathway, and the description of guided self-help has been amended to recommend that printed or digital materials that follow the principles of guided self-help are used including structured CBT, structured BA, problem solving or psychoeducation materials, delivered face-to-face or by telephone or online. The frequency and duration of sessions of psychological therapies has also now been removed from the recommendations, to allow more flexibility in the delivery of interventions.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

504	SH	Herefordshire and Worcestershire Healthy Minds	Guideline	26	General	Given that Psychological Wellbeing Practitioners have now been offered the opportunity to become accredited- reducing sessions to 15 minutes is demoralising to the role.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.

505	SH	Herefordshire and Worcestershire Healthy Minds	Guideline	26	General	The evidence provided in favour for this is all in relation to computerised cognitive behavioural therapy.	Thank you for your comment. Different self-help approaches (with or without support) were searched for and were eligible for inclusion. In addition to computerised approaches, there are also RCTs of cognitive bibliotherapy, behavioural bibliotherapy, expressive writing, mindfulness meditation CD, relaxation training CD, and third-wave cognitive therapy CD, included in the network meta-analyses (NMAs) for treatment of a new episode of depression. One intervention per class was used as an exemplar in the economic analysis, as it was not feasible to model all interventions included in the NMA. cCBT was selected as the exemplar from the class of self-help with support as it had a large evidence base and a high effect compared with other interventions in the same class. Thus, the clinical evidence and resource use data used to inform the economic analysis were specific to cCBT; consequently, the results of the economic analysis were specific to cCBT (but could also be extrapolated to any other intervention with similar acceptability, effectiveness and resource use). However, the treatment class effect size for self-help (with or without support) that was estimated from the NMA and reported in the clinical evidence sections of evidence review B, was informed by

							evidence from all interventions included in the treatment class. In addition, individual intervention effects have been reported in the evidence review B for all interventions within each class for the SMD outcome (for both less and more severe depression). In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. In response to stakeholder comments, the committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.

506	SH	We Are With You	Guideline	26	General	'Self-help with support' is recommended to be offered as an initial 30 minute session followed by eight 15 minute sessions over 16 weeks. This is a significant change from current models of delivering guided self-help in IAPT services and practitioners have concerns that a 15 minute appointment is insufficient for safe, effective practice accommodating agenda setting, risk review (and risk management, as needed), progress review (including review of clinical questionnaire responses) and collaborative working to explain concepts and overcome treatment barriers or challenges. This recommended way of working is significantly different to IAPT current practice and would require a substantial overhaul of Psychological Wellbeing Practitioner training and course curricula as well as practice in service. Practice changes in service could have a significant and unsettling impact on the existing Psychological Wellbeing Practitioner workforce, where retention is already a challenge.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.
507	SH	Sussex Partnership NHS Foundation Trust	Guideline	26	Table	In table on self-help with support – 15 min follow ups sound very short indeed (same on p.36).	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility

							and ensure effective delivery of low intensity interventions.
508	Individual	Individual 2	Guideline	26	Table 1	Table 1: Self-help with support – further sessions of 15 minutes. This recommendation will be incredibly difficult to put into practice given that a risk assessment must be completed each session, a review of homework, a new stage of intervention introduced and explained, COMB factors considered and a summing up. This means patients will not get the best care and thus this will become an ineffective therapy.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.
509	Individual	Individual 2	Guideline	26	Table 1	This puts patients in danger as risk assessments would be rushed and all possible concerns not fully explored.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

510	SH	Sport England	Guideline	26	Table 1	We support the inclusion of peer supportThere is strong evidence that peer-to-peer support is effective for improving mental health, and interactions with others with lived experience supports people to feel motivated (Kinnafick, Smith,Appleton,Tweed, Bayes & Tiler, 2017). Sport England's partnerships with Mind and Rethink take a peer support approach to physical activity as part of the treatment for mental health conditions. This has proven successful in supporting people with both mild and more severe mental health conditions.We are concerned about the frequency and duration information included within the exercise delivery information. We feel '60-minute sessions, usually 3 times a week for 10 weeks' could be unrealistic for people experiencing symptoms associated with mild depression i.e. low motivation and fatigue.Evidence demonstrates those living with diagnosed long term conditions are more likely to be inactive - 42% of adults aged between 25 and 64 years of age with long - term health conditions (including mental health conditions are inactive (completing less than 30 minutes of physical activity a week).We surmise the duration conclusion has been drawn from reviewing only academic research from structured exercise programme interventions using RCT methodology. Setting or advising a 'dose' of physical activity is challenging given the broad	Thank you for your comment. The committee noted that the evidence was for a structured formal exercise programme, with exercise of moderate to high intensity, but recognise there may be challenges to implement this. The committee has now removed the suggested duration of exercise sessions and modified the recommended frequency to allow more flexibility in the delivery of exercise programmes. The committee considered RCTs as the most appropriate study design to assess clinical and cost effectiveness. This is consistent with the NICE guidelines manual which recognises RCTs as the most valid evidence of the effects of interventions. This was outlined a priori in the review protocols, and on this basis non-randomised trials and real-life research were not included. In response to stakeholder comments, the committee supported less intense 'move more' exercise for general wellbeing (although not a treatment for depression) and made a new recommendation to reflect this. The description of interventions in the tables is based on information from the RCTs included in the network meta-analyses, supplemented by the committee's clinical experience on optimal

						spectrum of health outcomes and peoples varying starting points. Scientific evidence continues to support 150 minutes of MVPA per week spread across the week. However, there is also evidence that lower volumes (less than 150 minutes per week), lower intensities (i.e. light physical activity) and lower frequencies (one or two sessions per week) of physical activity may nevertheless confer health benefits (UK Chief Medical Officers' Physical Activity Guidelines, 2019). When considering the intensity, time, type, and frequency of physical activity improvements in health, it is important to tailor the intervention to the individual's needs (Review of Evidence Outcomes of Sport and Physical Activity, 2017). The inclusion of broader evidence to include non-randomised trials (NRTs) and informal, unstructured exercise approaches would surface a lower intensity and duration is also effective in combatting the symptoms associated with mild depression i.e. walking 30 minutes per day for 10 consecutive days or 20 minutes of running three times a week for 10 weeks (Review of Evidence on the Outcomes of Sport and Physical Activity, 2017) and Stubbs et al (2021) Movement for the Mind demonstrates clinically significant mental wellbeing benefits can be gained in two 30 minute sessions a week.We recommend the inclusion of behaviour change tools and techniques i.e. goal setting, chunking, self-monitoring, and	delivery of interventions within the NHS. The committee did not consider it appropriate to include the level of detail included in your comment about the content of the exercise intervention, in order to allow flexibility and tailoring based on individual clinical need. However, the committee did consider it important that the physical activity programme was specifically designed for people with depression, and included that in the recommendation. Treatment options were listed in order of recommended use in the tables based on the committee's interpretation of their clinical and cost effectiveness. In addition to the clinical and cost-effectiveness evidence, the committee also considered implementation issues, the volume of the evidence base for each treatment, and applicability of the evidence to the UK context. These considerations and the rationale for recommendations are outlined in the committee's discussion of the evidence sections in Evidence review B.

						planning are considered within intervention design. Interventions and resources which incorporate these principles have proven particularly successful in helping people to sustain activity levels and integrate into their daily lives beyond treatment pathways.QuestionsIt would be helpful to understand the NICE definition/interpretation of a 'trained practitioner' and 'a physical activity programme specifically designed for people with depression' which is referenced in the guidance. We are concerned that this recommendation may imply formal, structured physical activity only. We understand the table of treatment options is listed in order of recommended use, based on the committee's interpretation of clinical and cost effectiveness. What is the weighting of clinical effectiveness to cost effectiveness to determine the ranking position? Please indicate when the final guidelines are due to be published.	

511	SH	Psychological Professions Network	Guideline	26	Table 1	Session length for self-help with support can vary and reference to 'up to 15 minutes' introduces an arbitrary limit that does not align to the evidence base. We suggest this reference to 'up to 15 minutes' is removed	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.
512	SH	UK University Mindfulness Centres	Guideline	27	General	We recommend that the mindfulness-based cognitive therapy (MBCT) course should be the one and only mindfulness course that is recommended for people experiencing less severe depression. The MBCT course was designed specifically to target psychological mechanisms implicated in depression (1) and has a wealth of evidence from high-quality RCTs supporting its efficacy in the treatment of current depression (2,3). Less intensive mindfulness courses appear to produce weaker effects (4) and the recommendation as it stands could open the door to less intensive and less effective mindfulness courses being offered. There are also UK-wide and international standards for training and supervising MBCT therapists to ensure integrity, quality and safety (see https://bamba.org.uk and www.accessmbct.com respectively). Recommending MBCT specifically in the guideline would ensure that mindfulness	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. However, the committee did agree that MBCT should be given as an exemplar of the Group mindfulness or meditation class, and in

						courses would be of a high standard and would maximise the opportunity for recovery.	Table 1 of the recommendations when considering how to deliver group mindfulness or meditation it is recommended that 'a programme such as mindfulness-based cognitive therapy specifically designed for people with depression' is used.

513	SH	We Are With You	Guideline	27	General	IPT is currently offered as a high-intensity psychological therapy and not a first line treatment for mild or subthreshold depression. In IAPT services the expectation is that the majority of people with mild or moderate depression are offered brief, low-intensity treatments. Where IAPT services are commissioned on a payment-by-results model the tariffs for low intensity treatments are lower than those of high intensity treatments; 16 weekly sessions of IPT will be unaffordable as a treatment offer for subthreshold or mild depression. ****IAPT services use the PHQ9 as a standard measure of depression. Scores of 5-9 on the PHQ9 indicate symptoms of depression at a mild level, which also falls in the non-clinical (ie subthreshold range) for the clinical measure. Therefore the guidance is suggesting 16 weekly sessions of treatment for non-clinical level depression.	Thank you for your comment. The committee considered it important to provide a wide range of interventions to take into account individual needs and allow patient choice. Based on the clinical and cost-effectiveness data, the committee agreed that group CBT or group behavioural activation (BA) were treatments of choice for a new episode of less severe depression in adults, as they had shown a beneficial effect compared to treatment as usual, and appeared to be the most cost-effective classes in the economic analysis. However, the committee also noted that there was evidence of clinical and cost-effectiveness for self-help with support (including computerised CBT). In response to stakeholder comments, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive, least resource intensive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The self-help with support section has been relabelled as guided self-help, placed earlier in the treatment pathway, and the description of guided self-help has been amended.

							IPT had also been demonstrated to be cost-effective in less severe depression and so the committee recommended this intervention as an alternative to the interventions listed higher in Table 1. The committee agreed that, to allow choice of treatments, a wider range of treatments should be offered – and interventions such as IPT would provide alternatives to people who did not wish to have CBT or BA, or had tried them for a previous episode of depression and not found them to be effective. The position of IPT in the table is consistent with this intervention being considered for use after taking into account the other treatments that appear higher in the table.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

514	SH	Leeds Community Healthcare NHS trust	Guideline	27	Table	Offering interpersonal therapy for less severe depression. Not consistent with current offer. Will impact screening and treatment recommendations. Difficult to see how 16 sessions of interpersonal therapy for less severe depression is an effective use of resources.	Thank you for your comment. The committee considered it important to provide a wide range of interventions to take into account individual needs and allow patient choice. Based on the clinical and cost-effectiveness data, the committee agreed that group CBT or group behavioural activation (BA) were treatments of choice for a new episode of less severe depression in adults, as they had shown a beneficial effect compared to treatment as usual, and appeared to be the most cost-effective classes in the economic analysis. However, the committee also noted that there was evidence of clinical and cost-effectiveness for self-help with support (including computerised CBT). In response to stakeholder comments, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive, least resource intensive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The self-help with support section has been relabelled as guided self-help, placed earlier in the treatment pathway, and the description of guided self-help has been amended.

							IPT had also been demonstrated to be cost-effective in less severe depression and so the committee recommended this intervention as an alternative to the interventions listed higher in Table 1. The committee agreed that, to allow choice of treatments, a wider range of treatments should be offered – and interventions such as IPT would provide alternatives to people who did not wish to have CBT or BA, or had tried them for a previous episode of depression and not found them to be effective. The position of IPT in the table is consistent with this intervention being considered for use after taking into account the other treatments that appear higher in the table.

515	SH	UK Mindfulness Centres Collaboration	Guideline	27	Table 1	The row of table 1 on page 27 about group mindfulness / meditation needs considerable attention. Labelling this row 'group mindfulness or meditation' is problematic because that is very vague and broad heading. It could very easily be used to justify the provision of a variety of non-evidence-based interventions which may happen to include some elements of mindfulness / meditation. It would be much preferable to label this row Mindfulness Based Cognitive Therapy (MBCT).Mindfulness Based Cognitive Therapy was designed specifically for people experiencing depression. It has a very substantial evidence base both for depressive relapse prevention and symptom reduction and has been in the NICE depression guidelines since 2004. MBCT is a very well-established and highly respected approach with an extensive literature, rigorous training pathways, a system for the accreditation of training, national good practice guidelines, rigorous methods for assessment of therapist competency, a register of trained therapists, etc, etc.MBCT is a mandated therapy within Increasing Access to Psychological Therapies (IAPT). There is a Health Education England funded national training (entering its 4th year) for High Intensity therapists in IAPT services and so there is steadily increasing availability of MBCT provision across the country.The details in this row of the table are	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. However, the committee did agree that MBCT should be given as an exemplar of the Group mindfulness or meditation class, and in Table 1 of the recommendations when considering how to deliver group mindfulness or meditation it is recommended that 'a programme such as mindfulness-based cognitive therapy specifically designed for people with depression' is used. The recommended resource use was based on relevant information reported in the RCTs that

						misleading and appear to be written by someone who is not familiar with the approach. It would be best to involve an MBCT expert in re-writing it. For example: groups are sometimes delivered by just one practitioner rather than by two, as stated; 8 is often said to be the minimum group size but ideally there are 12-15 participants in a group; the sessions are quite often two and a quarter hours rather than two hours long; a full course of MBCT includes a day of practice, thus a total of 9 sessions rather than 8. The 'key features' and 'other things to think about' columns would also be better written by someone familiar with MBCT.	informed the guideline NMA and economic analysis of treatments for a new episode of depression, supplemented by the committee's clinical experience on optimal delivery of interventions within the NHS. This information has now been added in evidence review B, under Appendix N. Few studies reported the number of participants in group interventions and even fewer made specific reference to the number of therapists per group. For MBCT, only one study on the treatment of a new episode of less severe depression reported the number of participants per group as 8-15. The committee expressed the view that group interventions should be optimally delivered by two therapists, one leading the delivery of the intervention and another one observing, and that the optimal number of participants is around 8. This has been reflected in the economic modelling and the respective recommendations. The committee has now modified the recommendation for MBCT, based on their clinical expertise and available evidence. The suggested delivery is now 'preferably by 2 practitioners at least one of whom has therapy-specific training and competence' with 'usually 8-15 participants per group'. The suggested number of sessions is 'usually' 8 sessions to allow flexibility around the number of sessions

							needed. This also covers programmes that involve 9 sessions. The duration of each session has now been removed from recommended resource use to allow flexibility in the delivery of interventions.

516	SH	UK University Mindfulness Centres	Guideline	27	Table 1	We recommend that the word “meditation” is removed from this recommendation. Meditation is such a broad category. Our understanding is that the evidence for non-mindfulness meditation courses for depression is still very limited.	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. However, the committee agreed that mindfulness based cognitive therapy (MBCT) should be given as an exemplar of the Group mindfulness or meditation class, and in Table 1 of the recommendations when considering how to deliver group mindfulness or meditation it is recommended that 'a programme such as mindfulness-based cognitive therapy specifically designed for people with depression' is used.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

517	SH	UK University Mindfulness Centres	Guideline	27	Table 1	The recommendation is for mindfulness courses to be taught by 2 trained practitioners. This is not based on the research evidence. Almost all the major RCTs of MBCT for depression trials had one trained MBCT teacher teaching each group and health economic analyses were modelled on this. We suggest that this recommendation is changed to:“at least one MBCT teacher (or MBCT in training) who has been (or currently is being) trained and supervised in line with British Association of Mindfulness-Based Approaches good practice guidelines (https://bamba.org.uk).”	Thank you for your comment. The recommended resource use was based on relevant information reported in the RCTs that informed the guideline NMA and economic analysis, supplemented by the committee's clinical experience on optimal delivery of interventions within the NHS. This information has now been added in evidence review B, under Appendix N. Very few studies made reference to the number of therapists per group. The committee expressed the view that group interventions should be optimally delivered by two therapists, one leading the delivery of the intervention and another one observing. This has been reflected in the economic modelling and the respective recommendations. The committee has now modified the recommendation for MBCT, based on their clinical expertise and available evidence. The suggested delivery is now 'preferably by 2 practitioners at least 1 of whom has therapy-specific training and competence'.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

518	SH	UK University Mindfulness Centres	Guideline	27	Table 1	The recommendation for 8 participants in a group is not based on the research evidence. Almost all of the major RCTs of MBCT for depression had up to 15 participants in a group and health economic models were based on this. We recommend that this is changed to:“with up to 15 participants in the group”	Thank you for your comment. The recommended resource use was based on relevant information reported in the RCTs that informed the guideline NMA and economic analysis, supplemented by the committee's clinical experience on optimal delivery of interventions within the NHS. This information has now been added in evidence review B, under Appendix N. Few studies reported the number of participants in group interventions. For MBCT, only one study on the treatment of a new episode of less severe depression reported the number of participants per group as 8-15. The committee expressed the view that the optimal number of participants in a group intervention is around 8. This has been reflected in the economic modelling and the respective recommendations. The committee has now modified the recommendation for MBCT, based on their clinical expertise and available evidence. The suggested delivery is now 'usually 8-15 participants per group'.

519	SH	The Mindfulness Initiative	Guideline	27	Table 1	The reference to 'Group mindfulness or meditation' (emphasis added) in the treatment column of this table is too broad, and risks treatments being offered that are not linked to a solid evidence-base when it comes to being an effective treatment for people with depression. It also does not seem to tally with the rest of the columns in the table, where mindfulness, and MBCT specifically, seem to be the reference point (see for example columns 3 and columns 4).Mindfulness specifically encourages people to open up to all of their felt experience, and practice de-centring from their thoughts and ruminations. Mindfulness is therefore not the same as 'relaxation' meditation, or, indeed, other forms of meditation. Additionally, whilst mindfulness is often cultivated throughout meditation, the emphasis on bring attention to present experience, with an attitude of curiosity, openness and care, can be cultivated through any number of formal and informal activities. This means there are a number of ways in which an individual can access mindfulness as a practice. Mindfulness-Based Cognitive Therapy (MBCT) is a clinical programme that was specifically developed to help people at risk of depression. It incorporates elements of CBT that can be particularly useful for those with depression to manage and respond to the thoughts they are observing. It is provided by trained	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. However, the committee did agree that MBCT should be given as an exemplar of the Group mindfulness or meditation class, and in Table 1 of the recommendations when considering how to deliver group mindfulness or meditation it is recommended that 'a programme such as mindfulness-based cognitive therapy specifically designed for people with depression' is used.

						practitioners who are skilled in managing and supporting the symptoms of depression.To use all of these terms interchangeably/together within the guidance risks creating confusion and leading to ill-informed treatment choices being taken by individuals.It could also result in people with depression being offered meditation treatments that are not evidence-based mindfulness interventions and are ineffective in treating their symptoms. Finally, it paves the way for people with little or no training to offer meditation courses to people who really need specific support with their depression.We recommend that the words 'or meditation' in the treatment column are therefore removed in their entirety.	

520	SH	The Mindfulness Initiative	Guideline	27	Table 1	There is emerging evidence that there is a relationship between the intensity of a mindfulness course and the benefits, but at the same time we know that light-touch interventions do still have some benefits, particularly for people with sub clinical symptoms.[48] It is critical to set this out clearly within the table so that people can make an informed choice about their treatment.In relation to mindfulness-based interventions, there is a robust evidence base behind Mindfulness-Based Cognitive Therapy (MBCT) as an effective and targeted treatment for depression.We recommend therefore that in the row referring to 'Group mindfulness or meditation':the words 'Group mindfulness or meditation' in the treatment column are replaced with the words 'Mindfulness-Based Cognitive Therapy' the second bullet of the second column within this row is removed.a new row is inserted which refers to 'Group mindfulness (not MBCT)' and sets out group mindfulness courses that are run by trained mindfulness practitioners[49] and are specifically designed for supporting people with depression but are adapted for use by (1) particular communities or groups for whom MBCT may not be easily accessible or the preferred treatment choice or (2) people who wish to access a different mindfulness programme, such as MBSR, for personal choice. We recommend that the table is	Thank you for your comment. Based on their overall review of the clinical evidence the committee agreed that some treatment classes and interventions appeared to be more effective than others, but there was otherwise little to choose between treatments. The committee therefore reviewed the results of the health economic modelling which determined which treatments were cost-effective, and used this to develop a suggested prioritisation of which treatments should be offered to people with depression, or considered for use. In response to stakeholder comments some changes have been made to the tables guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. Interventions are arranged in the tables in the suggested order in which options should be considered, based on the committee's interpretation of their clinical and cost effectiveness and consideration of implementation factors. However, this is not a rigid hierarchy, all treatments included in Tables 1 and 2 can be used as first-line treatments, and it may be appropriate to recommend an intervention from lower down in the table where

						not ranked in order, but is rather given as a menu of choices for a person to select from. However, if the ranking system is maintained, the row detailing MBCT as a treatment option should be moved higher up the table.	this best matches the person's preferences and clinical needs. The committee were aware of the need to provide a wide range of interventions to take into account individual needs and allow patient choice. However, the committee did not consider it appropriate to present an entirely non-ranked list or to move MBCT up the list based on the evidence reviewed.

521	SH	The Mindfulness Initiative	Guideline	27	Table 1	The first bullet point in the second column refers to the group intervention being provided by 2 trained practitioners – In IAPT services our understanding is that MBCT is often given by 1 trained practitioner and is still effective. Also, RCTs of MBCT have mostly been based on MBCTs provided by 1 trained practitioner, not 2. We suggest that to prevent cost barriers to treatment, the first bullet therefore refers to 'a trained practitioner' rather than '2 trained practitioners'.	Thank you for your comment. The recommended resource use was based on relevant information reported in the RCTs that informed the guideline NMA and economic analysis, supplemented by the committee's clinical experience on optimal delivery of interventions within the NHS. This information has now been added in evidence review B, under Appendix N. Very few studies made specific reference to the number of therapists per group. The committee expressed the view that group interventions should be optimally delivered by two therapists, one leading the delivery of the intervention and another one observing. This has been reflected in the economic modelling and the respective recommendations. The committee has now modified the recommendation for MBCT, based on their clinical expertise and available evidence. The suggested delivery is now 'preferably by 2 practitioners at least 1 of whom has therapy-specific training and competence'.

522	SH	The Mindfulness Initiative	Guideline	27	Table 1	Randomised control trials (RCTs) of MBCT have generally included groups of up to 15 participants. We recommend the limit of 8 people is amended to 15 to improve choice, accessibility and reduce wait times for people wanting to access MBCT.	Thank you for your comment. The recommended resource use was based on relevant information reported in the RCTs that informed the guideline NMA and economic analysis, supplemented by the committee's clinical experience on optimal delivery of interventions within the NHS. This information has now been added in evidence review B, under Appendix N. Few studies reported the number of participants in group interventions. For MBCT, only one study on the treatment of a new episode of less severe depression reported the number of participants per group as 8-15. The committee has now modified the recommendation for MBCT, based on their clinical expertise and available evidence. The suggested delivery is now 'usually 8-15 participants per group'.
523	SH	The Mindfulness Initiative	Guideline	27	Table 1	We recommend adding a bullet to make it clear that MBCT groups can be offered in person but also via videoconferencing[50] so that people have a choice over how they access the MBCT programme.	Thank you for your comment. The guideline includes a recommendation in the access section of the guideline that commissioners and providers of mental health services should ensure that pathways have a range of different methods in place to deliver treatments in addition to face-to-face meetings, including online delivery.

524	SH	Sussex Partnership NHS Foundation Trust	Guideline	27	Table 1	There is concern that the presentation of the treatments in the order of the wheel is not fully supported by the evidence given the significant differences in trial quality between treatments.	Thank you for your comment. The treatment options presented in the tables and visual summaries (wheels) are in order of recommended use based on the committee's interpretation of their clinical and cost-effectiveness. The effect estimates were based on the bias-adjusted network meta-analysis (NMA) models. As the NMAs included a significant number of small studies, sensitivity analyses were carried out on selected outcomes (including the primary critical outcome for clinical analysis), which adjusted for bias associated with small study size effects. The analyses, which were based on the assumption that the smaller the study the greater the bias, attempted to estimate the “true” treatment effect that would be obtained in a study of infinite size.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

525	SH	Wellmind Health	Guideline	27	Table 1.	Table 1. lists the treatment options recommended for use for less severe depression, listed in order of the committee's interpretation of clinical and cost effectiveness, including individual CBT, however there is no mention of the digital delivery of CBT/MBCT, for which clinically proven courses are effective in significantly reducing levels of depression, stress, and anxiety, and which research has demonstrated can further reduce costs. A clinically proven digital therapeutic (DTx) MBCT course is already in use within the NHS, provided by GPs and mental health services, and further benefits of digital delivery are that it helps to increase access, reduce waiting times, reduce the stigma attached to accessing mental health treatment, and removes the need for face-to-face appointments when social distancing is required. Similarly, group mindfulness or meditation is listed as a treatment option, but the ability to deliver mindfulness and mediation training digitally is not included.	Thank you for your comment. The guideline recommends that people with depression are offered a choice about how all interventions will be delivered including options of face-to-face or remote delivery, and computerised CBT and computerised mindfulness are included under self-help or self-help with support treatment options. However, the committee also discussed the importance of patient choice and problems associated with digital exclusion or digital poverty: some people may prefer a face-to-face intervention either because they are not comfortable using technology, because they lack the appropriate device or internet connection, lack a private and confidential space, or because of wider issues associated with difficulties in accessing services. The committee therefore recommended interventions be available via a range of different methods, and the methods of delivery should be guided by patient choice.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

526	SH	Psychotherapy & Counselling Union	Guideline	28	39	Definition of counsellingThe definition of counselling in the draft guideline is confusing and contradictory. The guideline states that Counselling "Uses an empirically validated protocol developed specifically for depression" (Guideline, pp. 28-29, 33-34). This would suggest that it refers to something like the Person-Centred Experiential Therapy / Counselling for Depression (PCET/CfD) protocol approved for IAPT (see https://www.ucl.ac.uk/pals/research/clinical-educational-and-health-psychology/research-groups/core/competence-frameworks-7). However, the corresponding entries in the lists of assessed interventions (Evidence review B, pp. 291-292) refer to something much more generic, described as "non-directive/supportive/person-centred counselling [individual counselling]", and in discussing a recent study that looked at PCET/CfD, the guideline documents state that "the PCET used in this study was not the same as non-directive counselling" (Evidence review B, p. 146).	Thank you for your comment. All the evidence for counselling that was included in the review for the treatment of a new episode of depression was non-directive counselling, and the committee therefore did not consider it appropriate to recommend specific interventions (for example, Counselling for Depression/Person-Centred Experiential Therapy [PCET]) as the evidence was not reviewed for these interventions. However, based on informal consensus, the committee agreed that counselling should use an empirically validated protocol developed specifically for depression and this was included in the recommendation.

527	SH	University of Nottingham	Guideline	28	General	In the first column of the table, the treatment is labelled 'Counselling'. This is a generic and vague term with potential to cause confusion as there are many different forms of treatment which are referred to as counselling. The specific treatment referred to here is more often referred to in the research literature as "Counselling for Depression (CfD)" as for example in the treatment manual and competence framework cited elsewhere in the draft guideline (p013). The most precise and up-to-date label for the treatment is "Person-Centred Experiential Counselling for Depression" (PCE-CfD). It would aid clarity to refer to this treatment as PCE-CfD throughout the guideline. Use of the acronym PCE-CfD instead of 'counselling' would more clearly distinguish this treatment from other psychological treatments.In the second column of the table, the draft text reads "Usually consists of 8 weekly sessions, of 60 minutes each", however the competence framework recommends between 6 and 20 sessions. It would be more accurate for this range of 6-20 sessions to be specified in the guideline.	Thank you for your comment. All the evidence for counselling that was included in the review for the treatment of a new episode of depression was non-directive counselling, and the committee therefore did not consider it appropriate to recommend specific interventions (for example, Counselling for Depression/Person-Centred Experiential Therapy [PCET]) as the evidence was not reviewed for these interventions. However, based on informal consensus, the committee agreed that counselling should use an empirically validated protocol developed specifically for depression and this was included in the recommendation. The range of 8 sessions for counselling for a new episode of less severe depression is based on reported resource use in the studies that informed the NMA and economic analysis. This information has now been added in evidence review B, under Appendix N. The evidence for counselling came from studies assessing non-directive counselling, which reported a range of 6-16 sessions for less severe depression. This range was modified in the recommendation by the committee based on their clinical expertise. The committee considered that 8 sessions of a high intensity intervention is usually appropriate and adequate for a population with less severe depression. The recommendation suggests

							'usually' 8 sessions. This number serves only as guidance and can be modified depending on individual needs. This has now been clarified in the recommendations. The suggested duration of each session has now been removed to allow further flexibility in the delivery of the intervention.

528	SH	University of Nottingham	Guideline	28	General	In column 3, the description is inaccurate. The approach is based on the qualities of the relationship between client/patient and the PCE-CfD counsellor. It is a very disciplined approach that requires reflexive and experienced person-centred counsellors who have completed PCE-CfD training through attending the courses provided by a number of Universities in England.	Thank you for your comment. All the evidence for counselling that was included in the review for the treatment of a new episode of depression was non-directive counselling, and the committee therefore did not consider it appropriate to recommend specific interventions (for example, Counselling for Depression/Person-Centred Experiential Therapy [PCET]) as the evidence was not reviewed for these interventions. However, based on informal consensus, the committee agreed that counselling should use an empirically validated protocol developed specifically for depression and this was included in the recommendation.
529	SH	University of Nottingham	Guideline	28	General	This does not reflect the client base who access PCE-CfD. This approach offers an alternative to clients who seek an approach that offers non-directive counselling.	Thank you for your comment. All the evidence for counselling that was included in the review for the treatment of a new episode of depression was non-directive counselling, and the committee therefore did not consider it appropriate to recommend specific interventions (for example, Counselling for Depression/Person-Centred Experiential Therapy [PCET]) as the evidence was not reviewed for these interventions. However, based on informal consensus, the committee agreed that counselling should use an empirically validated protocol developed specifically for depression and this was included in the recommendation.

530	SH	University of Nottingham	Guideline	28	General	It may be worth having 'Counselling' as a separate offer, which has a different IAPT CPD to PCE-CfD and focused on Integratively qualified counsellors.	Thank you for your comment. All the evidence for counselling that was included in the review for the treatment of a new episode of depression was non-directive counselling, and the committee therefore did not consider it appropriate to recommend specific interventions (for example, Counselling for Depression/Person-Centred Experiential Therapy [PCET]) as the evidence was not reviewed for these interventions. However, based on informal consensus, the committee agreed that counselling should use an empirically validated protocol developed specifically for depression and this was included in the recommendation.

531	SH	We Are With You	Guideline	28	General	Counselling is currently offered as a high-intensity psychological therapy and not a first line treatment for mild or subthreshold depression. In IAPT services the expectation is that the majority of people with mild or moderate depression are offered brief, low-intensity treatments. Where IAPT services are commissioned on a payment-by-results model the tariffs for low intensity treatments are lower than those of high intensity treatments; 8 weekly 60 minute sessions of counselling will be unaffordable as a treatment offer for subthreshold or mild depression.****IAPT services use the PHQ9 as a standard measure of depression. Scores of 5-9 on the PHQ9 indicate symptoms of depression at a mild level, which also falls in the non-clinical (ie subthreshold range) for the clinical measure. Therefore the guidance is suggesting 8 weekly sessions of treatment for non-clinical level depression.	Thank you for your comment. The committee considered it important to provide a wide range of interventions to take into account individual needs and allow patient choice. Based on the clinical and cost-effectiveness data, the committee agreed that group CBT or group behavioural activation (BA) were treatments of choice for a new episode of less severe depression in adults, as they had shown a beneficial effect compared to treatment as usual, and appeared to be the most cost-effective classes in the economic analysis. However, the committee also noted that there was evidence of clinical and cost-effectiveness for self-help with support (including computerised CBT). In response to stakeholder comments, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive, least resource intensive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The self-help with support section has been relabelled as guided self-help, placed earlier in the treatment pathway, and the description of guided self-help has been amended.

							Counselling was found to be less cost-effective than other treatment options and did not appear to be cost-effective compared with GP care in less severe depression. However, the committee agreed that there may be some sub-groups of people in whom supportive empathetic counselling may help, particularly those with psychosocial, relationship or employment problems contributing to their depression, and that in these groups counselling may be more cost-effective than in the wider population of people with depression. On this basis, counselling was included as a potential option, however, the position of counselling in the table is consistent with this intervention being considered for use after taking into account the other treatments that appear higher in the table.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

532	Individual	Individual 7	Guideline	28	Table 1	Section on selective serotonin reuptake inhibitorsThere should be a statement that response to SSRIs in less severe depression may be poor and that the risks of side effects and withdrawal effects may outweigh the benefits of treatment.	Thank you for your comment. There was evidence for cost-effectiveness for antidepressants in less severe depression, which took into account side-effects so this statement has not been added.

533	SH	We Are With You	Guideline	29	General	STPP is currently offered as a high-intensity psychological therapy and not a first line treatment for mild or subthreshold depression. In IAPT services the expectation is that the majority of people with mild or moderate depression are offered brief, low-intensity treatments. Where IAPT services are commissioned on a payment-by-results model the tariffs for low intensity treatments are lower than those of high intensity treatments; 16 weekly sessions of STPP will be unaffordable as a treatment offer for subthreshold or mild depression.IAPT services use the PHQ9 as a standard measure of depression. Scores of 5-9 on the PHQ9 indicate symptoms of depression at a mild level, which also falls in the non-clinical (ie subthreshold) range for the clinical measure. Therefore the guidance is suggesting 16 weekly sessions of treatment for non-clinical level depression.	Thank you for your comment. The committee considered it important to provide a wide range of interventions to take into account individual needs and allow patient choice. Based on the clinical and cost-effectiveness data, the committee agreed that group CBT or group behavioural activation (BA) were treatments of choice for a new episode of less severe depression in adults, as they had shown a beneficial effect compared to treatment as usual, and appeared to be the most cost-effective classes in the economic analysis. However, the committee also noted that there was evidence of clinical and cost-effectiveness for self-help with support (including computerised CBT). In response to stakeholder comments, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive, least resource intensive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The self-help with support section has been relabelled as guided self-help, placed earlier in the treatment pathway, and the description of guided self-help has been amended.

							Short-term psychodynamic psychotherapy was found to be less cost-effective than other treatment options and did not appear to be cost-effective compared with GP care in less severe depression. However, the committee agreed that short-term psychodynamic psychotherapy may be useful (and therefore may be more cost-effective) where developmental difficulties in relationships contributed to depression. On this basis, short-term psychodynamic psychotherapy was included as a potential option, however, the position of short-term psychodynamic psychotherapy at the bottom of Table 1 is consistent with this intervention only being offered after the other interventions that appear higher in Table 1 have been considered for use.

534	SH	Sussex Partnership NHS Foundation Trust	Guideline	30	021-022	We suggest the phrase "psychiatrists, and other psychological therapists" suggests that psychiatrist are psychological therapists. We recommend the phrase is altered to "psychiatrists and other practitioners [or clinicians], such as psychological therapists", or a similar phrase.	Thank you for your comment. The phrase you refer to does not appear on page 30 of the guideline, or elsewhere in the guideline so the change you suggested has not been made.
535	SH	The Mindfulness Initiative	Guideline	30	14	We have concerns that by including moderate depression in the definition of 'more severe depression' the guidelines are restricting evidence-based, non-invasive, and non-stigmatising treatment options for people experiencing moderate depression, such as Mindfulness-Based Cognitive Therapy. Trials of MBCT for current depression did include people with moderate depression, so this recommendation as it stands is not based on the research evidence.	Thank you for your comment. The committee considered the distinction between less severe (subthreshold/mild) and more severe (moderate/severe) depression to be clinically meaningful in terms of supporting effective clinical decision making and being aligned with how clinicians conceptualize depression (in particular, GPs and other primary care staff, given that the majority of people with depression and almost all first line presentations of depression are managed in primary care). Based on this distinction, an anchor point of 16 on the PHQ-9 was selected as the cut-off between less severe and more severe depression, on the basis of alignment with the clinical judgement of the committee and eligibility criteria in the included studies. Published standardization of depression measurement crosswalk tables (Carmody 2006; Rush 2003; Uher 2008; Wahl 2014) were used in order to 'read-across' different symptom severity scales that were used in different studies.

536	SH	Voyage Care	Guideline	31	10	1.6.1 We agree there should be a choice regarding first line treatments but recognise this may be impacted due to availability of treatments and waiting lists. What advice should be given to the person under these circumstances.	Thank you for your comment. The committee were aware that waiting lists may impact on people's choice of treatments and so have added an additional recommendations in the section on the delivery of psychological treatments to reflect this, and also made a recommendation to commissioners in the section on the choice of treatments to advise the timely availability of NICE-recommended treatments.
537	Individual	Individual 10	Guideline	31	12	Table 2: Couple therapy for depression should be included in the list of treatment options for more severe depression. It seems as if the decision to leave it out was based on the incorrect assumption that is it only appropriate and effective for people who are in a distressed relationship, but this is not the case (e.g. Barbato, A. & D'Avanzo, B. (2020). The findings of a Cochrane Meta-Analysis of couple therapy in adult depression: Implications for research and clinical practice. Family Process, 59 (2), 1-15.)	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA). The committee did not consider it appropriate to include behavioural couples therapy in the tables of treatment options in the guideline as the evidence and recommendation for behavioural couples therapy was for a subgroup of people with depression, unlike the other interventions listed in these tables.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

538	Individual	Individual 10	Guideline	31	12	Table 2: Couple therapy for depression should be included in the list of treatment options for more severe depression. It seems as if the decision to leave it out was based on the incorrect assumption that is it only appropriate and effective for people who are in a distressed relationship, but this is not the case (e.g. Barbato, A. & D'Avanzo, B. (2020). The findings of a Cochrane Meta-Analysis of couple therapy in adult depression: Implications for research and clinical practice. Family Process, 59 (2), 1-15.)	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA). The committee did not consider it appropriate to include behavioural couples therapy in the tables of treatment options in the guideline as the evidence and recommendation for behavioural couples therapy was for a subgroup of people with depression, unlike the other interventions listed in these tables.
539	SH	British Society of Lifestyle Medicine	Guideline	31	12	Table 2 - We welcome this recommendation and the recommended first-line treatment options, but recognise that availability may be lacking or incur very long waiting lists	Thank you for your comment. The committee were aware that waiting lists may impact on people's choice of treatments and so have added an additional recommendations in the section on the delivery of psychological treatments to reflect this, and also made a recommendation to commissioners in the section on the choice of treatments to advise the timely availability of NICE-recommended treatments.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

540	SH	Association for Dance Movement Psychotherapy UK, British Association of Art Therapists, British Association of Music Therapists and the British Association of Dramatherapists	Guideline	31	12	Treatment for people with a new episode of more severe depression Table 2 presents treatment options for more severe depression listed in order of recommended use, based on the committee's interpretation of their clinical and cost effectiveness. We are concerned that evidence for arts therapies in reducing symptoms of more severe depression has been largely ignored. A single study (Albornoz, 2011) demonstrating significant reduction in depression scores in patients treated in a music therapy group was included alongside the study by Nan & Ho (2017) on the effects of clay art therapy on adult outpatients with major depressive disorder. However, we are concerned that arts therapies are not included as a treatment option for patients to choose from, despite the evidence that they are effective in reducing symptoms of severe depression and improving quality of life. Omitted studies include:Choi et al. (2020) The effects of combining art psychotherapy with pharmacotherapy in treating major depressive disorder: Randomized control study, The Arts in Psychotherapy. Vol. 70, ArtID 101689.N = 46. Randomised controlled trial. 16 had antidepressants versus 19 having antidepressants and art psychotherapy. Widely used measures of depression, anxiety, self-esteem, relationships and other indicatorsArt psychotherapy and	Thank you for your comment. As acknowledged in your comment, Albornoz 2011 is included in the network meta-analysis for the treatment of a new episode of more severe depression. However, this was the only included study for music therapy, and the committee considered the evidence too limited to make a recommendation. Nan 2017 is included in the further-line treatment review. However, this was the only included study for art therapy, and the committee considered the evidence too limited to make a recommendation. Choi et al. (2020) was not identified by the searches. However, in response to your comment the study has been assessed for eligibility for the further-line treatment review (as all participants receiving pharmacological treatment). However, it does not meet inclusion criteria as participants were not randomised at the point of non-response. This study has now been added to the excluded studies list of Supplement D. Blomdahl 2018 was identified by the searches but is not included as baseline severity could not

						antidepressants were better than antidepressants alone for depression, anxiety, interpersonal relationships and self-esteem. No difference in dropout, remission, or treatment satisfaction.Blomdahl et al. (2018). A manual-based phenomenological art therapy for individuals diagnosed with moderate to severe depression (PATd): A randomized controlled study. Psychiat Rehab J 41(3), 169-182.N=79. Multicentre randomised controlled trial. Art Therapy + treatment as usual versus treatment as usual alone. 43 AT, 36 TAU.Significantly reduced depression in art therapy, and more return to work compared to treatment as usual alone.Ciasca et al. (2018) Art therapy as an adjuvant treatment for depression in elderly women: A randomized controlled trial. Brazilian Journal of Psychiatry, 40(3), 256-263.N = 56 women over 60 years old with major depression and on antidepressants. 31 had art therapy, 25 no art therapy. Randomised. Standardised depression and anxiety scales.Significant improvement in depression and anxiety in art therapy compared to controlXiong L, Li M, Li Q. (2009) Influence of dance therapy on self-efficacy and rehabilitation of patients with depression [**舞蹈治**疗对抑郁症病人自我效能及康复的影响]. Chinese Nursing Research 23(12A):3138-3139.Xiong et al (2009), an RCT	be categorised (outcome measure outside protocol MADRS-self-report).This study is listed under excluded studies in Supplement B1. Ciasca 2018 was identified by the searches but is not included as the outcome measure is outside protocol (GDS-15). This study is listed under excluded studies in Supplement D. Xiong et al. (2009) was not assessed for eligibility as it is a non-English language study.

						conducted in China with people with moderate to severe depression, demonstrated significant rates of recovery and increased self-efficacy in patients treated with dance movement psychotherapy compared with the control group. It is also unclear why the following evidence has not been incorporated in the relevant calculations:Albornoz, Y. (2011). The effects of group improvisational music therapy on depression in adolescents and adults with substance abuse: a randomized controlled trial. Nordic Journal of Music Therapy, 20(3), 208-224. The effect of group improvisational music therapy on depression in adolescents and adults with substance abuse was investigated. It was hypothesized that group improvisational music therapy would relieve depressive symptoms. Twenty-four Spanish-speaking patients receiving treatment for substance abuse at Fundación José Felix Ribas (FJFR) in Mérida-Venezuela participated in the study. Participants completed the Beck Depression Inventory (BDI) and the Hamilton Rating Scale for Depression (HRSD) before being randomly assigned to experimental or control groups, each consisting of three cohort groups recruited over a nine-month period. The experimental group received 12 group improvisation sessions over a three-month period, along with the standard treatment program provided at the facility, and the control group	

						received only the standard treatment program. Post-test measures were completed at the end of each three-month treatment cycle. Differences between the groups (pre-test–post-test scores) were calculated (Mann–Whitney U Test). Results showed that both groups were equally matched on all pre-test measures. As for post-test measures, significant differences were found between the groups on HRSD but not the BDI. The experimental group was significantly less depressed after treatment than the control group, as measured by the HRSD. Improvisational music therapy led to statistically significant greater improvements in psychologist-rated depression (HRSD) when compared with the regular treatment program alone; improvisational music therapy had a clinically significant effect. Among limitations of the study were: a small sample size and the absence of a depression assessment tool for substance abuse.Nan & Ho (2017). Effects of clay art therapy on adult outpatients with major depressive disorder: A randomized controlled trial.Journal of Affective Disorders. 217, 237-245.Method: One-hundred and six adults with depression were randomized into a CAT group or visual art (VA) control group for six 2.5-h weekly sessions. Intervention effects were measured using the Beck Depression Inventory, 12-Item General Health Questionnaire (Chinese version), Body-	

						Mind-Spirit Well-Being Inventory, and 20-Item Toronto Alexithymia Scale (Chinese version) at baseline, immediately postintervention (T1), and 3-weeks postintervention (T2).Result: Multivariate analysis of covariance results indicated a more significant time × group effect for CAT than for VA on depressive signs, general health, and body-mind-spirit well-being (all p<0.05). Significant within-groups changes were observed in these three aspects after treatment and at T2 (all p<0.001) and in alexithymia at T2 (p<0.01) in the CAT group, but the change was nonsignificant in the VA group at T1 and T2.Limitations: The homogeneity of the participants affected the generalizability of the study findings. The short-term postintervention follow-up (3 weeks) presented difficulties in demonstrating the long-term effects of CAT.Conclusions: CAT can aid emotion regulation and benefit various aspects of mental health in adults. The short duration of the intervention suggests additional application value in treating depression. Further investigation is warranted regarding the potential effect of CAT on alleviating physical symptoms and improving social function.****	

541	SH	British Psychological Society	Guideline	31	12	Table 2 Behavioural couples therapy should be included in this table and the visual summary. This intervention is in the guidelines but it appears the decision to leave it out was in part based on an incorrect assumption that it is more or only appropriate for a subgroup of people with depression and studies were excluded from the research evaluation on this basis. If it is excluded from the tables and visual summaries, is very unlikely to be considered as an option. Options such as counselling and STPP were included as the committee recognised that these treatments, although with less evidence of effectiveness, may be helpful for some people. This argument also applies to behavioural couples therapy. The committee agreed this treatment was available through the Improving Access to Psychological Therapy (IAPT) services and should be included as an option in the guideline but if listed in isolation and not in the table and visual summary there is a real risk it will be overlooked by commissioners and providers. The NHS constitution (Department of Health, 2015) pledges that services should work in partnership with clients, their families and carers. The WHO's (2013) Mental Health Action Plan calls for greater collaboration with families. Despite this, behavioural couples therapy is the only family-inclusive therapy option listed. This type of therapy can be of particular value to some	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA). The committee did not consider it appropriate to include behavioural couples therapy in the tables or visual summaries of treatment options in the guideline as the evidence and recommendation for behavioural couples therapy was for a subgroup of people with depression, unlike the other interventions listed in these tables/visual summaries. There is a recommendation in the access section of the guideline for commissioners and providers of mental health services to ensure that pathways have a number of components in place in order to promote access and increased uptake of services and these include: services delivered in culturally appropriate or culturally adapted language and formats; and procedures to support active involvement of families, partners, and carers.

						minority ethnic and cultural groups who may find it harder to engage with services and do not all share individualistic and/or Western values. Couple therapy by definition involves the partner of the person with depression. Carers often feel ignored by healthcare professionals in decisions about their loved ones and want to be involved in discussions about treatment options (Healthwatch, 2020 What people want from the next ten of the NHS Newcastle: author). Couples therapy for depression should be more widely available to depressed people to help reduce the burden on partners and potentially prevent relationship breakdown (Priestley, J and McPherson, SJ and Davies, F (2018) Couples Disease: The Experience of Living with a Partner with Chronic Depression. Journal of Couple and Relationship Therapy, 17 (2). 128 - 145. ISSN 1533-2683).If couples therapy is not included in the tables and visual summaries, it will be less likely to be considered as an option. This could mean that people with depression, people from black, Asian and minority ethnic communities, and carers, will be particularly negatively impacted. It is very important that the choice of couples therapy alongside individual and group interventions is made more widely available within NHS services. We also suggest that this table should include arts therapies, arts on prescription and compassion-focused therapy and yoga given	There are also recommendations in the choice of treatment section of the guideline that people with depression should be given the option to include family members or carers in the discussion of treatment options, and to attend (some or all of) treatment with a family member or friend.

						the existence of evidence, listed below: Blomdahl et al. (2018). A manual-based phenomenological art therapy for individuals diagnosed with moderate to severe depression (PATd): A randomized controlled study. Psychiatric Rehabilittion Journal, 41(3), 169-182; Choi et al. (2020). The effects of combining art psychotherapy with pharmacotherapy in treating major depressive disorder: Randomized control study. The Arts in Psychotherapy, 70, ArtID 101689; Ciasca et al. (2018). Art therapy as an adjuvant treatment for depression in elderly women: A randomized controlled trial. Brazilian Journal of Psychiatry, 40(3), 256-263; Nan & Ho (2017). Effects of clay art therapy on adults outpatients with major depressive disorder: A randomized controlled trial. Journal of Affective Disorders, 217, 237-245; Thyme et al. (2007). The outcome of short-term psychodynamic art therapy compared to short-term psychodynamic verbal therapy for depressed women. Psychoanalytic Psychotherapy, 21(3), 250-264. Arts on prescription: All Party Parliamentary Group on Arts, Health and Wellbeing (2017) Creative health: The arts for health and wellbeing, https://www.culturehealthandwellbeing.org.uk/appg-inquiry/Publications/Creative_Health_Inquiry_Report_2017_-_Second_Edition.pdf Compassion	

						focused therapy: Craig, C. (2020) Compassion focused therapy: a systematic review of its effectiveness and acceptability in clinical populations. Expert Review of Neurotherapeutics, 20(4) ISSN: 1473-7175 Online ISSN: 1744-8360 Prathikanti S, Rivera R, Cochran A, Tungol JG, Fayazmanesh N & Weinmann E (2017). Treating major depression with yoga: A prospective, randomized, controlled pilot trial. PLOS ONE, March 16, https://doi.org/10.1371/journal.pone.0173869Other relevant evidence-based treatments that psychologists commonly use or draw from in the NHS (but aren't listed in the current guidelines) which should be considered for inclusion for depression:Acceptance and Commitment Therapy (ACT)Hayes, S. C. (2004).Behavior Therapy, 35, 639-665.Hayes, S. C. (2004). Acceptance and Commitment Therapy and the new behavior therapies: Mindfulness, acceptance and relationship. In S. C. Hayes, V. M. Follette, & M. Linehan (Eds.), Mindfulness and acceptance: Expanding the cognitive behavioral tradition (pp. 1-29). New York: Guilford.Hayes, S. C. (2000). Acceptance and Commitment Therapy in the treatment of experiential avoidance disorders.Hayes, S. C., Luoma, J., Bond, F., Masuda, A., & Lillis, J. (2006). Acceptance and Commitment Therapy: Model, processes, and	

						outcomes. Behaviour Research and Therapy, 44(1), 1-25Motivational Interviewing Miller, W.R. & T.B. Moyers (2017) Motivational Interviewing and the clinical science of Carl Rogers. Journal of Consulting and Clinical Psychology, 85(8), 757-766Miller, W.R. & Rollnick, S. (2013) Motivational Interviewing: Helping people to change (3rd Edition). Guilford Press..	

542	SH	Tavistock Relationships	Guideline	31	12	Table 2 Please include behavioural couples therapy in this table and the visual summary since it appears the decision to leave it out was in part based on an incorrect assumption that it is more or only appropriate for a subgroup of people with depression and studies were excluded from the research evaluation on this basis. This intervention is in the guidelines but, if excluded from the tables and visual summaries, is very unlikely to be considered as an option. Options such as IPT and STPP were included as the committee recognised that these treatments, although with less evidence of effectiveness, may be helpful for some people. This argument also applies to behavioural couples therapy. Please see additional points in Comment 6.	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA). The committee did not consider it appropriate to include behavioural couples therapy in the tables or visual summaries of treatment options in the guideline as the evidence and recommendation for behavioural couples therapy was for a subgroup of people with depression, unlike the other interventions listed in these tables/visual summaries.
543	Individual	Individual 11	Guideline	31	14	From experience as a carer many of these options would be impossible for someone with severe depression , are very unlikely to help with the depression and in many cases would divert funding into therapies which are unlikely to provide any benefit.	Thank you for your comment. The choice of treatments is based on the clinical and cost-effectiveness evidence reviewed by the committee for the treatment of more severe depression, but also allow shared decision-making and patient preference, with the aim of enabling people to receive a treatment that is both effective and acceptable to them.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

544	SH	Institute of Health Visiting	Guideline	31	General	Treatment for people with a new episode of more severe depression:In the 'treatment' column there should be an option for inpatient care as women who are depressed in the perinatal period may need admitting to a mother and baby unit as a first level treatment of severe depression (see MBBRACE report and NICE guidance) https://www.npeu.ox.ac.uk/assets/downloads/mbrrace-uk/reports/maternal-report-2021/MBRRACE-UK_Maternal_Report_2021_-_FINAL_-_WEB_VERSION.pdfhttps://www.nice.org.uk/guidance/ng201https://www.nice.org.uk/guidance/ng194In the 'other things to think about' section Consideration should be given to:The need for inpatient care in a Mother and Baby Unit due to rapid deterioration of mental health in the perinatal periodPregnancyBreastfeeding status Responsibility for the care of infants, babies and young childrenBarriers to accessing care due to stigma and the need for childcare.	Thank you for your comment. Women with antenatal or postnatal depression were not included in the scope of this guideline and the committee agreed that treatment for postnatal depression was a specialist area and would always need an individualised approach and the level of detail you suggest would not be appropriate to include in this guideline. However, a link to the NICE guideline on antenatal and postnatal mental health has been included in the section of the guideline on the delivery of treatments, to remind healthcare professionals to consider the care of these women separately.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

545	SH	Coventry and Warwickshire Partnership Trust	Guideline	31	General	I appreciate that currently these are only draft guidelines at this time, however, myself and many other SPWP's from across The Midlands Network as well as PWP's within Coventry and Warwickshire IAPT are concerned about the negative impact these guidelines will have on the Step 2 Workforce as well as clients, especially if they are designed to replace the current step 2 guidelines of 6 – 8 x 30 – 40 minutes Sessions that we adhere to in Coventry and Warwickshire IAPT services. The ambiguity of whether these guidelines are in addition to the current stepped care model, or as a replacement certainly is not clear from the draft proposal, so this in itself would need further clarification.	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive, least resource intensive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The self-help with support section has been relabelled as guided self-help, placed earlier in the treatment pathway, and the description of guided self-help has been amended . In response to stakeholder comments, the committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.

546	SH	Coventry and Warwickshire Partnership Trust	Guideline	31	General	There also appears to be some confusion over what is classed as step 2 and step 3 work, stating treatment for less severe depression would require individual intervention delivered by a practitioner with therapy specific training (again unclear about what qualification this would be?) and would consist of 8 weekly sessions of 60 minutes. This session length is not in line with current Step 2 interventions and appears to fit more with High Intensity Practices. So again, clarity is really needed here.	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. Frequency and duration have now been removed from the recommendation to allow flexibility in the delivery of interventions.
547	SH	Coventry and Warwickshire Partnership Trust	Guideline	31	General	Currently IAPT work within the Stepped Care Model with Guided self-help falling under remit of Step 2 within that model and the work is carried out and managed by the step 2 workforce of SPWP's and PWP's. At present, clients have a total of 3 – 4 hours of therapy offered in total at step 2, however under the new proposals this would be cut to a total of 2 Hours and 15 minutes, 30 minutes of which is a triage, so therapy sessions would be only 1 hour 45 minutes in total.	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The self-help with support section has been relabelled as guided self-help, placed earlier in the treatment pathway, and the description of guided self-help has been amended . In response to stakeholder comments, the committee agreed that PWPs may need more time and flexibility to fulfil their role and

							responsibilities. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.

548	SH	UK University Mindfulness Centres	Guideline	31	General	We agree that MBCT should not routinely be offered to people currently experiencing severe depression, if this is defined in line with our point #9 above (i.e., severe depression only, and not moderate or severe). However, we suggest that the guideline should make it clear that once someone has partially or fully recovered from a severe episode of depression (so that symptoms are no longer severe), that they should then be offered an MBCT course to either prevent relapse (if they are currently well), or to provide additional skills to support full recovery (if they are experiencing mild or moderate symptoms). We suggest that this could be made explicit in the guideline to avoid the possibility that people experiencing severe depression are denied the opportunity of an MBCT course in the future when their symptoms are no longer severe.	Thank you for your comment. The committee considered the distinction between less severe (subthreshold/mild) and more severe (moderate/severe) depression to be clinically meaningful in terms of supporting effective clinical decision making and being aligned with how clinicians conceptualize depression (in particular, GPs and other primary care staff, given that the majority of people with depression and almost all first line presentations of depression are managed in primary care). As highlighted in your comment, a group mindfulness or meditation intervention, such as MBCT, is a treatment option for less severe depression. A course of psychological therapy (group CBT or MBCT) is also recommended for people who have remitted from depression when treated with antidepressant medication alone, who do not wish to continue on antidepressants, but who have been assessed as being at higher risk of relapse.

549	Individual	Individual 2	Guideline	31	Table 2	Individual CBT as first choice treatment, the stepped model of IAPT which is based on evidence, states guided self-help should be offered first – i.e. 8 bi-weekly sessions of half an hour rather than 8 weekly sessions of 60 minutes. I am concerned that this will increase the waiting lists for CBT therapists and increase the wait times for patients unnecessarily when working at PWP level (step 2)would be effective in the first instance.	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The self-help with support section has been relabelled as guided self-help, and placed earlier in the treatment pathway. The frequency and duration of sessions of psychological therapies has also now been removed from the recommendations, to allow more flexibility in the delivery of interventions.
550	SH	The Mindfulness Initiative	Guideline	31	Table 2	There is evidence that Mindfulness-Based Cognitive Therapy is an effective first-line treatment for people with moderate (but not severe) depression, so we recommend that MBCT is included in the list of treatment options here (for moderate depression) to expand a person's choice over their treatment.[51]	Thank you for your comment. The committee considered the distinction between less severe (subthreshold/mild) and more severe (moderate/severe) depression to be clinically meaningful in terms of supporting effective clinical decision making and being aligned with how clinicians conceptualize depression (in particular, GPs and other primary care staff, given that the majority of people with depression and almost all first line presentations of depression are managed in primary care). Only a single study (Hojatifar 2017) was included in the NMA for MBCT for more severe

							depression, and on this basis the committee considered the evidence too limited to recommend a group mindfulness or meditation intervention for those with more severe depression.
551	SH	Wellmind Health	Guideline	31	Table 2.	Table 2. lists the treatment options recommended for use for more severe depression, listed in order of the committee's interpretation of clinical and cost effectiveness, including individual CBT, however there is no mention of the digital delivery of CBT/MBCT, for which clinically proven courses are effective in significantly reducing levels of depression, stress, and anxiety, and which research has demonstrated can further reduce costs. A clinically proven digital therapeutic (DTx) MBCT course is already in use within the NHS, provided by GPs and mental health services, and further benefits of digital delivery are that it helps to increase access, reduce waiting times, reduce the stigma attached to accessing mental health	Thank you for your comment. The guideline recommends that people with depression are offered a choice about how all interventions will be delivered including options of face-to-face or remote delivery, and computerised CBT and computerised mindfulness are included under self-help or self-help with support treatment options. However, the committee also discussed the importance of patient choice and problems associated with digital exclusion or digital poverty: some people may prefer a face-to-face intervention either because they are not comfortable using technology, because they lack the appropriate device or internet connection, lack a private and confidential space, or because of wider issues associated with difficulties in

						treatment, and removes the need for face-to-face appointments when social distancing is required.	accessing services. The committee therefore recommended interventions be available via a range of different methods, and the methods of delivery should be guided by patient choice.
552	SH	NHS Sheffield CCG	Guideline	32	General	Table 2: Regarding antidepressant medication, can we add the information about SSRI are generally well tolerated and safer in overdose and therefore considered as first choice for most patients into the second column (how is this delivered).	Thank you for your comment. The committee agreed that this text fitted better into column 3 of the table so this has not been moved.
553	Individual	Individual 7	Guideline	32	Table 2	Section on antidepressant medication: 'SSRIs . . . should be considered as the first choice for most patients.' This recommendation should be more specific. The systematic review and network meta-analysis by Cipriani & colleagues brought together data on both efficacy and acceptability. The findings are clear: when both efficacy and acceptability are considered together – as they must be in any clinical setting – one SSRI was superior to all others: escitalopram. This drug	Thank you for your comment. The committee discussed whether to make more detailed recommendations about the choice of antidepressants but agreed that there was a lack of head-to-head comparisons, that choice should be individualised , and that naming specific drugs might affect the longevity of the guideline as the choice of available antidepressants may change. Furthermore, escitalopram may not be

						should be recommended as the first-choice treatment for most patients unless there are compelling reasons why it should not be.Cipriani A, Furukawa TA, Salanti G, Chaimani A, et al. Comparative efficacy and acceptability of 21 antidepressant drugs for the acute treatment of adults with major depressive disorder: a systematic review and network meta-analysis. Lancet 2018; 391: 1357-1366	appropriate in all people due to its effects on QT prolongation.

554	SH	University of Nottingham	Guideline	33	General	In the first column of the table, the treatment is labelled 'Counselling'. This is a generic and vague term with potential to cause confusion as there are many different forms of treatment which are referred to as counselling. The specific treatment referred to here is more often referred to in the research literature as "Counselling for Depression (CfD)" as for example in the treatment manual and competence framework cited elsewhere in the draft guideline (p013). The most precise and up-to-date label for the treatment is "Person-Centred Experiential Counselling for Depression" (PCE-CfD). It would aid clarity to refer to this treatment as PCE-CfD throughout the guideline. Use of the acronym PCE-CfD instead of 'counselling' would more clearly distinguish this treatment from other psychological treatments.In the second column of the table, the draft text reads "Usually consists of 12 to 16 weekly sessions, of 60 minutes each", however the competence framework recommends between 6 and 20 sessions. It would be more accurate for this range of 6-20 sessions to be specified in the guideline.	Thank you for your comment. All the evidence for counselling that was included in the review for the treatment of a new episode of depression was non-directive counselling, and the committee therefore did not consider it appropriate to recommend specific interventions (for example, Counselling for Depression/Person-Centred Experiential Therapy [PCET]) as the evidence was not reviewed for these interventions. However, based on informal consensus, the committee agreed that counselling should use an empirically validated protocol developed specifically for depression and this was included in the recommendation. The range of 12-16 sessions for counselling for a new episode of more severe depression is based on reported resource use in the studies that informed the NMA and economic analysis. This information has now been added in evidence review B, under Appendix N. The evidence for counselling came from studies assessing non-directive counselling for more severe depression, which reported a range of 5-12 sessions. This range was modified in the recommendation by the committee based on their clinical expertise. The recommendation suggests 'usually' 12-16 sessions. This serves only as guidance and can be modified according to individual needs. This has now been clarified in the recommendation. The

							suggested duration of sessions has now been removed from the recommendation to allow further flexibility in the delivery of the intervention.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

555	Individual	Individual 7	Guideline	33	Table 2	Section on antidepressant medication: There is an observation that 'TCAs (particularly****amitriptyline and dosulepin) have safety concerns, and lofepramine has the best safety profile.' This could be strengthened and a clear recommendation given. Perhaps: amitriptyline and dosulepin have safety concerns and should be prescribed only in consultation with a consultant psychiatrist. Among TCAs, lofepramine has the best safety profile. However, patients are more likely to persist in treatment with SSRIs than with TCAs.	Thank you for your comment. The recommendation already makes it clear that SSRIs should be prescribed first line due to their tolerability. The warning relating to the use of tricyclics has been strengthened to advise about their potential danger in overdose and no longer refers to amitriptyline or dosulepin, so they no longer appear as named treatment options.

556	SH	Leeds Community Healthcare NHS trust	Guideline	33	Table 2	Unclear whether problem solving is a step 2 or step 3 treatment. Problem solving in 30 minutes is not likely as currently offering 50 minute cognitive behavioural therapy appointments.	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive, least resource intensive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The self-help with support section has been relabelled as guided self-help, placed earlier in the treatment pathway, and the description of guided self-help has been amended to recommend that printed or digital materials that follow the principles of guided self-help are used including structured CBT, structured BA, problem solving or psychoeducation materials, delivered face-to-face or by telephone or online. The frequency and duration of sessions of psychological therapies has also now been removed from the recommendations, to allow more flexibility in the delivery of interventions. The problem solving referred to in the recommendations is a high intensity intervention, and changes to recommendations for low intensity interventions are described above.

557	Individual	Individual 2	Guideline	35	Table 2	Self-help with support – further sessions of up to 15 minutes. This recommendation will be incredibly difficult to put into practice given that a risk assessment must be completed each session, a review of homework, a new stage of intervention introduced and explained, COMB factors considered and a summing up. This means patients will not get the best care and thus this will become an ineffective therapy.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.
558	Individual	Individual 2	Guideline	35	Table 2	This puts patients in danger as risk assessments would be rushed and all possible concerns not fully explored.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective patient assessment and delivery of low intensity interventions.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

559	SH	Mind	Guideline	35	Table 2	We support the inclusion of exercise as a treatment option for more severe depression.As with the delivery of group exercise for people with less severe depression, we are concerned about the recommended delivery of “60 minute sessions, usually 3 times a week for 10 weeks.” We feel that these are unrealistic frequencies and lengths of exercise sessions for people with depression, given symptoms including low motivation and fatigue, and that people will have different starting points for their physical fitness. A randomised control trial of the Movement for Mind programme (2021) demonstrated that clinically meaningful improvements to mental wellbeing can be gained in two 30-minute sessions a week - www.asics.com/gb/en-gb/mk/movement-for-mind-results. Setting and realising achievable targets for people with depression will foster self-esteem and build motivation. Setting these too high could further impact on the symptoms of mental ill health.We think it is vital that the recommendations for intensity and frequency of physical activity must be tailored to the individual’s needs. We would also recommend that physical activity options are broadened from just ‘group exercise’ given we know that there are a wide range of barriers to people with mental health problems becoming more active, these might include self-led exercise and community-based	Thank you for your comment. The committee noted that the evidence was for a structured formal exercise programme, with exercise of moderate to high intensity, but recognise there may be challenges to implement this. The committee has now removed the suggested duration of exercise sessions and modified the recommended frequency to allow more flexibility in the delivery of exercise programmes. In response to stakeholder comments, the committee also supported less intense 'move more' exercise for general wellbeing (although not as a treatment for depression) and made a new recommendation to reflect this.

						interventions open to the whole community (such as parkrun, our parks and similar).	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

560	SH	Sport England	Guideline	36	General	We support the inclusion of exercise as an optional first line treatment for people experiencing more severe depression. Sport England's partnership with Rethink Mental Illness has embedded informal physical activity into community support groups across England to support individuals experiencing severe mental health challenges to be more active and better manage their symptoms. An unpublished report by Rethink 2021 showed improvements in resilience, psychological wellbeing, quality of life, health, and motivation to be active. We support the inclusion of peer supportThere is strong evidence that peer-to-peer support is effective for improving mental health, and interventions with others with lived experience supports people feel motivated (Kinnafick, Smith, Appleton, Tweed, Bayes &Tyler, 2017). Sport England's major investments with Mind and Rethink Mental Illness take a peer-to-peer support approach and this has proven successful in supporting people with mild and severe mental health conditions. Peer to peer support has been particularly effective in informal, less structured exercise within these partnerships and has helped integrate moving more generally into everyday life. We are concerned about the frequency and duration information included within the delivery information'60-minute sessions, usually 3 times a week for 10 weeks'	Thank you for your comment. The committee noted that the evidence was for a structured formal exercise programme, with exercise of moderate to high intensity, but recognise there may be challenges to implement this. The committee has now removed the suggested duration of exercise sessions and modified the recommended frequency to allow more flexibility in the delivery of exercise programmes. In response to stakeholder comments, the committee also supported less intense 'move more' exercise for general wellbeing (although not as a treatment for depression) and made a new recommendation to reflect this.

						could be unrealistic for people experiencing symptoms associated with severe depression i.e. low motivation and fatigue. We know that individuals with depression tend to be more sedentary and less physically fit than their non-depressed counterparts. Considering this and our experience of working with people with mental health conditions this would be very challenging for patients in practice and lead to high attrition rates and recruitment issues. We recommend assessing what patient's current activity levels are (utilising the Short Active Lives survey) as a helpful starting point. Taking a starting point into account, those who are currently'inactive' (taking part in less than 30 minutes of moderate intensity exercise per week) focus on building up to 30 minutes a week'fairly active' (taking part in 30-149 minutes of moderate intensity exercise per week) focus on building up to doing 150 minutes a weekalready 'active' (meeting the CMO guidelines of 150 minutes of moderate intensity per week) focus on maintaining 150 minutes or increasing.	
561	SH	Oxford Health NHS Foundation Trust	Guideline	36	Table 2	As comment 9	Thank you for your comment. It has been addressed as per comment 9.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

562	SH	Psychological Professions Network	Guideline	36	Table 2	As comment 9	Thank you for your comment. It has been addressed as per comment 9.
563	SH	We Are With You	Guideline	37	3	Behavioural Couples Therapy for Depression is included as a treatment option for more severe depression but there is no mention of Couple Therapy for Depression. The national IAPT programme recognises two forms of couple therapy and supports training courses and practice in each. One closely follows the behavioural couple therapy model. The other is a broader approach with a systemic focus, with training courses accredited by Tavistock Relationships. The practice implications for IAPT practitioners trained to deliver Couple Therapy for Depression (as opposed to Behavioural Couples Therapy) are not clear - it looks as though Couple Therapy for Depression is not recommended.	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA). The guideline includes a recommendation to consider behavioural couples therapy for people with either less severe or more severe depression who have problems in the relationship with their partner if the relationship problem(s) could be contributing to their depression, or involving their partner may help in the treatment of their depression. The committee did not consider it appropriate to include behavioural couples therapy in the tables or visual summaries of treatment options in the guideline as the evidence and recommendation for behavioural couples therapy was for a subgroup of people with depression, unlike the

							other interventions listed in these tables/visual summaries.
564	Individual	Individual 10	Guideline	37	5	1.7 Behavioural couple therapy (BCT) for depression – this section recommends that behavioural couple therapy should be considered for people 'who have problems in the relationship with their partner' However, there is compelling evidence that couple-based interventions for depression can be of benefit for patients who are not in a distressed relationship. For example, a recent meta-analysis found that the beneficial effect of couple therapy on symptoms of	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA).

						depression was not more pronounced in studies what used relationship distress as an inclusion criterion. This meta-analysis also found comparable moderate effect sizes on symptoms of depression for both individual and couple-based interventions. Barbato, A. & D'Avanzo, B. (2020). The findings of a Cochrane Meta-Analysis of couple therapy in adult depression: Implications for research and clinical practice. Family Process, 59 (2), 1-15.	
565	Individual	Individual 10	Guideline	37	5	1.7 Behavioural couple therapy (BCT) for depression – this section recommends that behavioural couple therapy should be considered for people 'who have problems in the relationship with their partner' However, there is compelling evidence that couple-based interventions for depression can be of benefit for patients who are not in a distressed relationship. For example, a recent meta-analysis found that the beneficial effect of couple therapy on symptoms of depression was not more pronounced in studies what used relationship distress as an inclusion criterion. This meta-analysis also found comparable moderate effect sizes on symptoms of depression for both individual and couple-based interventions. Barbato, A. & D'Avanzo, B. (2020). The findings of a Cochrane Meta-Analysis of couple therapy in adult depression: Implications for	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA).

						research and clinical practice. Family Process, 59 (2), 1-15.	
566	SH	British Psychological Society	Guideline	37	5	Rec 1.7 It is welcomed that behavioural couples therapy is recommended for consideration for people with either less severe or more severe depression. However, it is incorrect to suggest this intervention is only or more appropriate for people who have problems in the relationship with their partner. It is suitable for anyone with depression who has a regular partner willing to attend with them. This is supported in line 9 where it says: 'involving their partner may help in the treatment of their depression'. There is evidence that it is effective for couples without relationship distress as well as those with relationship problems (Baucom, D., Fischer, M., Worrell, M., Corrie, S., Belus, J., Molyva, E. and Boeding, S. (2018) Couple-based intervention for depression: an effectiveness study in the national health service in England. Family Process, 57: 275–92. https://doi.org/10.1111/famp.12332).We strongly	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA). The committee did not consider it appropriate to change the wording of this recommendation as the evidence reviewed was for people with depression and problems in the relationship with their partner.

						request deleting the words in line 5 'who have problems in the relationship with their partner' and the word 'the' in line 7 so it reads as follows: Consider behavioural couples therapy for people with either less severe or more severe depression if• relationship problem(s) could be contributing to their depression, or• involving their partner may help in the treatment of their depression.	
567	SH	Tavistock Relationships	Guideline	37	5	Rec 1.7 It is welcomed that behavioural couples therapy is recommended for consideration for people with either less severe or more severe depression. However, it is incorrect to state that this intervention is only or more appropriate for people who have problems in the relationship with their partner. It is suitable for anyone with depression who has a regular partner willing to attend with them. This is supported in line 9 where it says: 'involving their partner may help in the treatment of their depression'. There is also evidence that it is effective for couples without relationship distress as well as those with relationship problems (Baucom, D., Fischer, M., Worrell, M., Corrie, S., Belus, J., Molyva, E. and Boeding, S. (2018) Couple-based intervention for	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA). The committee did not consider it appropriate to change the wording of this recommendation as the evidence reviewed was for people with depression and problems in the relationship with their partner.

						depression: an effectiveness study in the national health service in England. Family Process, 57: 275–92. https://doi.org/10.1111/famp.12332).We strongly request deleting the words in line 5 'who have problems in the relationship with their partner' and the word 'the' in line 7 so it reads as follows: Consider behavioural couples therapy for people with either less severe or more severe depression if• relationship problem(s) could be contributing to their depression, or• involving their partner may help in the treatment of their depression.	There are recommendations in the choice of treatment section of the guideline that people with depression should be given the option to include family members or carers in the discussion of treatment options, and to attend (some or all of) treatment with a family member or friend.
568	SH	Institute of Health Visiting	Guideline	37	General	Behavioural couples therapy for depressionTo include supporting parent and infant relationship if a woman is pregnant or has recently given birth/perinatal period as per antenatal and postnatal NICE guidance. https://www.nice.org.uk/guidance/ng201https://www.nice.org.uk/guidance/ng194	Thank you for your comment. The evidence the committee used as a basis for their recommendations on behavioural couples therapy related to depression in people who had problems with their relationship with their partner, so it is not possible to extend this recommendation to supporting parent and infant relationships.
569	SH	British Psychological Society	Guideline	38	001-005	We suggest clarifying whether this means medication or whether it includes psychological therapies.	Thank you for your comment. It has been clarified that this initial recommendation relates to both medication and psychological therapies.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

571	Individual	Individual 7	Guideline	38	3	Section 1.8.1The emphasis in this sentence should be stronger. Discuss with people that continuation of treatment after full or partial remission will reduce their risk of relapse and will help them stay well.It would be useful for practitioners to have available information on the difference in the risk of relapse with antidepressant continuation vs discontinuation.	Thank you for your comment. The committee agreed that the strength of the recommendation reflected the evidence reviewed. There are a number of recommendations in this section about the information that should be provided regrading the risk of relapse, key components that should be included in discussion, and that a shared decision should be reached on whether or not to continue a treatment for depression based on the person's clinical needs and preferences.
571	Individual	Individual 7	Guideline	38	4	Section 1.8.1Reaching a shared decision . . . consider adding: Agree a minimum time period (preferably 6 months) for continuation treatment and specify times when the need to continue treatment will be reviewed.	Thank you for your comment. The requirement to continue initial treatment for 6 months after the remission of symptoms is contained in the section on the delivery of pharmacological treatments and first line treatment. This section relates to continuation beyond that initial treatment period , and the duration of treatment in this case is covered in one of the following recommendations (1.8.5)
572	Individual	Individual 7	Guideline	38	004-005	Section 1.8.1It should be emphasised to the patient that, in the vast majority of cases, their clinical need is to continue antidepressant medication for at least 6 months after symptom remission because this will help them to stay well.	Thank you for your comment. The requirement to continue initial treatment for 6 months after the remission of symptoms is contained in the section on the delivery of pharmacological treatments and first line treatment. This section relates to continuation beyond that initial treatment period , and the duration of treatment in this case is covered in one of the following recommendations (1.8.5).

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

573	SH	British Psychological Society	Guideline	38	12	Rec 1.8.3. Suggest including in the list (under 'Discuss with people that the likelihood of having a relapse may be increased if they have:) the words 'relationship problems'. Evidence exists showing relationship discord predicts the development of depression, depression predicts future relationship discord and relationship distress is associated with poorer outcomes from individual therapy (Baucom, Donald H., Whisman, Mark A. and Paprocki, C. (2012) Couple-based interventions for Psychopathology. Journal of Family Therapy, 34: 250–70).	Thank you for your comment. In response to your comment, relationship problems have been added to this list of risk factors for relapse.
574	SH	Tavistock Relationships	Guideline	38	12	Rec 1.8.3. Suggest including in the list under 'Discuss with people that the likelihood of having a relapse may be increased if they have:' the words 'relationship problems'. Evidence exists showing relationship discord predicts the development of depression, depression predicts future relationship discord and relationship distress is associated with poorer outcomes from individual therapy (Baucom, Donald H., Whisman, Mark A. and Paprocki, C. (2012) Couple-based interventions for Psychopathology. Journal of Family Therapy, 34: 250–70).	Thank you for your comment. In response to your comment, relationship problems have been added to this list of risk factors for relapse.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

575	SH	EMDRIA	Guideline	38	22	In the later treatment sections, there is reference to identifying "personal, social and environmental factors that contributed to their depression and that are still present (for example, ongoing stress, poverty, isolation, unemployment) (e.g. 1.8.3)", but again no explicit mention of typical causal events – losses, illness, trauma, legal processes, experiences of harassment, stigmatisation, disability or discrimination. This is a conspicuous omission. It also means that there is little mention of possible interventions, either psychological or social, directed at resolving current stressors or the emotional impact of adverse or traumatic experiences. We ask that the committee consider including more explicit discussion of the kinds of adverse events that might be relevant to the development or maintenance of depression; and to highlight where there may be a role for interventions, be they psychological or social, aimed at mitigating their impact or supporting the person's coping.	Thank you for your comment. The role of trauma, life events and the other causal factors you list would be included in the 'personal, social and environmental factors' stated in recommendation 1.8.3 and reiterated in recommendation 1.8.11, where access to support from other agencies is also discussed.
576	SH	British Psychological Society	Guideline	38	022-024	We support the recommendation to advise people that they may experience depression again if they have an ongoing source of stress such as unemployment and poverty.	Thank you for your comment and support of this recommendation.
577	SH	NHS Nottingham and	Guideline	39	1	1.8.4 – Concerned that this recommendation implies that all antidepressants increase bleeding risk and have long term effects on sexual function when this isn't the case.	Thank you for your comment. This recommendation has been amended to clarify that these effects may not occur with all antidepressants.

		Nottinghamshire CCG					
578	SH	UK Mindfulness Centres Collaboration	Guideline	39	005 - 016	The guideline recommends that Mindfulness Based Cognitive Therapy (MBCT) should be considered as a relapse prevention intervention for people who have remitted from depression when treated with antidepressant medication alone and are at higher risk of relapse. In our view the link with previous antidepressant is not supported by theory or evidence and should be removed. It would be warranted and preferable to say that MBCT should be considered as a relapse prevention intervention for anybody who has remitted from depression and is at higher risk of relapse. This would be in keeping with recommendation in the 2009 NICE CG90 1.9.1.8 Psychological interventions for relapse prevention.	Thank you for your comment. The committee agreed that these recommendations should remain unchanged as there is a risk of moving people from one psychological treatment to another, so if people had remitted with a psychological intervention alone or a combined psychological and pharmacological intervention and were assessed as at higher risk of relapse it would be optimal for them to continue with the psychological intervention that they had achieved remission with.
579	SH	The Mindfulness Initiative	Guideline	39	6	The words 'antidepressant treatment alone' are too narrow and restrict choice. A person who is assessed as being at risk of relapse may wish to choose MBCT having tried treatment with antidepressant medication alone, in combination with another therapy, treatment with another therapy on its own, or who have recovered without any formal treatment[52]. This should include where people have recovered from severe	Thank you for your comment. The committee agreed that these recommendations should remain unchanged as there is a risk of moving people from one psychological treatment to another, so if people had remitted with a psychological intervention alone or a combined psychological and pharmacological intervention and were assessed as at higher risk of relapse it would be optimal for them to continue with the

						depression, as evidence shows it is effective in reducing further episodes.	psychological intervention that they had achieved remission with.
580	Individual	Individual 7	Guideline	39	8	Section 1.8.5The two-year treatment period should be an initial objective. After two years, the need to continue treatment should be reviewed. For many people, depression is a chronic illness and treatment will need to continue beyond two years. This needs to be made clear from the outset when relapse prevention is being considered.	Thank you for your comment. The committee agree that after 2 years treatment may need to be reviewed and continued, but that the evidence for treatment for longer than 2 years is limited. The decision to continue would therefore be an individualised clinical decision, and so the committee removed the cut-off point of 2 years from the recommendation.
581	SH	British Psychological Society	Guideline	39	008-016	Rather than advising people to stay on medication for at least two years if they might 'relapse', and only as a secondary consideration recommending group CBT or mindfulness-based therapy (or medication and CBT/mindfulness) we suggest that people should be offered support to come off medication and offered CBT or mindfulness straight away for relapse prevention. This is because of the risks of taking medication longer-term (for examples see https://www.verywellmind.com/long-term-effects-of-antidepressants-4158064 and https://www.nhs.uk/mental-health/talking-	Thank you for your comment. The evidence suggested that CBT/MBCT and antidepressants were equally effective for relapse prevention and so the committee were not able to recommend that all people on antidepressants should be changed from antidepressant medication to MBCT for relapse prevention. The recommendations do advise discussing the risks and benefits of staying on medication long-term with people so that an informed decision can be made. Signposting to other sources of support has been added to recommendation 1.8.11 in this section.

						therapies-medicine-treatments/medicines-and-psychiatry/antidepressants/side-effects/). In addition, if ongoing sources of stress such as unemployment and poverty have been identified, the recommendation should be to signpost to statutory and third-sector agencies that can offer relevant support.	
582	Individual	Individual 7	Guideline	39	009-010	Section 1.8.5'unless there is good reason to reduce it.' The approach should be: 'the dose that gets you well is the dose that will keep you well.' If side effects are intolerable, it is likely to be better to change the antidepressant rather than reduce the dose.	Thank you for your comment and for agreeing with the recommendation to maintain the same dose of antidepressant where possible. The committee agreed that if side-effects were a problem it would be reasonable to try a dose reduction and would not always be necessary to change the drug used, and so did not amend this part of the recommendation.
583	SH	UK University Mindfulness Centres	Guideline	39	11	For relapse prevention, the recommendation is for MBCT (or group CBT) "For people who have remitted from depression when treated with antidepressant medication alone, but who have been assessed as being at higher risk of relapse". This recommendation is not in line with the research evidence for MBCT. In the MBCT relapse prevention trials, participants had previously recovered in a variety of ways and not only following anti-depressant medication. Many participants had recovered following psychological	Thank you for your comment. The committee agreed that these recommendations should remain unchanged as there is a risk of moving people from one psychological treatment to another, so if people had remitted with a psychological intervention alone or a combined psychological and pharmacological intervention and were assessed as at higher risk of relapse it would be optimal for them to continue with the psychological intervention that they had achieved remission with.

						therapy or without any formal intervention. Participants in these trials were either currently well (no/minimal symptoms of depression) or were experiencing sub-threshold symptoms of depression (5) following previous episode(s) of depression. To be in line with the research evidence we suggest the recommendation is changed to:"For relapse prevention, MBCT should be offered to people who have a history of depression and are currently well, or who are experiencing sub-threshold symptoms"	
584	SH	UK Mindfulness Centres Collaboration	Guideline	39	20	This section talks about the number of sessions. MBCT often involves 9 sessions. It would therefore be better for this to read '8 or 9 sessions'	Thank you for your comment. The advice has been changed to 'usually' consists of 8 sessions to allow flexibility around the number of sessions needed. This also covers programmes that involve 9 sessions.
585	SH	Institute of Health Visiting	Guideline	39	General	For women planning a pregnancy or of reproductive age, relapse prevention should include planning for the management of mental health for future pregnanciesTo include asking the question about planning for having a baby.	Thank you for your comment. Women with antenatal or postnatal depression were not included in the scope of this guideline and the committee agreed that planning for mental health in future pregnancies would always need an individualised approach and the level of detail you suggest would not be appropriate to include in this guideline. However, a link to the NICE guideline on antenatal and postnatal mental health has been included in the section of the guideline on the delivery of treatments, to remind healthcare professionals to consider the care of these women separately.

586	SH	IPT-UK	Guideline	39	General	The guideline suggests that for individuals who have remitted from depression when treated with an anti-depressant alone and who are at risk of relapse should be considered for CBT or MBCT whether with or without their anti-depressant. Evidence review C, Page 69 documents that, "The majority of the evidence for psychological interventions for relapse prevention adopted a cognitive behavioural approach…. that the committee agreed to make particular reference to these interventions in their recommendations for psychological therapy for relapse prevention." The review ignores other modalities that demonstrated relapse prevention: e.g., IPT was shown to have both clinically important and statistically significant benefits of a combined IPT and antidepressant intervention in comparison to a pill placebo on rate of relapse (Agosti, 1997). We would also like to point out concerns regarding patient choice. We would like to commend the committee on taking on board previous consultation feedback that when relapse follows psychological therapy, with or without medication, that it can be followed up with more of the same therapy, which is strongly aligned with our research evidence for maintenance IPT. However, in relation to relapse following anti-depressants, options of psychological therapy have again been reduced to a singular modality when other modalities have	Thank you for your comment. In the evidence review for relapse prevention, there was only single-study evidence for IPT (Frank 1990). This study showed non-statistically significant effects on relapse prevention of IPT versus pill placebo, and IPT versus imipramine (where the effect favoured imipramine), and non-significant effects for combined IPT and imipramine relative to imipramine-only or pill placebo. On the basis of this limited and equivocal evidence, the committee did not consider it appropriate to recommend IPT for preventing relapse.

						also been shown to be effective. This appears to break with the overall ethos of this guidance supporting patient choice. We urge the committee to consider including IPT here.	
587	SH	British Psychological Society	Guideline	40	001-006	We suggest that this section should include assessment of environmental and social factors that may present risk for further depression. Practitioners should be aware of and be able to signpost people to relevant agencies where applicable, such as women's refuges, debt advice, disability support and advice, and agencies providing support and advice for addressing problems having employment rights honoured.	Thank you for your comment. Consideration of personal, social and environmental factors that may be contributing to ongoing depression is already covered in an earlier recommendation (1.8.3) and a later recommendation (1.8.11) so it has not been repeated here. However, a reminder to signpost people to other sources of support has been added to recommendation 1.8.11

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

588	SH	UK Mindfulness Centres Collaboration	Guideline	40	007-011	The guideline recommends that people who have remitted from depression when treated with a psychological therapy alone (and are at higher risk of relapse) should have a discussion about whether they wish to continue with their psychological therapy for relapse prevention. Whatever kind of therapy they have had in the past, Mindfulness Based Cognitive Therapy should be considered as a relapse prevention intervention for these individuals. This would be in keeping with the recommendation in the 2009 NICE CG90 1.9.1.8 Psychological interventions for relapse prevention.	Thank you for your comment. The committee agreed that these recommendations should remain unchanged as there is a risk of moving people from one psychological treatment to another, so if people had remitted with a psychological intervention alone or a combined psychological and pharmacological intervention and were assessed as at higher risk of relapse it would be optimal for them to continue with the psychological intervention that they had achieved remission with.
589	SH	UK Mindfulness Centres Collaboration	Guideline	40	012-016	The guideline recommends that people who have remitted from depression when treated with a combination of an antidepressant medication and psychological therapy (and are at higher risk of relapse) should have a discussion about whether they wish to continue 1 or both treatments. Whatever kind of treatment they have had, Mindfulness Based Cognitive Therapy should be considered as a relapse prevention intervention for these individuals. This would be in keeping with the recommendation in the 2009 NICE CG90 1.9.1.8 Psychological interventions for relapse prevention.	Thank you for your comment. The committee agreed that these recommendations should remain unchanged as there is a risk of moving people from one psychological treatment to another, so if people had remitted with a psychological intervention alone or a combined psychological and pharmacological intervention and were assessed as at higher risk of relapse it would be optimal for them to continue with the psychological intervention that they had achieved remission with.
590	SH	NHS Nottingham and	Guideline	40	23	1.8.11 – This recommendation will be a challenging change in practice as this responsibility will ultimately fall on primary care and GPs. 12 months	Thank you for your comment. The committee agreed that 6 months was an appropriate review period for people receiving antidepressants and did not agree to change this to 12 months.

		Nottinghamshire CCG				would be a more realistic review period given the high level of antidepressant prescribing.	
591	SH	NHS Sheffield CCG	Guideline	40	023-028	We welcome the suggestion for 6 monthly monitoring/review of people continuing treatment with antidepressant	Thank you for your comment and support of this recommendation.
592	SH	Janssen	Guideline	40	023-028	We are supportive of regular reviews for people continuing antidepressant medication to assess treatment outcomes and prevent relapse and the use of a validated rating scale to monitor mood. Again, we would reiterate that it would be worth specifying the rating scale to be used to ensure consistency in approach both in primary and secondary care, the consistent collection of outcomes to monitor treatment effectiveness and to formulate an ambition for what successful treatment outcome looks like for people with depression..	Thank you for your comment. Further detail on the use of validated scales has now been added to the section of the guideline on the delivery of treatments and so a cross-reference to those recommendations has been included from this section of the guideline.
593	SH	British Psychological Society	Guideline	40	027-028	We suggest adding a recommendation to signpost to agencies that can provide help and support with any environmental or social factors identified at this point.	Thank you for your comment. A reminder to signpost people to other sources of support has been added to recommendation 1.8.11
594	Individual	Individual 7	Guideline	41	1	Section 1.8.11'Discuss with them if they wish to continue treatment . . .' Consider adding: 'Take into account the likely risk of relapse and advise the patient accordingly whether stopping treatment is likely to result in relapse.'It is probably	Thank you for your comment. The recommendations already state that the risk of relapse should be considered, and some of the factors that may contribute to this, so this recommendation has not been amended.

						worthwhile repeating the factors that increase the risk of relapse from section 1.8.3	
595	SH	NHS Sheffield CCG	Guideline	41	001-003	We welcome the suggestion for 6 monthly monitoring/review of people continuing treatment with antidepressant	Thank you for your comment and support of this recommendation.
596	Individual	Individual 11	Guideline	41	8	4 weeks to respond to medication is a ridiculously short period. As an inpatient my daughter was allowed 12 weeks, and typically she does not see any benefit for 6-8 weeks	Thank you for your comment. The committee agreed that some response would be expected by 4 weeks if an antidepressant was likely to be effective and therefore a review after this period was appropriate.
597	SH	We Are With You	Guideline	41	8	A prompt to consider illicit substance use, use or misuse of prescribed medications and alcohol use would be a helpful addition to the further-line treatment content.	Thank you for your comment. The committee agreed this would be included in 'the review of personal and social factors' and 'alternative or comorbid conditions'
598	Individual	Individual 11	Guideline	41	12	Asking people with depression if there are reasons why they aren't recovering will in most depressed people elicit a torrent of reasons, as they typically blame themselves for being unwell..	Thank you for your comment. This part of the recommendation relates to other factors that may be contributing to or complicating depression and which, if dealt with, may aid their recovery.
599	Individual	Individual 11	Guideline	41	18	So after 6 weeks max, the person is going to be judged for not trying hard enough……	Thank you for your comment. This part of the recommendation relates to other factors that may be contributing to or complicating depression and which, if dealt with, may aid their recovery.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

600	SH	British Psychological Society	Guideline	41	018-019	We suggest adding recommendation to signpost to agencies that can provide help and support with any environmental or social factors identified at this point.	Thank you for your comment. This addition about signposting has been added to the recommendation.
601	Individual	Individual 11	Guideline	41	20	1.9.2 os after one failed treatment you are suggesting diagnosis is reviewed. This will result in yet more young women being diagnosed with a PD rather than receiving adequate treatment for depression.	Thank you for your comment. The committee agreed that it was important to investigate thoroughly why treatments were not working, to optimise treatment, and this would include considering alternative or comorbid conditions.
602	SH	British Psychological Society	Guideline	41	020-022	This section only refers to allowing time for "treatments" to work. It should also allow time for people to access any agencies to which they have been signposted (where applicable). In addition, before reviewing the diagnosis, the practitioner should check (where applicable) whether people have been able to access agencies they wanted to access for environmental and social factors. We are concerned that leaving these factors unaddressed may contribute to maintaining depression, and potentially to unnecessary further diagnostic labelling and growing hopelessness for both patient and clinician.	Thank you for your comment. The committee agreed that 'after addressing any problems raised' would include allowing time for other agencies to be involved, and so have not amended this recommendation.
603	Individual	Individual 7	Guideline	42	12	Section 1.9.4The word 'changing' is confusing. It could be interpreted as meaning changing the psychological therapy as well as adding an antidepressant. It would be better to write: adding an SSRI or mirtazapine to the psychological therapy.	Thank you for your comment. 'Changing' has been amended to 'adding' as you suggest.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

604	SH	NHS Sheffield CCG	Guideline	42	012-013	In this scenario, the patient has not tried an antidepressant before. Why are we recommending mirtazapine?	Thank you for your comment. The suggestion to use mirtazapine has been removed from this recommendation.
605	Individual	Individual 7	Guideline	42	013 - 014	Section 1.9.4If this is the first use of an antidepressant it should be an SSRI (preferably escitalopram), not mirtazapine. Since antidepressants have similar efficacy, the most important consideration for treatment is acceptability. SSRIs are generally better tolerated than mirtazapine, and so should be given preference.	Thank you for your comment. The suggestion to use mirtazapine has been removed from this recommendation.
606	SH	NHS Sheffield CCG	Guideline	42	14	Why mirtazapine? Is this where the evidence lies?	Thank you for your comment. The suggestion to use mirtazapine has been removed from this recommendation.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

607	SH	Sport England	Guideline	42	15	We support the inclusion of group exercise as an optional first line treatment for people experiencing severe depression. However, we feel there is significant opportunity for clinicians to promote a broader 'move more' message and integrate physical activity in adjunct to all treatment pathways for patients experiencing severe depression. This is because of the positive relationship between sport, physical activity and mental wellbeing. There are a broad range of beneficial outcomes within this relationship, including impacts on enjoyment and happiness, building confidence and self-esteem and reducing stress, anxiety and mild depression (Review of evidence on the outcomes of Sport and Physical Activity, 2017). Exercise is effective in the management of mental health conditions, with increased appetite for exercise as a support tool through the Covid pandemic. 67% of all adults and 72% of people with a mental condition or illness agree that they exercise to help manage their mental health during the outbreak (Source: Savanta ComRes, Attitudes and Behaviours. Wave 21, 05.11.2021 - 08.11.2021)There are many ways to be more physically active and a vast amount of national, free resources that support both clinicians and patients to move more and improve mental and physical wellbeing. We recommend referring and signposting to the following existing	Thank you for your comment. In response to stakeholder comments, the committee supported 'move more' exercise for general wellbeing (although not as a treatment for depression) and made a new recommendation to reflect this. Thank you for telling us about the existing physical activity programmes and campaigns. These will be passed on to the NICE shared learning team.

						support resources within the document:We Are Undefeatable – we have developed the inspiring, inclusive, and empathetic 'We are Undefeatable' campaign (https://weareundefeatable.co.uk/about-us) alongside 16 leading health and social care charities to support and encourage people with health conditions to find ways to be active. The campaign uses a behaviour change approach that reframes the message to recognise the motivations and barriers people face when living with a long term condition.Moving Medicine (https://movingmedicine.ac.uk) – a central hub to support healthcare professionals integrate physical activity conversations into routine clinical care (includes depression consultation guides).	
608	SH	British Psychological Society	Guideline	42	015-030	We recommend including advice not to suggest increasing or changing medication if the person has been on medication alone because of long waiting lists for psychological therapies.	Thank you for your comment. This recommendation relates to alterations to medication, and so the committee were not clear how this relates to waiting lists for psychological therapies.

609	Individual	Individual 11	Guideline	42	20	Adding group exercise for a severely depressed person ? Really? What evidence base is there for tis.	Thank you for your comment. There was some evidence from randomised controlled trials for clinical benefits associated with augmenting antidepressant treatment with group exercise programmes, in particular aerobic exercise groups, and the committee agreed that this option should be discussed with the person and offered. However, the committee took into account that this option may not suit everyone, and may be difficult for some people to engage with. Based on the evidence from randomised controlled trials of people whose depression had shown no or limited response to initial antidepressant treatment, or extrapolating from the evidence for first-line treatment for more severe depression where there was not direct evidence, the committee agreed that if a person's depression has had no or a limited response to treatment with antidepressant medication alone (and no obvious cause can be found and resolved) further treatment options include adding a group exercise intervention, switching to a psychological therapy, continuing antidepressant therapy either by increasing the dose or changing the drug, or changing to a combination of psychological therapy and medication, and that this should be a shared decision based on clinical needs and preferences.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

610	SH	British Psychological Society	Guideline	42	023-030	We welcome the mention of potential risks of increasing medication.	Thank you for your comment and support of this recommendation.
611	SH	NICE quality standards & indicators team	Guideline	42	29	Can you specify what 'more frequent monitoring' should be to improve measurability?	Thank you for your comment. The committee has removed the word 'more' from this recommendation as they agreed it was not meaningful without a comparator.
612	Individual	Individual 7	Guideline	43	001-002	Section 1.9.5It makes little sense to switch antidepressants within class if the first treatment has failed.	Thank you for your comment. The committee agreed that responses to antidepressants, even within the same class, did vary between individuals, and therefore switching within classes should be retained as an option.
613	SH	NHS Nottingham and Nottinghamshire CCG	Guideline	43	3	1.9.5 – Concerned that this recommendation suggests considering MAOIs at the same point as SNRIs or TCAs. Primary care clinicians are not as familiar with MAOIs and there are drug/food interactions that can be very dangerous if patients aren't adequately counselled.	Thank you for your comment. The committee amended the recommendation to clarify that SSRIs and SNRIs were suitable switches in primary care and that TCAs or MAOIs would both be options in secondary care.

614	Individual	Individual 7	Guideline	43	003-004	Section 1.9.5The options suggested here exclude agomelatine and vortioxetine. Since antidepressants have similar efficacy, the most important consideration for treatment is acceptability, particularly when treatment with a first-line SSRI has failed. Choosing an acceptable antidepressant at the earliest opportunity is crucially important. Key evidence comes from the systematic review and network meta-analysis by Cipriani & colleagues which brought together data on both efficacy and acceptability. The findings are clear: when both efficacy and tolerability are considered together – as they must be in any clinical setting – three antidepressants were found to be superior: agomelatine, escitalopram and vortioxetine. In accordance with the recommendation in this guideline, an SSRI should be used first. It should be escitalopram unless there are compelling reasons not to. If treatment fails, it makes no sense to switch to second-line treatment with another SSRI which is inferior to the first. As well as escitalopram, the Cipriani study identified two additional better-tolerated antidepressants: agomelatine and vortioxetine. These should be considered as second-line treatment options.Cipriani A, Furukawa TA, Salanti G, Chaimani A, et al. Comparative efficacy and acceptability of 21 antidepressant drugs for the acute treatment of adults with major depressive	Thank you for your comment. As pre-specified in the review protocol, agomelatine was not included. For inclusion in this review, the committee agreed that pharmacological interventions needed to be licensed in the UK and in routine clinical use for the first-line treatment of depression. The national prescription data for England in 2017 (Prescribing & Medicines Team, Health and Social Care Information Centre, 2017) was used to define routine usage of drugs: if a drug appeared in the top 15 antidepressants prescribed by volume it was included, with the exception of dosulepin which the BNF indicates should be initiated by a specialist. There is existing NICE guidance on the use of vortioxetine in treating major depressive episodes in adults (TA 367). In line with NICE processes on linking to published technology appraisals within NICE guidelines (see Developing NICE guidelines: the manual), the evidence on vortioxetine was intentionally not searched for or appraised by this guideline. Agomelatine was not included for a similar reason as it was the subject of a terminated technology appraisal. The NMA that you cite (Cipriani et al. 2018) had

						disorder: a systematic review and network meta-analysis. Lancet 2018; 391: 1357-1366	been identified by the searches and has been checked for additional relevant primary studies, and listed under excluded studies in Supplement B1 as it was not appropriate to include in its entirety due to different review questions. In response to your comment regarding escitalopram, the committee agreed that the evidence distinguishing individual SSRIs wasn't sufficiently robust to recommend one SSRI over another. The committee agreed that these decisions were best left to prescribers and patients based on current safety data. The recommendations include the option to switch to another antidepressant of the same class if a person's depression has had no or a limited response to treatment with antidepressant medication alone, due to different side effect profiles and there was limited direct evidence that switching to a different SSRI may confer benefits relative to continuing on the same SSRI.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

615	Individual	Individual 7	Guideline	43	008-009	Section 1.9.5This observation lacks clarity both about the level of risk and about what action a practitioner should take. Consider alternative wording: 'switching to or from an MAOI, especially to or from an SSRI, or from one MAOI to another, is potentially hazardous and should be done only in consultation with a specialist mental health pharmacist.'	Thank you for your comment. This has been amended to state that this switch should only take place in or with advice from secondary care.
616	SH	NHS Nottingham and Nottinghamshire CCG	Guideline	43	10	1.9.5 – Concerned that this recommendation isn't clear enough that amitriptyline and dosulepin should not be prescribed for depression.	Thank you for your comment. The warning relating to the use of tricyclics has been strengthened to advise about their potential danger in overdose and no longer refers to amitriptyline or dosulepin, so they no longer appear as named treatment options.
617	Individual	Individual 7	Guideline	43	010-011	Section 1.9.5This observation should be strengthened. Consider instead: 'Among TCAs, amitriptyline and dosulepin have safety concerns and should be prescribed only in consultation with a consultant psychiatrist. Lofepramine has the best safety profile. Treatment with TCAs is associated with high drop-out rates.'	Thank you for your comment. The warning relating to the use of tricyclics has been strengthened to advise about their potential danger in overdose and no longer refers to amitriptyline or dosulepin, so they no longer appear as named treatment options.
618	SH	NHS Sheffield CCG	Guideline	43	010-011	Can we add in a stronger recommendation regarding not using dosulepin in line with MHRA and NHS England guidance? Can we also make reference to the fact that trimipramine is expensive as per NHS England's guidance on items less suitable for prescribing? https://www.england.nhs.uk/wp-content/uploads/2019/08/items-which-should-	Thank you for your comment. The warning relating to the use of tricyclics has been strengthened to advise about their potential danger in overdose and no longer refers to amitriptyline or dosulepin, so they no longer appear as named treatment options. Trimipramine is also not suggested as a treatment option, so the committee did not

						not-routinely-be-prescribed-in-primary-care-v2.1.pdf	think it was necessary to state that it was not suitable for prescribing.
619	SH	The Mindfulness Initiative	Guideline	43	13	Although this is not an all-inclusive list we ask that 'MBCT' is included given the evidence behind its effectiveness for treating depression.	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. MBCT was included within the cognitive and cognitive behavioural therapies class for this review. The committee agreed to list CBT as an exemplar of this class as it was the only specific intervention in the cognitive and cognitive

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

							behavioural therapies class that had more than single-study evidence for further-line treatment.
620	Individual	Individual 7	Guideline	43	017-025	Section 1.9.6It is worth adding that only one change should be made at a time so that its effect can be assessed before considering further changes.	Thank you for your comment. The committee agreed that healthcare professionals would understand the need to make iterative changes to treatment and it was not necessary to specify that the changes should only be made 1 at a time.

621	Individual	Individual 7	Guideline	43	027-029	Section 1.9.7Current clinical evidence does not support this recommendation. On the contrary, there is strong evidence from the systematic review and network meta-analysis by Cipriani & colleagues to support the use of vortioxetine as a first-line treatment.The NICE Technology Appraisal Guidance on the use of vortioxetine stated: “The Committee concluded that no convincing evidence existed to show that vortioxetine was more or less effective than other antidepressants.” In this statement effectiveness was conflated with efficacy. To be accurate, the statement should perhaps have noted instead that there was no convincing evidence to show that vortioxetine had superior efficacy compared with other antidepressants; neither was there convincing evidence that other antidepressants had efficacy superior to vortioxetine.The NICE Technology Appraisal Guidance also stated (without offering any supporting evidence) that “evidence from trials in the first-line population was relevant to informing the relative effectiveness of vortioxetine compared with other antidepressants for second and subsequent lines of treatment.” The STAR*D trial, in which all patients started on the SSRI citalopram, found that response rates at the second and third lines of treatment were much lower than at the first line, while the proportions of patients experiencing intolerable side effects	Thank you for your comment. As acknowledged in your comment there is existing NICE guidance on the use of vortioxetine in treating major depressive episodes in adults (TA 367). In line with NICE processes on linking to published technology appraisals within NICE guidelines (see Developing NICE guidelines: the manual), the evidence on vortioxetine was intentionally not searched for or appraised by this guideline. It is outside the scope of this guideline to make amendments to TA 367.

						were higher. Response and side effect rates were as follows:Response:1st line 48.6%; 2nd line 28.5%; 3rd line 16.8%Intolerable side effects:1st line 16.3%; 2nd line 19.5%; 3rd line 25.6%.These results do not support the assertion made in the vortioxetine Technology Appraisal Guidance. Indeed, the STAR*D study makes a strong case for patients who have failed two attempts at antidepressant treatment to be considered treatment-resistant. The key to successful antidepressant treatment is keeping patients engaged in treatment beyond the acute treatment phase. When antidepressants have similar efficacy, acceptability becomes the most important consideration. Under the heading “Adverse reactions” the Technology Appraisal Guidance stated: “The Committee concluded that, based on the available (albeit sparse) evidence, vortioxetine may have a better overall safety profile than other antidepressants.” Evidence supporting the use of vortioxetine seems to have been downplayed. To say the drug “may” have a better side effect profile implies there is some doubt about the evidence. Since the safety data were obtained from the same clinical trials as the efficacy data, it seems disingenuous to describe the data as “sparse”.Since (a) vortioxetine has similar efficacy but a better side effect profile compared with other antidepressants and (b) it is crucially	

						important to offer patients treatments that they are able to tolerate for at least 6 months, it is difficult to make a strong clinical case or even see the logic for a recommendation that vortioxetine should be used only as a third-line treatment, by which time outcomes are likely to be poor and patients may have become treatment-resistant.Cipriani A, Furukawa TA, Salanti G, Chaimani A, et al. Comparative efficacy and acceptability of 21 antidepressant drugs for the acute treatment of adults with major depressive disorder: a systematic review and network meta-analysis. Lancet 2018; 391: 1357-1366Rush JA, Trivedi MH, Wisniewski SR, Nierenberg AA, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report.Am J Psychiatry 2006; 163: 1905–1917	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

622	SH	British Psychological Society	Guideline	44	001-004	We support the recommendation to advise people of the risks of taking more than one medication. This section should include the suggestion that if support for identified environmental or social factors has not helped, investigate this first. It should also include the recommendation not to add further medications for someone who is on the waiting list for psychological therapy and has not yet been able to access it. We are concerned about the potential risks of adding further medication and keeping people on medication longer, which makes it harder to reduce or stop them later, adding to any existing difficulties the person is coping with. Instead, we suggest connecting people to any local patient groups and supporting patients to campaign for increased psychological or social therapy provision.	Thank you for your comment. The identification of environmental and social factors has already been covered in an earlier recommendation. The sequential nature of the further-line treatments suggested states that combination medications should be offered to those who do not want psychological therapy, so a person on a waiting list for psychological therapy would not fall into this category.
623	SH	NHS Nottingham and Nottinghamshire CCG	Guideline	44	8	1.9.9 – Concerned that this recommendation isn't clear enough about exactly what is meant by a complementary mechanism of action. Specific examples would be better.	Thank you for your comment. The committee have changed the wording from 'complementary' to 'different mechanism of action' and have included an example of a possible combination (an SSRI and mirtazapine or trazodone)
624	SH	NHS Sheffield CCG	Guideline	44	019-020	Is there more evidence to support the use of liothyronine, as current NICE guidance does not routinely support its use in practice?	Thank you for your comment. There was evidence to support the use of liothyronine , and the committee therefore agreed to add this as an option in people in whom other treatments had been unsuccessful.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

625	SH	NHS Sheffield CCG	Guideline	44	021-022	Suggest this is moved to the top of these recommendations.	Thank you for your comment. Notifications about unlicensed use are placed as close to the recommendation to which they relate, which in this case is at the end of this recommendation.
626	SH	Janssen	Guideline	44	023-025	We are unclear of the context of the statement within the guideline and suggest that it requires further clarification regarding what point is being made regarding the antipsychotics mentioned here. As other antipsychotics are also used for the treatment of the depression. We also suggest that the statement should be clarified to make it clear that virtually all antipsychotics (apart from quetiapine) do not have a market authorisation for the use of depression.	Thank you for your comment. This statement relates to the use of antipsychotics in combination with an antidepressants (in the recommendation directly above this statement) which is an unlicensed indication for all antipsychotics, including quetiapine.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

627	SH	Association for Dance Movement Psychotherapy UK, British Association of Art Therapists, British Association of Music Therapists and the British Association of Dramatherapists	Guideline	45	7	1 1.10 Chronic depressive symptoms In this section evidence relating to arts therapies, which have been traditionally used with people with chronic depressive symptoms who do not respond well with verbal interventions is again omitted.Some examples include:Röhricht, F., Papadopoulos, N., & Priebe, S. (2013). An exploratory randomized controlled trial of body psychotherapy for patients with chronic depression. Journal of affective disorders, 151(1), 85-91. Röhricht et al (2013), a UK-based study that included dance movement therapists delivering a manualised intervention for patients with chronic depression. The study had low risk of bias and reported significant differences in the end scores of depression in the experimental group compared to the waiting list. More specifically, patients with chronic depressive syndromes (more than 2 years symptomatic) and a total score of ≥20 on the Hamilton Rating Scale for Depression (HAMD) were randomly allocated to either immediate BPT or a waiting group which received BPT 12 weeks later. BPT was manualized, delivered in small groups in 20 sessions over a 10 weeks period, and provided in addition to treatment as usual. In an intention to treat analysis, primary outcome were depressive symptoms at the end of treatment adjusted for baseline symptom levels. Secondary outcomes were self-esteem and subjective quality of	Thank you for your comment. Röhricht 2013 was identified by the searches but did not meet inclusion criteria for the chronic depression review (Evidence report E) as participants were not receiving first-line treatment or treatment to prevent relapse (prior to entering the study patients had completed a mean of 4 treatment courses with different antidepressants, and were receiving ongoing antidepressant medication at study entry). This exclusion is in line with the eligibility criteria outlined in the review protocol. Koch et al. (2019) and Gold et al. (2009) were not identified by the searches, however in response to your comment these systematic reviews have been checked for any additional relevant studies, no new eligible studies were identified. These systematic reviews have now been added to the excluded studies list of Supplement B1. Van Lith (2016) does not meet study design eligibility criteria (scoping/mapping review). The committee did not consider dramatherapy interventions to be interventions that were in regular clinical use for the treatment of depression. Therefore these interventions were

						life.Thirty-one patients were included and twenty-one received the intervention. At the end of treatment patients in the immediate BPT group had significantly lower depressive symptom scores than the waiting group (mean difference 8.7, 95% confidence interval 1.0–16.7). Secondary outcomes did not show statistically significant differences. When the scores of the waiting group before and after BPT (as offered after the waiting period) were also considered in the analysis, the differences with the initial waiting group remained significant.The results suggest that BPT may be an effective treatment option for patients with chronic depression. Difficulty recruiting and subsequent attrition was one of the limitations, but the findings merit further trials with larger samples and process studies to identify the precise therapeutic mechanisms.Mental health concernsReviews that looked at the effectiveness of arts therapies with populations with mental health concerns also reported on positive depression outcomes (Koch et al 2019; Gold 2009; Van Lith 2016; Bourne et al 2018).Chronic painOther co-morbid conditions reporting changes on depression scores in favour for arts therapies include chronic pain:Majore-Dusele, I., Karkou, V., & Millere, I. (2021). The Development of Mindful-Based Dance Movement Therapy Intervention for Chronic Pain: A Pilot Study With Chronic Headache	not specified in any of the review protocols and consequently the systematic review that you cite (Bourne et al. 2018) was not assessed for eligibility. As outlined in the review protocols, trials that specifically recruit participants with a physical health condition in addition to depression were excluded. Therefore, the studies you cite for chronic pain, medically unexplained symptoms, dementia and cancer would not have met the inclusion criteria for the reviews. Blomdahl 2018 was identified by the searches but is not included as baseline severity could not be categorised (outcome measure outside protocol MADRS-self-report).This study is listed under excluded studies in Supplement B1. Choi et al. (2020) was not identified by the searches. However, in response to your comment the study has been assessed for eligibility for the further-line treatment review (as all participants receiving pharmacological treatment). However, it does not meet inclusion criteria as participants were not randomised at the point of non-response. This study has now been added to the excluded studies list of Supplement D.

						Patients. Frontiers in Psychology, 12, 940. https://doi.org/10.3389/fpsyg.2021.587923In the pilot study by Majore-Dusele et al (2021), 29 patients with chronic headache were randomized to either the Mindful-Based Dance Movement Therapy (MBDMT) group or the waiting list control group (treatment as usual, TAU). The MBDMT group was offered 10 sessions in a clinical outpatient rehabilitation setting for 5 weeks. The findings revealed statistically significant reduction of pain intensity and depression scores in favour of the MBDMT group, and these improvements were maintained in the follow-up assessment. Lin, Y & Payne, H (2021) Effectiveness of the BodyMind Approach® for women with depression and medically unexplained symptoms in Taiwan. The Arts in Psychotherapy, 73, 101764.****Positive outcomes were also reported in the quasi-experimental study by Lin and Payne (2021) examined the effectiveness of the BodyMind Approach® for women with depression and medically unexplained symptoms with this approach being proposed as an alternative treatment in Taiwan.Older people with and without dementia:There is evidence for the impact of arts therapies on symptoms of depression amongst as older people with or without dementia (Li et al 2019; Quach 2017).Medical conditions and cancer careThere is also growing evidence on	Ciasca 2018 was identified by the searches but is not included as the outcome measure is outside protocol (GDS-15). This study is listed under excluded studies in Supplement D. Nan 2017 is included in the further-line treatment review. However, this was the only included study for art therapy, and the committee considered the evidence too limited to make a recommendation. Thyme 2007 was identified by the searches but is not included in the first-line treatment review as less than 80% of partipants had non-chronic depression (64% diagnosed with dysthymic disorder). This study is listed under excluded studies in Supplement B1.

						depression as a comorbid response to medical conditions. The most common medical condition is cancer with most studies reporting a significant change on depression scores (Xu et al 2020; Cheng et al 2021; Bosman et al 2020). Randomised trials on art therapy: Blomdahl et al. (2018). A manual-based phenomenological art therapy for individuals diagnosed with moderate to severe depression (PATd): A randomized controlled study. Psychiatric Rehabilittion Journal, 41(3), 169-182;Choi et al. (2020). The effects of combining art psychotherapy with pharmacotherapy in treating major depressive disorder: Randomized control study. The Arts in Psychotherapy, 70, ArtID 101689; Ciasca et al. (2018). Art therapy as an adjuvant treatment for depression in elderly women: A randomized controlled trial. Brazilian Journal of Psychiatry, 40(3), 256-263;Nan & Ho (2017). Effects of clay art therapy on adults outpatients with major depressive disorder: A randomized controlled trial. Journal of Affective Disorders, 217, 237-245; Thyme et al. (2007). The outcome of short-term psychodynamic art therapy compared to short-term psychodynamic verbal therapy for depressed women. Psychoanalytic Psychotherapy, 21(3), 250-264.References:Bosman, J. T., Bood, Z. M., Scherer-Rath, M., Dörr, H., Christophe, N., Sprangers, M. A. G., & van Laarhoven, H. W. M. (2021). The effects	

						of art therapy on anxiety, depression, and quality of life in adults with cancer: a systematic literature review. Supportive Care in Cancer, 29(5), 2289-2298.Bourne, J. Anderson-Warren, M. Hackett, S (2018) A systematic review to investigate dramatherapy group work with working age adults who have a mental health problem. Arts in Psychotherapy. https://doi-org.ezproxy.tees.ac.uk/10.1016/j.aip.2018.08.001Cheng, P., Xu, L., Zhang, J., Liu, W., & Zhu, J. (2021). Role of Arts Therapy in Patients with Breast and Gynecological Cancers: A Systematic Review and Meta-Analysis. Journal of Palliative Medicine, 24(3), 443-452.Gold, C., Solli, H. P., Kruger, V., & Lie, S. A. (2009). Dose-response relationship in music therapy for people with serious mental disorders: systematic review and meta-analysis. Clin Psychol Rev, 29(3), 193-207. https://doi.org/S0272-7358(09)00002-6 [pii]10.1016/j.cpr.2009.01.001Koch, S. C., Riege, R. F., Tisborn, K., Biondo, J., Martin, L., & Beelmann, A. (2019). Effects of dance movement therapy and dance on health-related psychological outcomes. A meta-analysis update. Frontiers in psychology, 10, 1806.Li, H. C., Wang, H. H., Lu, C. Y., Chen, T. B., Lin, Y. H., & Lee, I. (2019). The effect of music therapy on reducing depression in people with dementia: A systematic review and meta-analysis. Geriatric Nursing, 40(5), 510-516Quach J (2017) Do	

						music therapies reduce depressive symptoms and improve QOL for older adults with chronic disease? Nursing 2017;47(6):58-63Van Lith, T. (2016). Art therapy in mental health: A systematic review of approaches and practices. The Arts in Psychotherapy, 47, 9-22.Xu, L., Cheng, P., Wu, Y., Zhang, J., Zhu, J., Cui, J., & Yu, R. (2020). The effects of art therapy on anxiety and depression in breast cancer patients: An updated meta-analysis. European Journal of Cancer Care, 29(5), e13266.	

628	SH	British Psychological Society	Guideline	45	007-018	We suggest the recommendations for chronic depression should include choices of arts therapies, arts on prescription and compassion-focused therapy, given the evidence listed below: Blomdahl et al. (2018). A manual-based phenomenological art therapy for individuals diagnosed with moderate to severe depression (PATd): A randomized controlled study. Psychiatric Rehabilittion Journal, 41(3), 169-182; Choi et al. (2020). The effects of combining art psychotherapy with pharmacotherapy in treating major depressive disorder: Randomized control study. The Arts in Psychotherapy, 70, ArtID 101689; Ciasca et al. (2018). Art therapy as an adjuvant treatment for depression in elderly women: A randomized controlled trial. Brazilian Journal of Psychiatry, 40(3), 256-263; Nan & Ho (2017). Effects of clay art therapy on adults outpatients with major depressive disorder: A randomized controlled trial. Journal of Affective Disorders, 217, 237-245; Thyme et al. (2007). The outcome of short-term psychodynamic art therapy compared to short-term psychodynamic verbal therapy for depressed women. Psychoanalytic Psychotherapy, 21(3), 250-264. Arts on prescription: All Party Parliamentary Group on Arts, Health and Wellbeing (2017) Creative health: The arts for health and wellbeing, https://www.culturehealthandwellbeing.org.uk/ap	Thank you for your comment. Art therapy was an intervention of interest and is listed in the review protocols. Nan 2017 is included in the further-line treatment review. However, this was the only included study for art therapy, and the committee considered the evidence too limited to make a recommendation. Blomdahl 2018 was identified by the searches but is not included as baseline severity could not be categorised (outcome measure outside protocol MADRS-self-report).This study is listed under excluded studies in Supplement B1. Choi et al. (2020) was not identified by the searches. However, in response to your comment the study has been assessed for eligibility for the further-line treatment review (as all participants receiving pharmacological treatment). However, it does not meet inclusion criteria as participants were not randomised at the point of non-response. This study has now been added to the excluded studies list of Supplement D. Ciasca 2018 was identified by the searches but is not included as the outcome measure is outside protocol (GDS-15). This study is listed under excluded studies in Supplement D.

						pg-inquiry/Publications/Creative_Health_Inquiry_Report_2017_-_Second_Edition.pdf Compassion focused therapy: Craig, C. (2020) Compassion focused therapy: a systematic review of its effectiveness and acceptability in clinical populations. Expert Review of Neurotherapeutics, 20(4) ISSN: 1473-7175 Online ISSN: 1744-8360Other relevant evidence-based treatments that psychologists commonly use or draw from in the NHS (but aren't listed in the current guidelines) which should be considered for inclusion for depression:Acceptance and Commitment Therapy (ACT)Hayes, S. C. (2004).Behavior Therapy, 35, 639-665.Hayes, S. C. (2004). Acceptance and Commitment Therapy and the new behavior therapies: Mindfulness, acceptance and relationship. In S. C. Hayes, V. M. Follette, & M. Linehan (Eds.), Mindfulness and acceptance: Expanding the cognitive behavioral tradition (pp. 1-29). New York: Guilford.Hayes, S. C. (2000). Acceptance and Commitment Therapy in the treatment of experiential avoidance disorders.Hayes, S. C., Luoma, J., Bond, F., Masuda, A., & Lillis, J. (2006). Acceptance and Commitment Therapy: Model, processes, and outcomes. Behaviour Research and Therapy, 44(1), 1-25Motivational Interviewing Miller, W.R. & T.B. Moyers (2017) Motivational Interviewing and	Thyme 2007 was identified by the searches but is not included in the first-line treatment review as less than 80% of partipants had non-chronic depression (64% diagnosed with dysthymic disorder). This study is listed under excluded studies in Supplement B1. The Arts on prescription: All Party Parliamentary Group on Arts, Health and Wellbeing (2017) citation was not considered by the committee as it does not meet study design eligibility criteria. The committee did not consider compassion focused therapy or motivational interviewing to be interventions that are in regular clinical use for the treatment of depression. Therefore these interventions were not specified in any of the review protocols and consequently the studies that you cite would not have met the inclusion criteria for the reviews. As such the evidence on compassion focused therapy and motivational interviewing has not been appraised and the committee were not able to make any recommendations on their use. Acceptance and commitment therapy (ACT) is included under the cognitive and cognitive behavioural therapies class as a third-wave

						the clinical science of Carl Rogers. Journal of Consulting and Clinical Psychology, 85(8), 757-766Miller, W.R. & Rollnick, S. (2013) Motivational Interviewing: Helping people to change (3rd Edition). Guilford Press.	cognitive therapy. However, Hayes 2004 is not included in the first-line treatment review as more than 20% of participants have a coexisting personality disorder (52% had an Axis II disorder). This study is listed in the excluded studies list of Supplement B1. The other Hayes references cited in your comment do not meet study design eligibility criteria and were not considred for inclusion.

629	SH	NHS Sheffield CCG	Guideline	45	12	Can we add in a stronger recommendation regarding not using dosulepin in line with MHRA and NHS England guidance? Can we also make reference to the fact that trimipramine is expensive as per NHS England's guidance on items less suitable for prescribing? https://www.england.nhs.uk/wp-content/uploads/2019/08/items-which-should-not-routinely-be-prescribed-in-primary-care-v2.1.pdf	Thank you for your comment. The warning relating to the use of tricyclics has been strengthened to advise about their potential danger in overdose and no longer refers to amitriptyline or dosulepin, so they no longer appear as named treatment options. Trimipramine is not suggested as a treatment option so the committee did not think it was necessary to include that it was less suitable for prescribing.
630	Individual	Individual 7	Guideline	45	012-015	Section 1.10.2Recommendations for treatment options should be based on the same considerations as those for acute depressive episodes, whether they are less severe or more severe. Because acceptability is crucial, an SSRI (preferably escitalopram) should be preferred over a TCA as a first-line treatment.	Thank you for your comment. The recommendations for chronic depression do already include SSRIs (suggested first) or TCAs (suggested second).

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

631	SH	British Psychological Society	Guideline	45	019-023	We suggest that the focus on rumination and avoidance should be balanced with recognition that these ways of coping have been shaped by life experiences and represent their survival mechanisms. We would like to see a recommendation that practitioners not only ask about social and environmental factors but also work with relevant agencies who can help with these.	Thank you for your comment. The recommendations for chronic depression recognise that avoidance and rumination may be coping mechanisms, but agreed that they could lead to the persistence of symptoms seen with chronic depression and so recommended treatment focused on chronic depression to help people find alternative methods of coping. The committee did not include specific recommendations in the section on chronic depression relating to social and environmental factors and their role in the aetiology and treatment of depression as these are already considered in the over-arching recommendations on initial assessment, but the final recommendation in the chronic depression section does include consideration of the use of other forms of support and this has been expanded to include other agencies.
632	SH	British Psychological Society	Guideline	45	23	Rec 1.10.3 For people with chronic depressive symptoms and interpersonal difficulties, suggest that behavioural couples therapy may be a useful alongside or instead of cognitive behavioural therapy since this directly addresses and treats the relational elements of the depression.	Thank you for your comment. Couple interventions were not listed as an intervention of interest in the review protocols for the chronic depression (first-line treatment or relapse prevention) review or in the further-line treatment review (that includes further-line treatment of chronic depression). Consequently the evidence was not reviewed for these interventions for people with chronic depression and the committee were not able to recommend

							behavioural couples therapy for chronic depression. There are recommendations in the choice of treatment section of the guideline that people with depression should be given the option to include family members or carers in the discussion of treatment options, and to attend (some or all of) treatment with a family member or friend. It is also recommended in the access to services section that commissioners and providers of mental health services should promote access, and increased uptake and retention, by ensuring that pathways have in place procedures to support active involvement of families, partners and carers (if agreed by the person with depression).
633	SH	Tavistock Relationships	Guideline	45	23	Rec 1.10.3 For people with chronic depressive symptoms and interpersonal difficulties, suggest that behavioural couples therapy may be useful alongside or instead of cognitive behavioural therapy since this directly addresses and treats the relational elements of the depression.	Thank you for your comment. Couple interventions were not listed as an intervention of interest in the review protocols for the chronic depression (first-line treatment or relapse prevention) review or in the further-line treatment review (that includes further-line treatment of chronic depression). Consequently the evidence was not reviewed for these interventions for people with chronic depression and the committee were not able to recommend

							behavioural couples therapy for chronic depression.
634	SH	Institute of Health Visiting	Guideline	45	General	Treatment choice should take account of the needs of any dependent children and/ or unborn baby where applicable. To include assessing for child safeguarding and a review of risk and resilience factors including family support.https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/942454/Working_together_to_safeguard_children_inter_agency_guidance.pdf	Thank you for your comment. The committee agreed that the safeguarding issues relating to children of people with depression, or any mental health condition, would always be very important but this is covered in professional and statutory guidance and therefore is not restated in all NICE guidelines. Women with antenatal or postnatal depression were not included in the scope of this guideline and the committee agreed that treatment in these women would always need an individualised approach and the level of detail you suggest would not be appropriate to include in this guideline. However, a link to the NICE guideline on antenatal and postnatal mental health has been included in the section of the guideline on the delivery of treatments, to remind healthcare professionals to consider the care of these women separately.

635	SH	IPT-UK	Guideline	45	General	Chronic Depression. We are unclear why IPT has not been included within this section, taking into account the finding that there were not clinical or statistically significant differences between IPT and CBT in the one RCT which made a direct comparison (Evidence Review E, page 66). Again this limits patient choice, which is not in keeping with these guidelines, and is essential for a population who are more likely to have already experienced an initial psychological therapy modality	Thank you for your comment. For the chronic depression review, for IPT versus pill placebo, there was only single-study evidence suggesting no significant difference. For IPT versus antidepressants, there was data from 3 studies for the depression symptoms outcome showing a statistically significant effect in favour of antidepressants. For IPT versus counselling, data from 2 studies for the depression symptoms outcome shows no significant differences. For the CBT versus IPT comparison, there is only small single-study evidence showing no significant difference. For the comparison of IPT + antidepressants versus antidepressants-only, data from 3 studies for the depression symptoms outcome shows no significant differences. Based on this limited and equivocal evidence, and bearing in mind that none of these studies was sufficiently powered for non-inferiority trials, the committee did not consider it appropriate to recommend IPT for the first-line treatment of chronic depression.

636	SH	UK University Mindfulness Centres	Guideline	45	General	In the first draft of the revised guideline published in July 2017 MBCT was recommended as a second line intervention for people with limited response and treatment-resistant depression. This was in line with evidence from RCTs of MBCT for treatment-resistant depression (6,7). We suggest that MBCT is recommended for people experiencing chronic depression in order to increase patient choice amongst evidence-based interventions.	Thank you for your comment. For all reviews, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. For the further-line treatment review (that includes further-line treatment of chronic depression), MBCT was included within the cognitive and cognitive behavioural therapies class. The committee agreed to list CBT as an exemplar of this class as it was the only specific intervention in the cognitive and cognitive behavioural therapies class that had more than single-study evidence for further-line treatment. For the chronic depression review (first-line treatment or relapse prevention), there was only single-study evidence for MBCT that compared a combined MBCT group and medication to medication only for people with dysthymia or double depression. Based on this limited evidence the committee did not consider it appropriate to make a recommendation for MBCT for the treatment of chronic depression.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

637	Individual	Individual 7	Guideline	46	001-002	Section 1.10.6Almost by definition, chronic depressive symptoms will significantly (what does that word even mean in this context?) impair personal and social functioning. There is no need to be so specific about personal and social functioning.	Thank you for your comment. The committee agreed that it was important to emphasise that chronic depression should be treated if it impaired personal and social functioning, and that although people may have lived with unidentified chronic depression for a period of time, it may require treatment.
638	SH	Janssen	Guideline	46	001-004	We are supportive of the clear recommendation on the referral to specialist for the people with chronic depression in this section and in comment 9 believe this should be made clearer in Section 1.9 Further Line treatment of the guideline as well.	Thank you for your comment and support of this recommendation. The recommendations on further-line treatment already include reference to specialist mental health support when using more specialist medication, combination antidepressants, augmentation, lithium or ECT, so a separate recommendation on specialist referral has not been added.
639	Individual	Individual 7	Guideline	46	002-003	Section 1.10.6‘who have not responded to a TCA or 1 or more SSRIs . . .’ The order of words here gives an implicit suggestion that TCAs should be tried before SSRIs.	Thank you for your comment. The order has been amended here, so SSRIs are listed before TCAs.
640	SH	NICE Social Care and Leadership Team	Guideline	46	17-25	This is a helpful recommendation but it may be helpful if it was re-worded so it is less scientific sounding and more person-centred. For example, instead of referring to personal or social functioning, to refer to having a sense of purpose and meaningful relationships and connections, which are central to avoiding depression.	Thank you for your comment. The phrase 'chronic depressive symptoms that significantly impair personal and social functioning' has been used throughout this section, so it has been retained here to ensure consistency. The recommendation explains that this relates to people who would benefit from social support and the suggested actions (befriending and rehabilitation) explain it is for people who have

							withdrawn from work on social activities, so the wording you suggest would duplicate this.
641	Individual	Individual 11	Guideline	47	1	1.10.9 This reads for people who have not recovered at this point in the guideline there is nothing. This for my 28 year old daughter condemns her to a lifetime living in a living hell. It is impossible to live with severe depression as every moment is hell. It is impossible to live with severe depression as every moment is hell.	Thank you for your comment. The committee were sorry to hear about your daughter and agree that finding effective treatment of depression can sometimes be a difficult process. However, this recommendation suggests that if standard treatments are not working then additional treatments and support should be provided.
642	SH	British Psychological Society	Guideline	47	001-008	We support the consideration of discussing stopping medication that has been taken over many years and has not worked. It would be advisable that this section and the section on page 46 lines 1 to 14 are combined. The way they are currently written, these contradictory paragraphs send conflicting messages. Although page 46 does not explicitly refer to medication that has been taken long-term, it does not exclude the possibility that this has been the case. Furthermore, it advises adding or increasing medication for chronic depression, which would likely lead to long-term	Thank you for your comment. The recommendations on page 46 refer to 'second-line' antidepressant options for chronic depression, so the committee do not agree that they contradict the recommendation to stop medication if it has been taken for a long time and is not effective.

						use, potential health risks, and withdrawal difficulties if it has not already happened.	
643	SH	Practice Plus Group	Guideline	47	9	depression in people with personality disorder , from experience using antidepressant for a short period in combination with psychological therapy helps , rather than a prolonged time frame.	Thank you for your comment. On the basis of their knowledge and clinical experience, and their concerns that some people may not receive an adequate 'dose' of treatment, the committee decided that it was important to specify that it may be necessary to extend the duration of treatment, relative to the length and frequency of treatment that individuals experiencing a depressive episode without a coexisting personality disorder may receive. They noted that this will not always be appropriate, and therefore decided to add the qualifying statement 'if needed' to indicate that this is best left to clinical judgement.

644	SH	University of Nottingham	Guideline	47	9	There is no definition of "personality disorder". NICE Guidance previously refers to specific personality disorders in the past e.g. borderline personality disorder, antisocial personality disorder. Which personality disorder does this refer to or is this a new category or diagnosis lumping every type of personality disorder together? There is a need for guidance on how to diagnose and also what is a personality disorder in the context of chronic depression. People with chronic depression often have very low self-esteem and reduced resilience to psychosocial stress even when their other symptoms of depression go away. They show this all the time and under all circumstances. Is that enough for a diagnosis of personality disorder or does the term personality disorder require evidence of personality disorder before the onset of the latest episode of depression or perhaps even before the first onset of depression? Does personality disorder include personality change following depression? DSM-V and WHO distinguish personality disorder from personality change after a mental, neurological or medical illness. It is very unclear what this guidance refers to and the studies included in the summary of evidence are very inclusive of almost any definition of personality disorder given by the authors.	Thank you for your comment. The depression guideline is not able to make recommendations about the diagnosis of personality disorders. The committee noted that this review covered people with depression comorbid with a personality disorder, but that there are different types of personality disorder and it was not always clear from the evidence which types had been included, or if all types had been combined and considered. The committee agreed that one of the most common types is emotionally unstable personality disorder (previously known as borderline personality disorder) and they were aware that there is existing NICE guidance about the treatment of people with borderline personality disorders with comorbid depression which recommends treatment within a well-structured treatment programme for borderline personality disorder. The committee therefore wanted to make recommendations that were in line with the existing NICE guideline on borderline personality disorder, and so recommended that referral to a specialist personality treatment disorder programme should be considered.

645	SH	University of Nottingham	Guideline	47	11	Previously guidance for a comorbidity for a personality disorder or another mental health disorder and depression would have been to offer both a treatment for a personality disorder and depression. In clinical practice this has most often been antidepressants and a psychological treatment for a specific personality disorder like dialectical behaviour therapy for women with borderline personality disorder who self-harm. Now the recommendation is to give antidepressants and a psychological treatment for chronic depression. The evidence review did not even review the evidence base for treatments designed specifically for personality disorder with depression such as radically open dialectical behaviour therapy even though there are such trials and they are of better quality than the trials that were reviewed e.g. Lynch 2020 Br J Psychiatry with a sample size much higher than any of the RCTs included in the review and also specifically designed to answer whether such treatments improve outcomes for people with overcontrolled personality disorder and depression.	Thank you for your comment. Lynch 2020 was identified by the searches. However, it did not meet inclusion criteria for any of the treatment reviews. It did not meet criteria for the first-line or relapse prevention of depression with coexisting personality disorder review as less than 80% of participants had coexisting personality disorder. It did not meet criteria for the further-line treatment review as although refractory depression was defined as either chronic depression (depression lasting at least 2 years) or treatment-resistant depression, 72% were chronically depressed and not receiving further-line treatment. Finally, the study did not meet criteria for the chronic depression (first-line treatment or relapse prevention) review as more than 20% of participants had a coexisting personality disorder. Lynch 2020 is listed in the excluded studies of Supplement D. These were stipulations of the review protocols in order to create a homogenous data set, and there is not a question that specifically looks at a heterogeneous population where 21-79% of participants have depression with a coexisting personality disorder and are receiving first-line treatment for depression. The committee appreciated that it was unfortunate that studies would be excluded on this basis. However, the rationale was that looking at the evidence from a

							very heterogeneous population would not provide good evidence for any of these groups. The committee did, however, use their knowledge of pragmatic studies, such as this study, when interpreting the evidence from the systematic review and making recommendations. The committee noted that there was some evidence of benefit on depression symptomatology for 2 of the comparisons of monotherapies: CBT alone compared to pill placebo, and behavioural therapy alone compared to short-term psychodynamic psychotherapy. There was also evidence for clinical benefit from studies with combined psychological (either IPT or short-term psychodynamic psychotherapy) and pharmacological treatment when compared with pharmacological monotherapy. The committee noted that although, based on the evidence, treatments combining an antidepressant with a high-intensity psychological intervention appeared to be the most effective, the evidence base for this question was limited in volume, with only small RCTs of low or very low quality. Consequently, they were only able to recommend combination treatment be 'considered' and they were not able to

							recommend a specific antidepressant or psychological therapy, but agreed that this would depend on the person's preference.

646	SH	University of Nottingham	Guideline	47	11	The recommendation has been made on evidence that would not normally be considered robust enough to make any recommendation. To quote from the summary of evidence pertaining to personality disorder and depression: "Overall the evidence was of low to very low quality. It was downgraded due to high risk of bias across multiple domains and wide confidence intervals (imprecision commonly associated with small sample sizes). Additionally, although there were a large number of comparisons, these largely included only single studies." Not only that, but almost all the studies were sub-analyses, sometimes post-hoc, of RCTs which were not designed to answer the question of efficacy or effectiveness of treatments for personality disorder and depression. They all used very different criteria and were usually for anxious, avoidant, dependent, paranoid or "eccentric" personality disorder rather than borderline personality disorder. Antisocial personality disorder was excluded altogether. Of 13 planned comparisons, the only evidence found for benefits from any of the reviewed psychological or drug treatments for depression were as follows: Very low quality evidence from 1 RCT (n=24), behaviour therapy was superior to short-term psychodynamic psychotherapy at end of treatment and 6 months but not at 1,3 and 8 months i.e. any significant	Thank you for your comment. The committee noted the limitations of the evidence, both in terms of quantity and quality in the committee discussion of the evidence section. Eligibility criteria were outlined in the review protocols and inclusion/exclusion criteria aimed to create a homogenous data set. The committee noted that there was some evidence of benefit on depression symptomatology for 2 of the comparisons of monotherapies: CBT alone compared to pill placebo, and behavioural therapy alone compared to short-term psychodynamic psychotherapy. There was also evidence for clinical benefit from studies with combined psychological (either IPT or short-term psychodynamic psychotherapy) and pharmacological treatment when compared with pharmacological monotherapy. The committee noted that although, based on the evidence, treatments combining an antidepressant with a high-intensity psychological intervention appeared to be the most effective, the evidence base for this question was limited in volume, with only small RCTs of low or very low quality. Consequently, they were only able to recommend combination treatment be 'considered' and they were not able to

						effects were probably due to chance.Very low quality evidence from 1 RCT (n=93), cognitive behaviour therapy was superior to pill placebo at end of study, effect statistically significant but not clinically importantLow quality evidence from 1 RCT (n=32), combined IPT and fluoxetine versus fluoxetine on depression at the end of the study. However, this analysis excluded seven participants and in an analysis of all 39 participants there was no effect on remission from depression. This analysis should have been downgraded to very low evidence of an effect.Very low evidence from 1 RCT (n=85), combined short-term psychodynamic psychotherapy plus an antidepressant versus an antidepressant n remission from depression. The effect was statistically significant but not clinically important.To summarise, there is no evidence at all that any treatments for depression are both clinically and statistically significant on any comparison despite a large number of comparisons that were attempted. The searches ignored other evidence that is more robust. The recommendation is unsafe and requires amendment..	recommend a specific antidepressant or psychological therapy, but agreed that this would depend on the person's preference. The committee were aware that people with personality disorder have been excluded from receiving treatment for their depression, and therefore considered it important to emphasise access to psychological interventions. In response to stakeholder comments, a new recommendation has also been added that diagnosis of personality disorder should not be used to exclude people from treatment.

647	SH	Association for Dance Movement Psychotherapy UK, British Association of Art Therapists, British Association of Music Therapists and the British Association of Dramatherapists	Guideline	47	11	1.11.1 For people with depression and a diagnosis of personality disorder consider a combination of antidepressant medication and a psychological treatment (for example, BA, CBT, IPT or STPP). To help people choose between these psychological treatments, see the information on them provided in Table 1 and Table 2. [2021]The evidence of the impact of arts therapies on depression when working with people with personality disorder is summarised in the Havsteen-Franklin et al (2019), which, unfortunately, is missing from this draft. A good example of an RCT that has been omitted is the following:Haeyen, S., van Hooren, S., van der Veld, W., & Hutschemaekers, G. (2018). Efficacy of art therapy in individuals with personality disorders cluster B/C: A randomized controlled trial. Journal of personality disorders, 32(4), 527-542.The objective of this study is to evaluate the effects of an art therapy intervention on psychological functioning of patients with a PD. In this randomized controlled trial, 57 adult participants diagnosed with a PD cluster B/C (SCID-II) were randomly assigned to either weekly group art therapy (1.5 hours, 10 weeks) or a waiting list group. Outcome measures OQ45, AAQ-II, and SMI were assessed at baseline, at post-test (10 weeks after baseline), and at follow-up (5 weeks after post-test). The results show that art therapy is an effective treatment for PD patients because it not	Thank you for your comment. The references cited in your comment would not be eligible for inclusion as they include people with a personality disorder, rather than people with both depression and a personality disorder. Art therapy was listed as an intervention of interest in the review protocol. However, no eligible evidence was identified for this review, and the committee did not consider it appropriate to recommend art therapy for people with depression and a coexisting personality disorder.

						only reduces PD pathology and maladaptive modes but it also helps patients to develop adaptive, positive modes that indicate better mental health and self-regulation.Understanding how and why art therapy may be helpful:Chilvers et al. (2021). 'Life is easier now': lived experience research into mentalization-based art psychotherapy, International Journal of Art Therapy, 26, 17-28. Havsteen-Franklin, D., Haeyen, S., Grant, C., & Karkou, V. (2019). A thematic synthesis of therapeutic actions in arts therapies and their perceived effects in the treatment of people with a diagnosis of Cluster B personality disorder. The Arts in Psychotherapy, 63, 128-140.	
648	SH	British Psychological Society	Guideline	47	011-015	We suggest that the recommendation for depression in people with personality disorder should include mentalisation-based psychodynamic therapy (Vogt, K and Norman, P, 2019, Is mentalization-based therapy effective in treating the symptoms of borderline personality disorder? A systematic review. Psychology and Psychotherapy: Theory, Research and Practice 92,	Thank you for your comment. The references cited in your comment would not be eligible for inclusion as they include people with a personality disorder, rather than people with both depression and a personality disorder.

						441–464) and possibly mentalisation-based art therapy (Chilvers et al. 2021. 'Life is easier now': lived experience research into mentalization-based art psychotherapy, International Journal of Art Therapy, 26, 17-28.). Both of these studies reported a reduction in depression.	
649	SH	Voyage Care	Guideline	48	2	1.11.3 We agree specialist personality disorder treatment programmes can be effective however the challenge is these are limited at best and at worst non- existent.	Thank you for your comment. The committee recognised that these treatment services are limited but hoped that recommending their use in NICE guidelines, may contribute to their availability becoming improved.
650	SH	Association for Dance Movement Psychotherapy UK, British Association of Art Therapists, British Association of Music Therapists and the British Association of Dramatherapists	Guideline	48	009-014	Regarding psychotic depression, the recommendation for inpatients should include art therapy: Montag, C., Haase, L., Seidel, D., Bayer, M., Gallinat, J., Herrmann, U., & Dannecker, K. (2014). A pilot RCT of psychodynamic group art therapy for patients in acute psychotic episodes: Feasibility, impact on symptoms and mentalising capacity. PLOS ONE, 9 (11), e112348. doi:10.1371/journal.pone.0112348	Thank you for your comment. Montag et al. (2014) would not be eligible for inclusion as it includes people exepriencing acute psychotic episodes, rather than people with psychotic depression. Art therapy was listed as an intervention of interest in the review protocol. However, no eligible evidence was identified for this review, and the committee did not consider it appropriate to recommend art therapy for people with psychotic depression.

651	SH	British Psychological Society	Guideline	48	009-014	We support the recommendation of psychological treatments for psychotic depression. The recommendation, for someone in an inpatient setting should include art therapy: Montag, C., Haase, L., Seidel, D., Bayer, M., Gallinat, J., Herrmann, U., & Dannecker, K. (2014). A pilot RCT of psychodynamic group art therapy for patients in acute psychotic episodes: Feasibility, impact on symptoms and mentalising capacity. PLOS ONE, 9 (11), e112348. doi:10.1371/journal.pone.0112348	Thank you for your comment. Montag et al. (2014) would not be eligible for inclusion as it includes people exepriencing acute psychotic episodes, rather than people with psychotic depression. Art therapy was listed as an intervention of interest in the review protocol. However, no eligible evidence was identified for this review, and the committee did not consider it appropriate to recommend art therapy for people with psychotic depression.
652	SH	British Psychological Society	Guideline	48	015-016	We support the recommendation of shared decision-making. NICE and NHS advocate shared decision making. True shared decision making involves exploring all the options, the evidence for those options and the limitations of the evidence. This should mean that NICE guidance could include more treatment options along with their evidence base for use by clinicians.	Thank you for your comment. The guideline recommends that a shared decision is made between options for which there is evidence of effectiveness and cost-effectiveness, and this is why not every possible option for the treatment of depression has been included.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

653	SH	Institute of Health Visiting	Guideline	48	General	To include consideration of the care, safety and needs of any dependent children (including unborn babies)	Thank you for your comment. The committee agreed that the safeguarding issues relating to children of people with depression, or any mental health condition, would always be very important but this is covered in professional and statutory guidance and therefore is not restated in all NICE guidelines. Women with antenatal or postnatal depression were not included in the scope of this guideline and the committee agreed that treatment in these women would always need an individualised approach and the level of detail you suggest would not be appropriate to include in this guideline. However, a link to the NICE guideline on antenatal and postnatal mental health has been included in the section of the guideline on the delivery of treatments, to remind healthcare professionals to consider the care of these women separately.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

654	SH	Institute of Health Visiting	Guideline	48	General	To include consideration of the care, safety and needs of any dependent children (including unborn babies)	Thank you for your comment. The committee agreed that the safeguarding issues relating to children of people with depression, or any mental health condition, would always be very important but this is covered in professional and statutory guidance and therefore is not restated in all NICE guidelines. Women with antenatal or postnatal depression were not included in the scope of this guideline and the committee agreed that treatment in these women would always need an individualised approach and the level of detail you suggest would not be appropriate to include in this guideline. However, a link to the NICE guideline on antenatal and postnatal mental health has been included in the section of the guideline on the delivery of treatments, to remind healthcare professionals to consider the care of these women separately.
655	SH	Greater Manchester Mental Health Services	Guideline	49	8	There is no mention of continuation and Maintenance ECT even as an option in this section nor in relapse prevention	Thank you for your comment. The committee only identified a very small amount of evidence relating to continuation and maintenance ECT and did not agree to make recommendations based on this due to uncertainty over the risks and benefits of this approach, but has made a research recommendation.

656	SH	Mind	Guideline	49	8	We welcome much of what the guideline says about ECT, but there are very serious gaps, listed below. We are also very concerned that the process of effectively updating the 2003 technology appraisal via clinical guidelines means that there has been no thorough reappraisal of ECT in almost two decades. This is despite the 2003 TA making strong statements about deficiencies in practice and the need for monitoring, mechanisms to prevent coercion, research into the long-term safety and efficacy of ECT, and supplementing trial data with lived experience. A 2019 audit (updating a similar audit for 2011-15) shows there continues to be very wide variation in the use of ECT, divergence from law and NICE guidance, and lack of data on outcomes including adverse effects: John Read, Christopher Harrop, Jim Geekie, Julia Renton and Sue Cunliffe (2021) 'A second independent audit of electroconvulsive therapy in England, 2019: Usage, demographics, consent, and adherence to guidelines and legislation', Psychology and Psychotherapy: theory, research and practice - https://bpspsychub.onlinelibrary.wiley.com/doi/full/10.1111/papt.12335 In this study, in which 37 trusts provided useable data, there was a 47-fold difference usage of ECT between the trusts with the highest and lowest rates per capita. Only one trust was able to report the number of patients	Thank you for your comment. The committee discussed the care and considerations that need to be taken into account when delivering ECT, such as informing people of the risks and benefits, obtaining consent, monitoring cognitive function and stopping ECT. The committee amended the existing recommendations on these topics but agreed that there are now recognised up to date standards produced by the Royal College of Psychiatrists, which provide guidance on how a safe and effective ECT service should be delivered, in the context of an ECT accreditation service (ECTAS). The committee added a recommendation, and subsequently strengthened this recommendation in response to stakeholder comments, that clinics should only provide ECT if they are ECTAS-accredited, provide ECT in accordance with ECTAS standards, and submit data (including outcomes) on each course of acute and maintenance ECT they deliver as needed for the ECTAS minimum dataset. There is also a recommendation that trusts which provide ECT services should ensure compliance with the ECTAS standards for administering ECT through board-level performance management.

						who had received a psychological therapy before having ECT. Four of the 22 trusts that provided information about consent had not used the correct combination of professionals, required by law, to inform second opinions. Only six trusts could provide data on outcomes, only 11 reported using validated depression/mood scales for measuring outcomes and nine named one or more validated measures of cognitive function in measuring adverse effects. Only seven provided data for adverse effects.In addition, the study's literature review provides a critique of meta-analyses of research into efficacy.We recommend that NICE conducts a reappraisal of ECT that proactively seeks and uses lived experience.	The committee did not review the audit evidence for ECT (such as the paper cited, Read et al. 2021), as this was outside the scope of this update. However, the committee were aware that the ECTAS standards were developed with a wider range of ECT experts than were available on the guideline committee, and were updated on a regular basis, and therefore agreed that it was more appropriate to refer to these standards than create new recommendations. The committee have reiterated their call for more research into the place in therapy of ECT, and will also recommend to NICE that it explore doing future work on neuromodulatory techniques (and/or rapidly acting treatments) including ECT.
657	Individual	Individual 11	Guideline	49	13	A fast response may also be needed if someone is suicidal.	Thank you for your comment. The committee did not identify any evidence relating to the use of ECT in cases of suicidal ideation and so were unable to include this specifically in their recommendations.

658	SH	Healthwatch Bristol	Guideline	49	17	Section 1.13.2 'Make sure people with depression who are going to have ECT are fully informed of the risks, and of the risks and benefits specific to them.' The comments HealthWatch has received suggest that information about risks, except for temporary mild effects, is often not given, meaning that informed consent did not happen:(Son had ECT in 2010): Due to some awareness of the dangers of ECT, I was strongly opposed to my son receiving it. I was concerned about harm, but the psychiatrist dismissed my concerns….His memory was not formally tested before, during and after ECT. The psychiatrist did not inform us of its short and long term devastating effects on the brain and overall health. Neither my son, nor I were warned about possible brain injury.(Woman whose husband had ECT in 2015): After just three weeks the depression and suicidal ideation returned and despite us being told you may have a headache on the day of the treatment and perhaps a memory lapse around the event we were not told about the major memory lapses and absolutely no memory of certain occasions and blanks of memory that are unable to be retrieved. He has been robbed of his ability to do his loved hobbies and absolutely nothing is quite the same. From an extremely intelligent and kind man who held a job with the same company for over 25 years he can now no longer work. Cognitive deficits means day-to-day	Thank you for your comment. The committee discussed the fact that people need to be fully informed about the risks and benefits of ECT prior to its administration, and need to make an informed decision to have ECT. For this reason the committee stregthened the recommendations from the previous version of the guideline and added the requirement for clinics providing ECT to be ECTAS-accredited, with board level accountability for compliance with ECTAS standards.

						life is very challenging and memory disturbances are persistent. The loss of structure, status and financial security has been devastating. This life changing and demeaning treatment has resulted in creating no hope of recovery from brain damage and delivers a loss of self and purpose. This has meant suicide is a constant and daily consideration.(Person who had ECT in 2015) I was not advised of any long term side effects, just memory loss for possibly 24 hours, and headache. I was not informed that there were any long term side effects, and I was certainly not informed that the procedure could result in brain damage. I consented to the procedure on the basis of what I had been told. This cannot be considered informed consent.(Person who had ECT in early 2000s) In 2004, following another hospital admission I was persuaded to have ECT again by the psychiatrist. I agreed on the condition that I had no more than 8 treatments, they gave me over 20 treatments and my memory has been severely impaired. I recently saw a neuropsychologist who acknowledged that my brain scan shows 'hypersensitivities' which could have been caused by ECT and that my cognitive difficulties could also be a direct result of the ECT. I profoundly regret being given the treatment, and especially that they gave me so many when I was not well enough to make an informed choice and refuse further treatment.	

659	SH	Healthwatch Bristol	Guideline	49	17	Section 1.13.2 'Make sure people with depression who are going to have ECT are fully informed of the risks, and of the risks and benefits specific to them.' Comments submitted to HealthWatch suggest that the full extent and potential severity of the harms from ECT is rarely acknowledged: (Man who ECT in his fifties): *Severe headache - unlike any other head pain I have ever experienced*****Disorientation & dizziness - often for a couple of days after a treatment*****Occasional nausea & vomiting*****Cognitive damage - reduced ability to read, make sense of News programmes, documentaries & films.*****I felt unbearably strong emotions such as FEAR, ANGER, DESPAIR, POWERLESSNESS & FRUSTRATION. These emotions were often seen as signs/symptoms of my illness & therefore a reason to persist with ECT.*****Severe memory loss - has, for many years, caused me feelings of embarrassment, and inferiority, amongst family, friends, health care professionals & out in public.****I had my Driving Licence revoked, as a result of the damage caused by extensive ECT, in 2015(Last had ECT in 2015): Headaches, nausea, vomiting & confusion lasting between a few hours & days/weeks following treatments.Long-term memory lossPsychological traumaPost traumatic stress, ongoing flashbacks & recurring nightmaresFear of electrically powered	Thank you for your comment. The committee discussed the fact that people need to be fully informed about the risks and benefits of ECT prior to its administration, and need to make an informed decision to have ECT. For this reason the committee stregthened the recommendations from the previous version of the guideline and added the requirement for clinics providing ECT to be ECTAS-accredited, with board level accountability for compliance with ECTAS standards.

						objectsCognitive impairment - ongoing difficulties with cognitive processing & carrying out everyday tasks of daily living.The ECT interventions mirrored my experiences of repeated & sadistic childhood sexual abuse - eg. I was lying powerless on a bed, surrounded by individuals in authority, told that everything would be fine & anaesthetised whilst the procedure was carried out.(Last had ECT in 2015): The effects of ECT in my life have been as follows: · I could not spell my own name · I did not recognise myself when I looked in a mirror · I did not remember or recognise members of my own family · I was doubly incontinent · I had seizures · My vocabulary was very limited and I couldn't spell words · I could not do simple maths or understand the value of money · I had to rely on shop assistants to take money and give correct change as I couldn't compute it · I couldn't remember how to brush my teeth, run a bath etc · I couldn't remember how to cook a meal or make a cup of tea · I couldn't plan anything · I couldn't remember how to use a computer · I walked into door frames regularly and had many falls · I had one hour's sleep a night at best · I couldn't recognise the difference between day and night · When I did go out, I got lost · I didn't understand the world any more · I lost my creativity. I had written many books of poems prior to ECT · I was bedbound for a considerable time · I could not remember how to	

						use household appliances · I could not remember most of my life · I could not form and hold new memories · I suffered face blindness (prosopagnosia) · I suffered from constant and loud 'white noise' in my brain. ECT has caused irreparable damage with my family as they do not understand what has happened to me. (Man given ECT as a teenager) Once one is faced with the true realisation of the damages caused, the rage & powerlessness one feels, has to be managed forever. Spent a year in front of a TV set, a semi-zombie brain damaged ….OCD & contamination phobias from their ' brain rape ', until I could leave the area & its memories completely. An irreparably & catastrophically damaged ' shell' of a person, physically & in every way, all adolescent development savagely brutalized & cast into a permanent zombie-like void of an inner-hell of flashbacks & confusion. It is precisely because I knew, immediately after ECT, the " dreadfulness " of what they'd done, & that I was no longer " me ", that I felt so ashamed, so violated, that I could not tell anyone….Primarily, in order to survive at all, I had to convince myself that tha damage was reversible...to ' carry on as normal ' .This is how I know that when one sees the truth, that one has been ' altered', many would choose suicide...& that is a very reasonable reaction….. My 20's were characterised by memory ' blackouts eg bicycle	

						somewhere, & hours later at home, realise my bike was missing..i left it somewhere & had no idea where I'd left it locked up. People I knew & maybe been with hours earlier, I knew I knew them well, but could only say " I don't know who you are or your name ". It was petrifying...this has continued over 30 years! Facial recognition, memory blackouts, coordination loss, severe inability to navigate or sense direction. Any sensory overload, crowds, noise, busy roads utterly exhaust me & make my head swim.(Woman who last had ECT in 2018): I couldn't and still can't remember much of my life until this point. I forget what I'm doing and can't remember the 3 years surrounding ECT much at all. I forget people that were important to me and their faces. My concentration is appalling. I cannot solve problems well and act without thinking. I have been told I am a different person post ECT, my parents say it is not comparable. That upsets me. I have lost friendships and relationships as well as hobbies and countless other opportunities due to the damage that has been caused. This is due to my personality changes, loss of shared interests and memories with other people and knowledge as well as so many other issues I face. My ability to find words has improved but can be a struggle sometimes. I have gotten used to counting money and had to teach myself basic maths again. My hands still shake and my	

						balance problems are quite bad, I sway and stumble but have been dismissed by my GP as they don't know how to help me. I look drunk and I feel anxious in public. Due to fatigue and memory/ learning/concentration/problem solving issues I don't think I will ever be normal. This damage has made me suicidal and will continue to if I let it. It still gets me down but I try to distract myself. I shouldn't have to be doing this at my age. (Son had ECT in 2010) Prior to the ECT my son was studying at college and was doing well. He had anambition of going to university to study for a Forensic Science degree and to work in that field. However after ECT he struggled to complete his college studies, because of the memory issues and diminished cognitive functioning. His concentration, ability to learn and retain information and hisproblem solving skills were dramatically reduced due to the cognitive and executive function problems. His energy level became very low and it was impossible for him to do any studies since then. Therefore he cannot gain any independence and live his life productively, as a mature adult of his age would do. As time passed, my son started having more of the long term effects of ECT. Itcaused a compromise to his cognitive and executive functions - memory and attention, a compromise to his emotional health and stress coping	

						mechanism. It likely caused his brain volume loss, which showed on his MRI scan. His balance became greatly affected. Once he fell off a chair while sitting. On several occasions he tripped over and fell, when walking on the street. His ability to make basic calculations, to manage money and to find a correct address, when going somewhere unfamiliar, all diminished. His personality dramatically changed since receiving ECT. His moods started to fluctuate a lot. He became more irritated, frustrated, angry and overwhelmed. He finds it difficult to control his emotions.(Woman who last had ECT in 2016) My children's birthdays, first days at school, significant events that happened to them, in the most I do not remember. I made them character birthday cakes when they were young and only for photos, I wouldn't have known this. There is so little from my childhood I remember. Friends, groups we belonged to, holidays we went on, my graduation for my Honours Degree, gone…..I lost years of my life and time being a mother to my children because my trauma history was not treated and I was rendered barely functional on high doses of meds and ECT.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

660	SH	Mind	Guideline	49	17	We agree with the recommendation at 1.13.2 about ensuring the patient is fully informed. However, audit has shown shortcomings in patient information leaflets including minimising the risk of memory loss: Christopher Harrop, John Read, Jim Geekie and Julia Renton (2021) 'How Accurate Are ECT Patient Information Leaflets Provided by Mental Health Services in England and the Royal College of Psychiatrists? An Independent Audit', Ethical Human Psychology and Psychiatry, vol 23, issue 1, DOI: 10.1891/EHPP-D-21-00003 - https://connect.springerpub.com/highwire_display/entity_view/node/153185/full. We recommend that the guideline sets out more explicitly what information should be communicated to the patient on the risks and benefits of ECT.	Thank you for your comment. The committee discussed the fact that people need to be fully informed about the risks and benefits of ECT prior to its administration, and need to make an informed decision to have ECT. For this reason the committee stregthened the recommendations from the previous version of the guideline and added the requirement for clinics providing ECT to be ECTAS-accredited, with board level accountability for compliance with ECTAS standards. The ECTAS standards include detailed information on the content of patient information leaflets.
661	SH	Citizens Commission on Human Rights	Guideline	49	17	1.13.2 Line 17: A July 2018 United Nations Human Rights Council report on "Mental health and human rights," called on governments to recognise that forced psychiatric treatment, including ECT, "as practices constituting torture or other cruel, inhuman or degrading treatment or punishment…."(Ref: "Mental health and human rights: Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development," Annual report of the United Nations High Commissioner for Human Rights and reports of the Office of the High Commissioner and the Secretary-General,	Thank you for your comment. The recommendations include advice on obtaining informed consent for ECT and what to do if a person cannot give consent, including respecting advance treatment decisions.

						Human Rights Council, 10-28 Sept. 2018, p. 14, point 46.)	
662	SH	Citizens Commission on Human Rights	Guideline	49	17	1.13.2 Line 17: The Thymatron System IV is an ECT device being used in the majority of ECT clinics in England. It is manufactured by an American company called Somatics, LLC (Limited Liability Company). Dantec Medicals Limited, located in Bristol, is a UK distributor for the device. A 2018 lawsuit in the United States made reference to the use of ECT devices manufactured by Somatics, LLC. In Riera v. Somatics, LLC, the United States District Court for the Central District of California ruled that there was sufficient evidence for a reasonable jury to find that the prominent manufacturer of ECT devices, Somatics, LLC, caused brain injury in the plaintiffs by failing to warn their treating physicians of the risk of brain injury associated with ECT, and also through a failure to investigate and report to the FDA (Food and Drug Administration) complaints of brain damage and death resulting from ECT." (Ref: David Karen, "ECT Litigation Update: Are Patients Being Warned of Brain Damage Risk?" MAD, 13 June 2019,	Thank you for your comment. The committee discussed the fact that people need to be fully informed about the risks and benefits of ECT prior to its administration, and need to make an informed decision to have ECT. For this reason the committee stregthened the recommendations from the previous version of the guideline and added the requirement for clinics providing ECT to be ECTAS-accredited, with board level accountability for compliance with ECTAS standards. The ECTAS standards include detailed advice on the information to be provided to people to obtain informed consent.

						https://www.madinamerica.com/2019/06/ect-litigation-patients-not-warned-brain-damage-risk/)This should be included in information relating to informed consent prior to receiving ECT.	
663	SH	Citizens Commission on Human Rights	Guideline	49	17	1.13.2 Line 17: Somatics, LLC's website and disclaimer specifically states:"In rare cases, patients may experience permanent memory loss or permanent brain damage." (http://www.thymatron.com/catalog_cautions.asp)This should be included in information relating to informed consent prior to receiving ECT.	Thank you for your comment. The committee discussed the fact that people need to be fully informed about the risks and benefits of ECT prior to its administration, and need to make an informed decision to have ECT. For this reason the committee stregthened the recommendations from the previous version of the guideline and added the requirement for clinics providing ECT to be ECTAS-accredited, with board level accountability for compliance with ECTAS standards. The ECTAS standards include detailed advice on the information to be provided to people to obtain informed consent.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

664	SH	Citizens Commission on Human Rights	Guideline	49	17	1.13.2 Line 17: Information about ECT that's made available to patients by Trusts in the UK consistently fails to mention the potential of permanent brain damage. It would therefore be expected that any representations of ECT, either online or in consent-to-treatment documents, would reflect the risk of brain damage to avoid potential consumer fraud.	Thank you for your comment. The committee discussed the fact that people need to be fully informed about the risks and benefits of ECT prior to its administration, and need to make an informed decision to have ECT. For this reason the committee stregthened the recommendations from the previous version of the guideline and added the requirement for clinics providing ECT to be ECTAS-accredited, with board level accountability for compliance with ECTAS standards. The ECTAS standards include detailed advice on the information to be provided to people to obtain informed consent.
665	SH	Citizens Commission on Human Rights	Guideline	49	17	1.13.2 Line 17: Harmful results were identified in a Food and Drug Administration (FDA) Executive Summary for a Panel investigating the appropriate classification for the ECT device. Among the effects reported to the FDA were the following:memory dysfunction, general cognitive complaints, brain damage, death (including reports of reduced life span), onset/exacerbation of psychiatric symptoms, general motor dysfunction, seizures (including prolonged seizures, physical trauma, skin burns, neurological symptoms (e.g., pareasthesis, dyskinesias), respiratory complications/prolonged apnea, sleep disturbance, visual changes, hypertension, hypotension, suicidality, homicidality, substance abuse, coma.The FDA's adverse event reporting index (MAUDE	Thank you for your comment. The committee discussed the fact that people need to be fully informed about the risks and benefits of ECT prior to its administration, and need to make an informed decision to have ECT. For this reason the committee stregthened the recommendations from the previous version of the guideline and added the requirement for clinics providing ECT to be ECTAS-accredited, with board level accountability for compliance with ECTAS standards. The ECTAS standards include detailed advice on the information to be provided to people to obtain informed consent.

						(Manufacturer and User Facility Device Experience) database) adds strokes to this listing and emphasises brain damage and death.This should be included in information relating to informed consent prior to receiving ECT.	
666	SH	Citizens Commission on Human Rights	Guideline	49	17	1.13.2 Line 17: The United Nations Convention on the Rights of Persons with Disabilities (CRPD) recommends that patients should not be put at risk of “torture or cruel, inhuman or degrading treatment or punishment” and recommends prohibiting “coercive practices such as forced admission and treatment, seclusion and restraint, as well as the administering of antipsychotic medication, electroconvulsive therapy (ECT) and psychosurgery without informed consent.”(Ref: “Guidance on Community Mental Health Services: Promoting Person-Centered and Rights-Based Approaches,” World Health Organization, 10 June 2021, p. 7, https://www.who.int/publications/i/item/9789240025707 to download reportThis should be included in information relating to informed consent prior to receiving ECT.	Thank you for your comment. The committee discussed the fact that people need to be fully informed about the risks and benefits of ECT prior to its administration, and need to make an informed decision to have ECT. For this reason the committee stregthened the recommendations from the previous version of the guideline and added the requirement for clinics providing ECT to be ECTAS-accredited, with board level accountability for compliance with ECTAS standards. The ECTAS standards include detailed advice on the information to be provided to people to obtain informed consent.

667	SH	Healthwatch Bristol	Guideline	49	General	Section 1.13 GeneralWe have received comments about what NICE should recommend:(Man who last had ECT in 2015): I am in no doubt that, in most cases, I was prescribed ECT with the best of intentions. However, the thought of this BARBARIC, DANGEROUS & OUT DATED practice being allowed to continue, in this day & age, is beyond my comprehension.(Woman who last had ECT in 2018): Anyone receiving ECT in the future should be made aware of the unknown number of different injuries possible. They should be made aware that these injuries could be permanent and life changing. They should have a full formulation of their diagnoses and assessed to see if therapy or anything else would help. This didn't happen in my case. People receiving ECT should have easy access to statistics about efficacy of ECT, placebos and injuries reported. They should be told before each treatment that if possible they can stop at that point.(Person who last had ECT in 2015) Psychiatrists should be monitoring patients for their cognitive function, which they are failing to do despite this being in NICE guidance. (Woman who last had ECT in 2016) I fail to comprehend how the issues being raised about ECT are not being taken seriously. Proper monitoring and regulation. Informed consent and consistency of information to given to patients and carers. Recognition of the harms and actions to redress this. Adequate data	Thank you for your comment. The committee discussed the fact that people need to be fully informed about the risks and benefits of ECT prior to its administration, and need to make an informed decision to have ECT. For this reason the committee stregthened the recommendations from the previous version of the guideline and added the requirement for clinics providing ECT to be ECTAS-accredited, with board level accountability for compliance with ECTAS standards. The ECTAS standards include detailed advice on the information to be provided to people to obtain informed consent.

						being collected about issues relevant to those receiving the treatment. And proper, unbiased research. Where else in healthcare would such a lack of proper governance be tolerated and why will those with any powers not take action?	

668	SH	UK ECT Improving Standards campaign group	Guideline	49	General	These comments are submitted on behalf of the UK ECT Improving Safety Campaign Group, which consists of clinicians, researchers, ECT recipients and their family members/carers. Our shared aim is to ensure that the use of ECT is based on sound evidence, safe administrative practices, with comprehensive assessments for adverse effects, rehabilitation for patients if injured, and effective governance and regulation processes. We have called for an Independent Review along the lines of the recent Cumberlege report into pelvic meshes as one way of achieving this (see our blog here: http://cepuk.org/2020/09/07/blog-call-for-an-independent-review-into-the-practice-of-ect/).A number of organisations support our call for an independent review and safer practice, including:MIND (the UK's largest MH NGO): 'At Mind, we back calls for a comprehensive review into the use of Electroconvulsive Therapy (ECT), a potentially risky physical treatment that is still used to treat mental health problems in rare cases. We know that some people have found it effective for improving symptoms of mental health problems – particularly depression – when nothing else has worked. However, we still don't know why it works or how effective it is. Some people who have had ECT may have found they experience adverse side effects that are worse than the symptoms of the problem they're trying to treat, including short	Thank you for your comment. The committee discussed the fact that people need to be fully informed about the risks and benefits of ECT prior to its administration, and need to make an informed decision to have ECT. For this reason the committee stregthened the recommendations from the previous version of the guideline and added the requirement for clinics providing ECT to be ECTAS-accredited, with board level accountability for compliance with ECTAS standards. The ECTAS standards include detailed advice on the information to be provided to people to obtain informed consent.

						term or longer term memory loss'. https://www.mind.org.uk/news-campaigns/news/mind-backs-calls-for-a-review-into-the-use-of-electroconvulsive-therapy-ect/, The Association of Clinical Psychologists UKThe National Counselling Society, The Royal College of NursingPlatfform, the Welsh MH charityThe Council for Evidence-based PsychiatryHeadway (the national brain injury charity); and others. 25 MPs from across the political spectrum, and Dr Rosena Allin-Khan, Shadow Minister for Mental Health Given our core purpose, we have chosen to comment solely on Section 1.13 of the Draft Consultation Guideline, although we welcome many aspects of the broader Draft Guideline, such as an increased emphasis on alternatives to anti-depressants in moderate or severe depression as well as in mild depression.	
669	SH	UK ECT Improving Standards campaign group	Guideline	49	General	We are pleased to see the following requirements:documenting the assessment and consent discussion in relation to ECT (1.13.2); emphasis on strict adherence to guidelines on consent including the involvement of advocates and carers (1.13.3); recommendation to take	Thank you for your comment and support for these recommendations.

						advance treatment decisions into account (1.13.4); encouragement of ECT clinics to obtain/maintain ECTAS-accreditation (1.13.6); recommendation that ECTAS standards should be monitored through board-level performance management (1.13.7).	
670	SH	UK ECT Improving Standards campaign group	Guideline	49	General	We welcome updated NICE guideline given recent ECT research, updated ECT device manufacturer warnings of serious adverse effects and international device regulatory bodies required warnings. However draft guidelines do not touch on recent research, updated device warnings and manufacturer admissions.Had NICE 2003's robust guidelines (reiterated in NICE 2009) been implemented, refining ECT's auditing standards and procedures (NICE 2003 Appendix D) could have ensured informed consent and safe practice, preventing many harms reported by ECT recipients. For that reason we would like to address significant omissions and limitations of Section 1.13. The NICE 2003 Committee also took a robust stance in relation to an appeal by the Royal College of Psychiatrists against the recommendation that ECT should be used in severe depressive illness only (NICE cited the unfavourable benefits/harms ratio in 'moderate' illness) https://www.nice.org.uk/guidance/ta59/resources/appraisal-of-electroconvulsive-therapy-decision-of-the-appeal-panel2 .We are concerned that failure to comply with NICE 2003	Thank you for your comment. The committee included ECT as an intervention in a number of evidence reviews and were disappointed by the lack of new evidence for ECT, which hampered their ability to update the ECT recommendations made in 2003 (and already updated once in 2009). However, the committee were aware that implementation of the recommendations about the administration of ECT may not have been ideal, and so strengthened these recommendations and added the requirement for clinics providing ECT to be ECTAS-accredited, with board level accountability for compliance with ECTAS standards.

						recommendations, despite regular calls for urgent action, contravenes the principle and purpose of NICE guidelines and condones future inaction. The ECT section of the Draft Guideline is an opportunity to revisit and reinforce these important recommendations with an urgency that is, if anything, now greater than before. In detailing our concerns, we have drawn on our collective experience, dating back several decades in the case of some members, derived from our research (and that of others), clinical work, personal experience and peer support in relation to ECT. We illustrate some of our points with testimony from survivors of ECT and their family members/carers who have shared their experiences with us.	

671	SH	UK ECT Improving Standards campaign group	Guideline	49	General	We are very concerned that the call for robust research into efficacy and safety made by NICE in 2003, and reiterated in 2009 and 2014, has been dropped from the present Draft Guideline. NICE 2003 noted a number of key areas in which essential evidence was lacking: 'Further research is urgently required to examine the long-term efficacy and safety of ECT…' 'Of particular concern is the lack of long-term evidence regarding adverse effects on cognitive function….''In addition to the use of appropriately validated psychometric scales, outcome measures should include user perspectives on the impact of ECT…. …..(and on) incidence and impact of important side effects such as cognitive functioning, and mortality'.'Further research into the mechanism of action of ECT is encouraged, because it may provide important information on aetiology and future treatment strategies.' Recommended that there should be evidence-based national patient information leaflets on ECTRecommended that an audit cycle should be set up in all ECT units to ensure NICE guidelines are being met, and provided a set of standards in NICE 2003 Appendix D. NICE 2018 noted in its review of the evidence for these guidelines: 'The review of ECT for the updated guideline found little additional data to update the reviews undertaken for the original NICE TA (NICE, 2003) and the revision of the	Thank you for your comment. NICE has, as you state, called for greater research to improve the evidence base for ECT and although ECT was included as an intervention for a number of evidence reviews the committee were disappointed by the lack of new or recent evidence available. This hampered their ability to update the recommendations. However, the committee were aware that implementation of the recommendations about the administration of ECT may not have been ideal, and so strengthened these recommendations and added the requirement for clinics providing ECT to be ECTAS-accredited, with board level accountability for compliance with ECTAS standards. While NICE actively encourages research in areas where the guideline development process has identified gaps in evidence, and works with the NIHR, it does not have control over the research that is funded or conducted. However, a research recommendation relating to the place in therapy of ECT has been added back into the guideline to ensure this remains a current topic where NICE encourages further research.

						guideline in 2009 (NICE, 2009).' Neither the Royal College of Psychiatrists nor the profession as a whole has set up such an audit or research programme in the 19 years since NICE 2003. We are extremely concerned not only that ECT guidelines continue to be based on evidence that is weak or absent, but that NICE has not reiterated its earlier strong and urgent calls for these gaps to be filled. We would like to hear the Developer's view on this. We have spelled out our concerns in more detail in the comments below. Where relevant we have added information and research from a range of researchers, including our own members, which has been not been considered by the Committee, but which does throw some light on these serious gaps. For completeness, we have also listed this and other missing evidence under our comments on the Evidence Reviews and the Clinical Supplement Tables.	

672	SH	UK ECT Improving Standards campaign group	Guideline	49	General	NICE 2003 stated: 'Further research is urgently required to examine the long-term efficacy and safety of ECT…' In relation to efficacy, we believe the following evidence since NICE 2003/2009/2014 must be included:A 2017 audit of ECT clinics based on FOI information requests returned by 32 of 56 ECT provider NHS Trusts, discovered that only 12.1% of Trusts who responded could provide outcome data. 43.5% of respondents did not use validated measures of efficacy. Four of the 56 ECT Clinics provided data for positive outcomes based on a 3 question measure by the referring clinician at the start and end of treatment, risking clinician bias. None of the Trusts provided any data on efficacy beyond the end of treatment. (Read J, Harrop C, Geekie J, Renton J. An audit of ECT in England 2011-2015: Usage, demographics, and adherence to guidelines and legislation. Psychol Psychother Theory, Res Pract. Published online October 20, 2017. doi:10.1111/papt.12160)A 2019 follow-up audit found that only 6 of 56 ECT clinics could provide any data for positive outcomes. Again, no trusts provided data on efficacy beyond the end of treatment. Only 30% of respondents were using validated measures of efficacy. (Read J, Harrop C, Geekie J, Renton J, Cunliffe S. A second independent audit of electroconvulsive therapy in England, 2019: Usage, demographics, consent, and adherence to guidelines and legislation. Psychol	Thank you for your comment. The committee noted the limitations of the evidence for ECT for further-line treatment, both in terms of quantity and quality in the committee discussion of the evidence section. However, the committee were also aware that ECT may be beneficial for some people and that removing it as an option would be detrimental to some people with depression. The recommendations on ECT limit its use (to when a rapid response is needed, when other treatments have failed, or based on patient preference). On this basis, the committee did not consider it appropriate to remove this recommendation, but did amend the wording to emphasise that ECT should generally not be used, and should only be considered in the limited circumstances described. The recommendation does not specify the use of ECT to prevent suicide, and an example is provided to clarify what is meant by life threatening. Recent meta-analyses on the effectiveness of ECT including those included in Read 2019 (Janicak 1985; Kho 2003; Mutz 2019; Pagnin 2004; UK ECT Review Group 2003) have been checked for additional relevant eligible studies. Read 2019 is listed in the excluded studies of Supplement D (further-line treatment) as it is not eligible for inclusion in its entirety (but has been

						Psychother Theory, Res Pract. 2021;94(3):603-619. doi:10.1111/papt.12335) A 2019 meta-analysis of all available ECT randomized controlled trials concluded: 'The quality of most SECT–ECT studies is so poor that the meta-analyses were wrong to conclude anything about efficacy, either during or beyond the treatment period. … Given the high risk … [and] this longstanding failure to determine whether or not ECT works means that its use should be immediately suspended until a series of well designed, randomized, placebo-controlled studies have investigated whether there really are any significant benefits against which the proven significant risks can be weighed' (Read J, Kirsch I, McGrath L. Electroconvulsive Therapy for Depression: A Review of the Quality of ECT versus Sham ECT Trials and Meta-Analyses. Ethical Hum Psychol Psychiatry. 2019;21(2):64-103. doi:10.1891/EHPP-D-19-00014)A 2010 analysis of placebo controlled studies showed minimal support for effectiveness of ECT in depression during the course of treatment (i.e. only for some patients, on some measures, sometimes perceived only by psychiatrists but not by other raters), and no evidence of any benefits beyond the treatment period. (Read J, Bentall R. The effectiveness of electroconvulsive therapy: A literature review. Epidemiol Psichiatr Soc. 2010;19(4):333-347. doi:10.1705/539.6428) It is relevant to note the	checked for relevant additional primary studies). Read et al. (2010) had not been previously identified but in response to your comment, it has been checked for additional eligible studies and no new studies have been identified for inclusion. The committee discussed the care and considerations that need to be taken into account when delivering ECT, such as informing people of the risks and benefits, obtaining consent, monitoring cognitive function and stopping ECT. The committee amended the existing recommendations on these topics but agreed that there are now recognised up to date standards produced by the Royal College of Psychiatrists, which provide guidance on how a safe and effective ECT service should be delivered, in the context of an ECT accreditation service (ECTAS). The committee added a recommendation, and subsequently strengthened this recommendation in response to stakeholder comments, that clinics should only provide ECT if they are ECTAS-accredited, provide ECT in accordance with ECTAS standards, and submit data (including outcomes) on each course of acute and maintenance ECT they deliver as needed for the ECTAS minimum dataset. There is also a recommendation that

						2018 mandatory warnings listed in all updated ECT device user manuals as required by the US FDA state: 'When used as intended this device provides short-term relief of symptoms. The long-term safety and effectiveness of ECT treatment has not been demonstrated.' The FDA refused to remove mandatory warnings 'because it is understood that cessation of active treatment will be associated with cessation of treatment benefits' (US Food and Drug Administration. Neurological Devices; Reclassification of Electroconvulsive Therapy Devices; Effective Date of Requirement for Premarket Approval for Electroconvulsive Therapy Devices for Certain Specified Intended Uses. US Department of Health and Human Services: Food and Drug Administration; 2019:66103-66124.) http://thymatron.com/downloads/System_IV_Instruction_Manual_Rev21.pdf Thymatron machines are used throughout the UK: see spreadsheethttps://docs.google.com/spreadsheets/d/1UZa40w37s01QsP-EAprU2QURhcgRHX0S2QtUANaXzDU/edit?usp=drivesdkPrevious findings identified that 'patients with established medication resistance during the index episode have an inferior response to ECT' (Sackeim HA. In reply to "Relapse of depression after electroconvulsive therapy." J Am Med Assoc. 2001;285(24):3088. doi:10.1001/jama.285.24.3087Three recent studies	trusts which provide ECT services should ensure compliance with the ECTAS standards for administering ECT through board-level performance management. The committee did not review the audit evidence for ECT (such as the papers cited: Read et al. 2018, 2021) or non-RCT evidence for benefits or harms (such as Peltzman et al. 2020; Sackeim 2001; Tsai et al. 2021), as this was outside the scope of this update. The committee were aware that the ECTAS standards were developed with a wider range of ECT experts than were available on the guideline committee, and were updated on a regular basis, and therefore agreed that it was more appropriate to refer to these standards than create new recommendations. The committee have reiterated their call for more research into the place in therapy of ECT, and will also recommend to NICE that it explore doing future work on neuromodulatory techniques (and/or rapidly acting treatments) including ECT.

						found that ECT recipients have an increased suicide risk, contrary to claims that it reduces suicide: 'Suicide mortality was significantly higher among patients who received ECT (RR, 5.71) [during 2 years following index mental health encounter']. Peltzman T, Gottlieb DJ, Shiner B, Riblet N, Watts B V. Electroconvulsive Therapy in Veterans Health Administration Hospitals: Prevalence, Patterns of Use, and Patient Characteristics. J ECT. 2020;36(2):130-136. doi:10.1097/YCT.0000000000000635'The RR of a suicide attempt in the year or year prior was more than 16 times greater among individuals who received ECT compared with those who did who did not' (Peltzman T, Shiner B, Watts B V. Effects of Electroconvulsive Therapy on Short-Term Suicide Mortality in a Risk-Matched Patient Population. J ECT. 2020;36(3):187-192. doi:10.1097/YCT.0000000000000665)Homeless US veterans who did not receive ECT had less suicidal ideation than matched groups of US veterans: (TSAI, J. et al. 2021. Effects of Electroconvulsive Therapy on suicidal behavior and emergency department use among homeless veterans: a propensity score-matched study. Journal of Clinical Psychiatry, 82(6), 21m13935.)In summary, the research evidence for efficacy of ECT, including claims that it reduces suicide, is almost entirely lacking, and clinical outcome data are rarely	

						collected. The literature cited above suggests that there continues to be very little justification, in our present state of knowledge, for recommending its use. We welcome the Developer's comments.	

673	SH	UK ECT Improving Standards campaign group	Guideline	49	General	NICE 2003 stated that 'Further research is urgently required to examine the long-term efficacy and safety of ECT…(including) mortality….' 'Of particular concern (was) the lack of long-term evidence regarding adverse effects on cognitive function…..' In relation to this recommendation about potential harms, we note the omission of two recent studies:A recent audit found that few Trusts could supply records serious adverse event records during after treatment. None could supply records for serious adverse events reported after the end of treatment. (READ, J., et al. 2018, An audit of ECT in England 2011-2015: Usage, demographics, and adherence to guidelines and legislation. Psychology and Psychotherapy: Theory, Research and Practice, 91, 263-277;)Only 24% of trusts use standardized measures of cognitive dysfunction (READ, J., et al. 2021 A second independent audit of ECT in England: Usage, demographics, consent, and adherence to guidelines and legislation in 2019. Psychology and Psychotherapy: Theory, Research and Practice, 94, 603-619) However, ample evidence suggests that serious harms do occur:Two ECT patient deaths investigated by formal death inquisition are not documented in MHRA serious adverse event reports2015 Woman died after ECT given without consent or SOAD https://www.mirror.co.uk/news/uk-news/woman-	Thank you for your comment. The committee discussed the care and considerations that need to be taken into account when delivering ECT, such as informing people of the risks and benefits, obtaining consent, monitoring cognitive function and stopping ECT. The committee amended the existing recommendations on these topics but agreed that there are now recognised up to date standards produced by the Royal College of Psychiatrists, which provide guidance on how a safe and effective ECT service should be delivered, in the context of an ECT accreditation service (ECTAS). The committee added a recommendation, and subsequently strengthened this recommendation in response to stakeholder comments, that clinics should only provide ECT if they are ECTAS-accredited, provide ECT in accordance with ECTAS standards, and submit data (including outcomes) on each course of acute and maintenance ECT they deliver as needed for the ECTAS minimum dataset. There is also a recommendation that trusts which provide ECT services should ensure compliance with the ECTAS standards for administering ECT through board-level performance management. The committee did not review the audit evidence for ECT (such as the papers cited: Read

						died-after-nhs-electric-75409012018 Woman died after ECT due to "suffering a seizure that stopped her heart" https://www.readingchronicle.co.uk/news/18215628.hungerford-mum-suffering-catatonic-depression-died-session-electroconvulsive-therapy-inquest-heard/?ref=rss A 2019 systematic review of all published literature on ECT mortality from 1980 to 2016 (284 studies) identified that 'Major adverse cardiac events and death after ECT … occur in about one in 50 patients and after about one in 200 – 500 ECT treatments.' (This is more serious than typical general anaesthesia effects and should be regarded as both 'serious' and 'common'), (Duma A, Maleczek M, Panjikaran B, Herkner H, Karrison T, Nagele P. Major adverse cardiac events and mortality associated with electroconvulsive therapy: A systematic review and meta-analysis. Anesthesiology. 2019;130(1):83-91. doi:10.1097/ALN.0000000000002488)A 2019 comprehensive review of ECT trials revealed a slight but significant risk of death, and that between 12% and 55% suffer brain damage in the form of permanent memory loss. (Read et al 2019 Electroconvulsive Therapy for depression: A Review of the quality of ECT vs sham ECT trials and meta-analyses. Ethical Human Psychiatry and Psychology, 21, 64-103) A 2016 study found that 21% of ECT recipients 'reported severe or long	et al. 2018, 2021) or non-randomised studies on benefits or harms, as this was outside the scope of this update. However, the committee were aware that the ECTAS standards were developed with a wider range of ECT experts than were available on the guideline committee, and were updated on a regular basis, and therefore agreed that it was more appropriate to refer to these standards than create new recommendations. Recent meta-analyses on the effectiveness of ECT including those included in Read 2019 (Janicak 1985; Kho 2003; Mutz 2019; Pagnin 2004; UK ECT Review Group 2003) have been checked for additional relevant eligible studies. Read 2019 is listed in the excluded studies of Supplement D (further-line treatment) as it is not eligible for inclusion in its entirety (but has been checked for relevant additional primary studies). The committee have reiterated their call for more research into the place in therapy of ECT, and will also recommend to NICE that it explore doing future work on neuromodulatory techniques (and/or rapidly acting treatments) including ECT.

						term memory loss' (Maguire S, Rea SM, Convery P. Electroconvulsive Therapy-What Do Patients Think Of Their Treatment? ABSTRACT Background The Regulation and Quality Improvement Authority (RQIA) monitors the administration of electroconvulsive. Ulster Med J. 2016;85(3):182-186. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5031106/) In 2015 ECTAS's Interim Report on Patient Perspectives identified nearly one in 5 people reporting severe or long-term memory effects. (Hailey E, Hodge S, Buley N. ECTAS Interim Report-Patient Perspectives Introduction to ECTAS.; 2015. Accessed September 26, 2018. https://www.rcpsych.ac.uk/pdf/ECTAS Interim Report.pdf) A 2010 literature review identified strong evidence of 'persistent and, for some, permanent brain dysfunction, primarily evidenced in the form of retrograde and anterograde amnesia, and the evidence of a slight but significant increased risk of death.' (Read J, Bentall R. The effectiveness of electroconvulsive therapy: A literature review. Epidemiol Psichiatr Soc. 2010;19(4):333-347. doi:10.1705/539.6428) A 2003 systematic review found one third of patients reporting long-term cognitive impairment when survey was conducted by third-party not in charge of treatment, concluding ECT recipients may feel more willing to disclose treatment consequences	

						with someone other than their ECT provider. (Rose D, Fleischmann P, Wykes T, Leese M, Bindman J. Patients' perspectives on electroconvulsive therapy: systematic review. BMJ. 2003;326(7403):1363. doi:10.1136/BMJ.326.7403.1363) The manual for ECT machine manufacturer Thymatron 2019 "Instruction for Use" manual now includes FDA mandated warning which states: 'Long-term safety and effectiveness of ECT treatment has not been demonstrated, and long-term follow-up may be needed.'(see page 7) http://thymatron.com/downloads/System_IV_Instruction_Manual_Rev21.pdf We have established that at least 72 ECT devices are currently in use throughout the UK are manufactured by Thymatron; see spreadsheethttps://docs.google.com/spreadsheets/d/1UZa40w37s01QsP-EAprU2QURhcgRHX0S2QtUANaXzDU/edit?usp=drivesdk Thymatron's 2019 user manual added a lengthy list of potential 'Serious Adverse Effects': 'cardiac complications, including arrhythmia, ischemia/infarction (i.e., heart attack), acute hypertension, hypotension, and stroke; cognition and memory impairment; brain damage; dental/oral trauma; general motor dysfunction; physical trauma (i.e., if inadequate supportive drug treatment is provided to mitigate unconscious	

						violent movements during convulsions); hypomanic or manic symptoms; neurological symptoms (e.g., paresthesia, dyskinesias); tardive seizures; prolonged seizures; non-convulsive status epilepticus; pulmonary complications (e.g., aspiration/inhalation of foreign material, pneumonia, hypoxia, respiratory obstruction such as laryngospasm, pulmonary embolism, prolonged apnea); visual disturbance; auditory complications; onset/exacerbation of psychiatric symptoms; partial relief of depressive anergia enabling suicidal behavior; homicidality; substance abuse; coma' (See page 10) http://thymatron.com/downloads/System_IV_Instruction_Manual_Rev21.pdfWe ask the Guideline to consider of this evidence, and to reiterate NICE 2003's previous concerns about failure to monitor outcomes and adverse events of all kinds, despite growing evidence of a range of harms and safety concerns, and recommendations by ECT machine manufacturers themselves. We welcome the Developer's comments on the implications for assessing the benefit/harm ratio in prescribing ECT.	

674	SH	UK ECT Improving Standards campaign group	Guideline	49	General	The Draft Guideline should strongly recommend monitoring for serious adverse events related to ECT and reporting them to CQC and MHRA. This is necessary because:Medicines and Healthcare products Regulatory Agency (MHRA) MHRA stated in 2017 that they have no reports of ECT adverse effects via their 'Yellow Card' system, despite the 2015 death of Elsie Tindal https://www.mirror.co.uk/news/uk-news/woman-died-after-nhs-electric-7540901 ECTAS reported in a personal communication 'Over the past 24 months we have not needed to contact the CQC or any other regulator regarding serious concerns about an ECT service. It is not possible to definitively answer the question before this time period.' This admission is particularly alarming given the well-publicised 2018 death of Kathryn Carbone and the subsequent formal inquiry. (https://www.readingchronicle.co.uk/news/18215628.hungerford-mum-suffering-catatonic-depression-died-session-electroconvulsive-therapy-inquest-heard/?ref=rss)As an in in-house quality improvement network, ECTAS has no incentive to report adverse events. Consequently, serious adverse events (even death) are not a Type 1 ECTAS standard for accredited clinics. ECTAS did not require follow-up data about adverse events until this year, when an additional standard of assessing memory and cognitive effects at 2	Thank you for your comment. The committee included ECT as an intervention in a number of evidence reviews and were disappointed by the lack of new evidence for ECT, which hampered their ability to update the ECT recommendations made in 2003 (and already updated once in 2009). The committee have reiterated their call for more research into the place in therapy of ECT, will also recommend to NICE that it explore doing future work on neuromodulatory techniques (and/or rapidly acting treatments) including ECT and have also included research recommendations relating to ECT. The committee recognised the safety concerns around the use of ECT and stregthened the recommendations from the previous version of the guideline and added the requirement for clinics providing ECT to be ECTAS-accredited, with board level accountability for compliance with ECTAS standards. The ECTAS standards include detailed advice on monitoring and assessing its effects.

						months was added. Clearly there are many other possible adverse outcomes as well. Patients who experience serious adverse effects are abandoned without access to comprehensive testing and rehabilitation interventions despite radical functional deficits. Drastic reduction in quality of life may be part of the reason ECT recipients are 5.7x more likely to suicide within two years of ECT. (Peltzman T, Gottlieb DJ, Shiner B, Riblet N, Watts B V. Electroconvulsive Therapy in Veterans Health Administration Hospitals: Prevalence, Patterns of Use, and Patient Characteristics. J ECT. 2020;36(2):130-136. doi:10.1097/YCT.0000000000000635)	

675	SH	UK ECT Improving Standards campaign group	Guideline	49	General	NICE 2003 stated: 'Further research into the mechanism of action of ECT is encouraged, because it may provide important information on aetiology and future treatment strategies.' In relation to this crucial question, we note that a large body of relevant evidence has been omitted from the Guideline. There is no official consensus on ECT's mechanism of action of ECT. One study concluded 'ECT may affect the brain in a similar manner as severe stress or brain trauma which activates the HPA axis and the dopamine system and may compromise frontotemporal functions.'(Fosse R, Read J. Electroconvulsive treatment: Hypotheses about mechanisms of action. Front Psychiatry. 2013;4(AUG):1-10. doi:10.3389/fpsyt.2013.00094)Experts have conceptualised ECT as an acquired brain injury caused by repetitive electrical trauma to the brain. Dr. Bennet Omalu, neuropathologist who first identified Chronic Traumatic Encephalopathy, 'confirmed repetitive head trauma causes functional injuries that are not readily seen on standard scans. … He also [confirmed] that the neuropathology of electrical injury is well recognised as causing extensive functional changes to brain activity and should be considered in the context of both electrical injury and repetitive electrical trauma to the head (Omalu B, Hansen S, Williams E, et al. Traumatic Brain Injury Advisory	Thank you for your comment. Examining mechanisms of action was outside the scope of this guideline. The committee have reiterated their call for more research into the place in therapy of ECT, and will also recommend to NICE that it explore doing future work on neuromodulatory techniques (and/or rapidly acting treatments) including ECT.

						Board Meeting Minutes.; 2019. https://www.dor.ca.gov/Content/DorIncludes/documents/TBI/TBI Full Committee Meeting Minutes 8-26-19.docx .) Examining ECT through the lens of repetitive traumatic brain injury:During ECT, hypoxic/anoxic injury can be potentially caused by because the seizure is so violent that postictal suppression (absence of brain activity) can last for more than six minutes. According to medical records obtained by our group, some ECT recipients awake from coma activity more than 30 minutes after anaesthetic administration. Doctors cannot control how long postictal suppression lasts after the seizure since it will be a unique response in each patient based on multiple factors (age, seizure threshold, length of time exposed to stimulus, etc). During brain activity silence, the brain stem is not engaging respiratory activity or regulating cardiac activity. Anoxic brain injury begins at four minutes without oxygen and blood circulation. Typically, traumatic brain injuries are classified by the length of time the patient has a loss of consciousness. Less than 30 minutes as indicated by brain activity is technically a Mild Traumatic Brain Injury. Greater than 30 minutes, but less than 24 hours, is technically a Moderate Traumatic Brain Injury. Doctors do not record the length of time postictal suppression lasts, nor do they record the length of time the patient's oxygen	

						saturation is below 90%. In repetitive electrical injury, there is electroporation (opening of tiny pores in cell membrane when pulsed electricity is driven through living cells). Pulsed electricity causes acquired channelopathies (dysregulation of electrolytes) (Hancock SP. Acquired Channelopathies Secondary to Repetitive High Energy Field "Low-Voltage" Electrical Injury.; 2020. doi:10.13140/RG.2.2.15825.15207). Channelopathies can cause episodic paroxysmal neuromuscular disorders, cardiac arrythmia and migraines. Though there are no brain scans with the capacity to identify damage from electrical injury, rejecting the possibility of microstructural damages due to the absence of evidence on standard brain scans is akin to denying the possibility of a broken bone before the advent of the x-ray machines. Like those living with CTE, microstructural damages will be confirmed at autopsy with neuropathology study using proper staining technique. The testimonies of many of our members illustrate the devastating real-life impacts of such injuries (see for example these videos: https://www.youtube.com/watch?v=AdiVaSdU6Fw&t=2s https://www.youtube.com/watch?v=nv35WaFGpUc&t=2899s) We do not take the view that, as most ECT patient information leaflets state, 'The exact mechanism of action of ECT is not known.' On the	

						contrary, we believe the mechanism is very clear. Either way, we do not think it is acceptable for the Draft Guideline to fail to make any statement about the need for clarification and consensus in this area. Existing evidence, as cited above, should also be included in any decisions or recommendations about the benefit/harms ratio of ECT, and in patient information leaflets. We welcome the Developer's comments.	

676	SH	UK ECT Improving Standards campaign group	Guideline	49	General	The Draft Guidelines fails to reinforce NICE 2003's statement that 'RCTs….did not adequately capture the experience of service users' and that their testimony must be taken into account to balance findings from quantitative studies. NICE 2018 Draft Consultation Guidelines on Depression in Adults noted that, in their small sample, personal experiences were largely negative: 'Four service users recounted their experience of ECT; the majority had negative experiences 40 because of the frightening nature of the intervention and loss of memory post-treatment: 'I have massive blanks, short-term and long-term … I get angry with the professionals 3 that this wasn't explained that this could happen … I've tried to talk about it with the 4 doctors at the hospital and they say, "Give me an example" and I give them an 5 example and they say, "Oh that's normal, that's just normal, that's not the ECT … 6 that's normal".' (p.92). This echoes one of the strongest themes in NICE 2003: 'Committee took special note of the evidence from observations of users' experiences relating to the adverse effects of ECT. In particular, the incidence, extent and timescale of cognitive impairment following ECT was discussed in detail. It was apparent that the nature of cognitive impairment experienced by users was variable and often long lasting to such a degree that it outweighed their perception of any benefit from ECT treatment. The	Thank you for your comment. The committee were aware of the negative experiences of some people with depression who had been treated with ECT, and also aware that it was beneficial for some people and that removing it as an option would be detrimental to some people with depression. ECT was included as an intervention in a number of the evidence reviews and the committee were disappointed with the lack of new or recent studies, but obtaining or using additional patient testimony was not prioritised for inclusion in the guideline. The committee have reiterated their call for more research into the place in therapy of ECT ,and will also recommend to NICE that it explore doing future work on neuromodulatory techniques (and/or rapidly acting treatments) including ECT. While NICE actively encourages research in areas where the guideline development process has identified gaps in evidence, and works with the NIHR, it does not have control over the research that is funded or conducted. The committee stregthened the recommendations from the previous version of the guideline and added the requirement for clinics providing ECT to be ECTAS-accredited, with board level accountability for compliance with ECTAS standards. The ECTAS standards

						Committee considered that further research, both qualitative and quantitative, was needed to define the effect of ECT on cognitive impairment… These factors featured significantly in the Committee's deliberations, and specifically in its decision to restrict the use of ECT to situations in which all other alternatives had been exhausted or where the nature of the mental illness was considered to be 'life-threatening' (4.3.2). NICE 2018 noted that there is a significant gap between most professional views and most patient experiences: 'In its modern form ECT is perceived by many healthcare professionals to be a safe 30 and effective treatment for severe depression that has not responded to other standard treatments (Geddes et al., 2003b). But many others, including some patient groups, consider it to be an outdated and potentially damaging treatment'. While we recognise that some people report benefits from ECT, and others feel that the positive effects outweighed the negative ones, the life-changing harms reported to us by some patients are no longer represented in any way in this Draft Guideline. We would have liked to see much greater use of patient testimonies in the Draft Guidelines, such as those cited by Rose et al, 2003(Patients' perspectives on electroconvulsive therapy: BMJ).	include detailed advice on monitoring and assessing cognitive impairment.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

677	SH	UK ECT Improving Standards campaign group	Guideline	49	General	In summary, in relation to the concerns raised by NICE 2003 about the safety and efficacy of ECT, section 1.13 of the Draft Guideline fails even to acknowledge the serious gaps in the evidence for its recommendations, let alone (unlike NICE 2003) to make an urgent call for those gaps to be filled. We note that similar concerns were raised by the UK Advocacy Network in their 2007 submission to the consultation for NICE Technology Appraisal Guidance no. 59: 'UKAN's policy on ECT, as voted by our member groups at our Annual General Meeting, is that we call for this 'treatment' to be suspended until there is conclusive proof that it is safe. In the opinion of the majority of groups that make up our membership there is significant evidence that ECT is damaging. We believe the fact that it appears to help some people would not be seen as an adequate reason for continuing its use in any other form of medicine.' No significant progress has been made since then.We believe we have identified clear breaches of NICE's commitments to: Use evidence that is relevant, reliable and robust; propose new research questions and data collection to resolve uncertainties in the evidence; liaise with the research community to ensure they are addressed; take into account the advice and experience of people using services and their carers or advocates; and update recommendations in line	Thank you for your comment. The committee included ECT as an intervention in a number of evidence reviews and were disappointed by the lack of new evidence for ECT, which hampered their ability to update the ECT recommendations made in 2003 (and already updated once in 2009). The committee have reiterated their call for more research into the place in therapy of ECT, and will also recommend to NICE that it explore doing future work on neuromodulatory techniques (and/or rapidly acting treatments) including ECT, and have included a research recommendation relating to ECT. While NICE actively encourages research in areas where the guideline development process has identified gaps in evidence, and works with the NIHR, it does not have control over the research that is funded or conducted. The committee recognised the safety concerns around the use of ECT and stregthened the recommendations from the previous version of the guideline and added the requirement for clinics providing ECT to be ECTAS-accredited, with board level accountability for compliance with ECTAS standards. The ECTAS standards include detailed advice on monitoring and assessing its effects.

						with new evidence (https://www.nice.org.uk/about/who-we-are/our-principles). This section of the Guideline also fails to demonstrate NICE's commitment to ensuring patient safety arising out of the recent Cumberlege review (https://www.nice.org.uk/about/what-we-do/our-programmes/patient-safety_In the words of the distinguished psychologist and Fellow of the British Academy Professor Richard Bentall, ECT is 'a classic failure of evidence-based medicine' http://cepuk.org/2020/06/04/guest-blog-by-richard-bentall-ect-is-a-classic-failure-of-evidence-based-medicine/For all these reasons, we argue that ECT should now be placed in the category 'Research only' until there is a solid evidence-base for its safe and effective use.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

678	SH	UK ECT Improving Standards campaign group	Guideline	49	General	We are concerned at the failure to reiterate important limitations on practice cited in NICE 2003, including 'used only to achieve rapid and short-term improvement of severe symptoms after an adequate trial of other treatment options has proven ineffective and/or when the condition is considered to be potentially life-threatening'; 'Clinical status should be assessed following each ECT session and treatment should be stopped when a response has been achieved, or sooner if there is evidence of adverse effects' and 'Not recommended as a maintenance therapy in depressive illness.' We are personally aware of several current cases where this guidance is being blatantly breached. There is a risk that failure to reiterate and strengthen these statements will make such situations even Informed more common.	Thank you for your comment. The recommendations on ECT do still limit its use to very limited circumstances (rapid responses, when other treatments have failed, patient preference) and it is not recommended for maintenance treatment. It is also recommended to stop it if side-effects outweigh the benefits. The committee were aware of safety concerns around the use of ECT and that previous recommendations on monitoring had not been well-implemented and so strengthened the recommendations from the previous version of the guideline and added the requirement for clinics providing ECT to be ECTAS-accredited, with board level accountability for compliance with ECTAS standards. The ECTAS standards include detailed advice on monitoring and assessing its effects.

679	SH	UK ECT Improving Standards campaign group	Guideline	49	General	There is no statement about the failure to produce national evidence-based patient information leaflets, as recommended by NICE 2003, as a basis for ensuring informed consent: 'National information leaflets should be developed through consultation with appropriate professional and user organisations to enable individuals and their carers/advocates to make an informed decision regarding the appropriateness of ECT for their circumstances. The leaflets should be evidence based, include information about the risks of ECT and availability of alternative treatments.' A recent audit of current ECT information leaflets, based on FOI requests, was carried out by members of our group (HARROP, C., et al. 2021 How accurate are ECT patient information leaflets provided by mental health services in England and the Royal College of Psychiatrists? Ethical Human Psychology and Psychiatry, 23, 5-24.) It found that current leaflets contain numerous serious inaccuracies, one of the commonest being 'minimisation of memory loss.' 10 Trusts do not mention risks of permanent brain damage or permanent memory loss. The Royal College of Psychiatrists' updated 2020 leaflet was found to be less accurate than previous ones https://www.rcpsych.ac.uk/mental-health/treatments-and-wellbeing/ect.. We believe that none of the existing leaflets meets NICE	Thank you for your comment. The committee were aware of the adverse effects some people had experienced due to ECT and for this reason had strengthened their recommendations. The recommendations now state that clinics providing ECT should be ECTAS-accredited and provide ECT in accordance with ECTAS standards, and this includes detailed requirements about the level and type of patient information to be supplied, and the monitoring of cognitive function recommended. The guideline also recommends that informed consent should be obtained based on a discussion of the risks and benefits of ECT for that individual.

						standards for Patient Decision Aids:https://www.nice.org.uk/corporate/ecd8/chapter/content-and-process-standards-for-patient-decision-aidsThis shows that NICE 2003's concerns about informed consent, including that: '….the potential for cognitive impairment following ECT may not be highlighted during the consent process', are still valid. The risk of serious harm is still publicly denied; (e.g. former RCP President Dr Wendy Burn, stated that 'There is no evidence that ECT causes brain damage' https://twitter.com/wendyburn/status/1038530873409323008) This directly contradicts the warning that Thymatron ECT machine manufacturers require doctors to make, which includes the risk of 'cardiac complications… general motor dysfunction… permanent memory loss or permanent brain damage' and a long list of other potential adverse events (http://www.thymatron.com/downloads/System_IV_Regulatory_Update.pdf) ECT recipients have reported to us a scale of outcomes due to the large number of variables associated with dosing practices. While some are mild and transient, others include a range of effects which suggest, per international brain Injury guidelines, an acquired brain injury (ABI), which can be a life-long disability. Among the effects reported to us are: losing years of memories; struggling to learn new	

						things; difficulty concentrating for complex tasks; easily forgetting what has just happened or what they need to do; issues recognising familiar faces and remembering familiar people's names; issues navigating familiar routes; struggling with basic maths; reading comprehension/visual changes, vision fatigue; difficulty remembering words; slurred speech when tired; changes in balance and motor coordination; personality changes; problems with organisation and problem solving. While some of these improve, others worsen over time, with neurocognitive fatigue leading, in some cases, to a struggle to speak, walk or perform the most basic of tasks like cooking. According to typical NHS Risk Assessment Scoring and Matrix, we acknowledge some ECT recipients meet Type I (negligible) consequences, other ECT recipients experience serious adverse effects identified by device manufacturers meet the type 4 (Major) and type 5 (Catastrophic) descriptors as defined below:Type 4 (Major)—Major injury leading to long-term incapacity/disability Type 5 (Catastrophic)—Multiple permanent injuries or irreversible health effects including death.We ask NICE how it would categorize serious adverse effects (above) using NHS Risk Assessment matrix.Based on GMC 2020 risk disclosure legalities, in the interest of providing legal informed consent, NICE's updated Guideline should strongly recommend updating all patient	

						information leaflets to reflect recent research including ECT device warnings, make recommendations for appropriate comprehensive testing and rehabilitation for known serious adverse effects, and ensure that consent is based on knowledge of the full range of potential harms. We argue that information leaflets should be updated to include:Warning that positive effects are short-term, and serious adverse events can be devastating and permanent.Damage caused by electricity does not always show up on brain scans.ECT has unpredictable results and there is a risk of life-long disability.The risk of brain injury risks increase with dosing variables, including Bilateral electrode placement; Closely spaced treatments; Larger numbers of treatments; Taking psychotropic medications when exposed to ECT; High dosage of barbiturate anaesthetic agents.The ECT dosing regime is not firmly establishedECT prescribers are not specialty trained in electrical injury or repetitive mild-traumatic brain injuryThere is currently no formally recognized rehabilitation interventions for ECT's adverse effects.There must be regular testing for known serious adverse events.There must be appropriate standardized assessments to investigate patient/carer serious adverse event concerns and report them to the MHRA.Patients must re-consent with each electrical dose increase because a	

						700mC dose is more risky than an initial dose of 60mC or 90mC.	

680	SH	UK ECT Improving Standards campaign group	Guideline	49	General	We draw the Committee's attention to the fact that fully informed consent is even more urgent in the light of the Montgomery (2015) ruling which requires even relatively rare risks to be mentioned. Specifically, and in line with the GMC 2020 informed consent guidelines, this would include informing patients about the risk of permanent brain damage and permanent memory loss among other adverse events. In 2018, a regulatory update to the instruction manual of Thymatron ECT machines required doctors using these machines to '….read and follow the warnings and recommendations of the Task Force Report of the American Psychiatric Association as set forth in "The Practice of Electroconvulsive Therapy" (APA, 2001), which states, in part, that "A small minority of patients treated with ECT later report devastating cognitive consequences. Patients may indicate that they have dense amnesia extending far back into the past for events of personal significance or that broad areas of cognitive function are so impaired that the patients are no longer able to engage in former occupations...in some patient self-reports of profound ECT-induced deficits may reflect objective loss of function...In rare cases, ECT may result in a dense and persistent retrograde amnesia extending to years...' Among the risks that patients are required to know about, are 'cardiac complications…	Thank you for your comment. The committee were aware of the concerns that ECT may lead to adverse effects and so strengthened their recommendations relating to the provision of ECT to include the fact that ECT should only be used for limited indications, that informed consent should obtained (as is now the requirement for all medical procedures post Montgomery ruling), that risks and benefits should be described and the discussion documented. In addition, the recommendations now state that clinics providing ECT should be ECTAS-accredited to ensure that standards relating to information, consent and monitoring are applied when delivering ECT.

						general motor dysfunction… permanent memory loss or permanent brain damage.' There is a long list of other potential adverse events that doctors are also required to make patients aware of: (http://www.thymatron.com/downloads/System_IV_Regulatory_Update.pdf) FOI requests made by our group have revealed that of the 129 Trusts using ECT in UK & Ireland, at least 72 use Thymatron devices (see spreadsheet): https://docs.google.com/spreadsheets/d/1UZa40w37s01QsP-EAprU2QURhcgRHX0S2QtUANaXzDU/edit?usp=drivesdk Since ECT devices work in similar fashion, risks recognized by one manufacturer apply to anyone undergoing ECT, regardless of device type. The risk of permanent brain damage along with other risks must therefore be included in the consent process. The absence of informed consent is the basis for present prospective legal cases undertaken by Freeths law firm on behalf of injured patients who weren't legally consented: https://www.freeths.co.uk/legal-services/individuals/clinical-negligence/electroconvulsive-therapy-ect/ Serious adverse events carry risk management implications for NHS Trusts and doctors performing ECT, along with potential life-long consequences for ECT recipients.	

681	SH	UK ECT Improving Standards campaign group	Guideline	49	General	We support the Committee's statement that valid and informed consent should be given without pressure or coercion and call attention to NICE 2003 guidelines which state 'since many people are unaware of their rights and may be subject to both explicit and implicit coercion …..mechanisms to monitor and prevent this from occurring must be developed and implemented'. In the absence of such mechanisms, we are confident that coercion occurs. We are aware of a number of recent cases in which patients were subject to both overt threats and implicit coercion if/when ECT is refused. One former patient who suffered serious adverse ECT effects two years ago told us: 'I saw the ECT psychiatrist as an outpatient to discuss it in 2014. I was not sectioned at this time. After a discussion we agreed I did not accept ECT as a valid treatment at all under any circumstances, and refused. I was distressed but not suffering from a disease. When admitted on section in 2016 and offered it again I refused, but was forced to have it. No physical force was used, but it was implied that I had no option.'	Thank you for your comment. The recommendations have been modified to further emphasise that the use of ECT should be a 'shared decision…based on their clinical needs and preferences' and the recommendations still advise to obtain consent 'without pressure or coercion'.

682	SH	UK ECT Improving Standards campaign group	Guideline	49	General	NICE 2003 noted that: 'The ongoing deficiencies in current practice were highlighted to the Committee, and the Committee strongly believed that action is required to ensure that appropriate standards of care are enforced whenever ECT is undertaken and that outcomes are continuously monitored.' We agree with the recommendation that 'Trusts which provide ECT services should ensure compliance with the ECTAS standards for administering ECT through board-level performance' (1.3.7.) However, we are concerned that this on its own will create the false impression that patient safety can be guaranteed. There are 4 important reasons why this is not sufficient to rectify or prevent the 'deficiencies in practice' identified by NICE 2003, and reported to us by many former patients. These are:1 ECTAS standards are totally inadequate for this task, as already described. 2 ECTAS was set up by the Royal College of Psychiatrists in 2004 on the basis of NICE 2003 recommendations. Therefore it does not offer independent monitoring. 3 ECTAS standards do not address the quality of the clinical decision to give ECT in the first place: 'These standards relate to the process of administration of ECT and to the facilities; they do not consider the quality of clinical decisions about which patients should be given this therapy' (Caird, Worrell and Lelliott 2004.) In other words, completely inappropriate	Thank you for your comment. The committee were aware that that implementation of the guideline's previous recommendations had not been optimal and agreed that the recommendations should be strengthened to include ECTAS-accreditation and board level oversight of this, in order to address shortfalls in areas such as information provision and monitoring of adverse effects. The committee agreed that ECT should remain available as a treatment option and that it could be safe and effective if used in accordance with NICE recommendations.

						clinical decisions may be made, but the clinic will meet ECTAS standards if the ECT is administered 'properly.'4 Regardless of the appropriateness of ECTAS standards, membership is optional. The ECTAS website states 'ECTAS is a voluntary network which uses a system of peer review.' Elsewhere ECTAS stresses that 'ECTAS does not provide regulation or monitoring of ECT' (Sivasanker, et al., 2022). 25% of UK ECT clinics are not currently accredited by ECTAS, and we have been refused permission to see the ECTAS reports on those clinics that have been inspected. We thus have a situation where practice standards are seriously inadequate; ECTAS does not provide regulation or monitoring of its standards; it is impossible to find out which of these standards have been met by any specific clinic; and accreditation to these standards is optional, meaning that clinics can legally operate without meeting the most basic criteria for safety or best practice. This would be unacceptable in any other medical intervention, and we are deeply concerned that NICE considers its current recommendations adequate to address it. We welcome the Developer's comments.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

683	SH	UK ECT Improving Standards campaign group	Guideline	49	General	A founder member of our group writes:Dr Sue Cunliffe is a founder member of our group, has made her story public on a number of occasions, and is willing to be named in this submission. She spoke at the RCPSYCH ECTAS conference and at the Maudsley Debate series about the harms which forced her to abandon her medical career, and has featured in numerous newspaper articles, TV and radio interviews and podcasts. 'I was admitted to hospital in the context of an abusive marriage. Instead of receiving therapy and support, I was persuaded to undergo 21 sessions of ECT. My medical notes clearly demonstrate lack of monitoring and supervision. They list my complaints about my memory deteriorating, my speech slowing up, feeling continuously 'sedated' and my motor and coordination being affected. Instead of reviewing the treatment plan, the dose was increased from 90Millicoumbs to 700MCs with devastating consequences. Reading my notes has proven hard. It's a comprehensive account of my brain being blown to bits and my life stolen from me with 20 negligent flicks of a switch….. ECT victims have been waiting for nearly 90 years to have our voices heard publicly. Members of our group we have suffered devastating, catastrophic brain damage that has changed our lives forever and yet we consented on the basis that ECT was safe with no long term effect, and would cure us.	Thank you for your comment. The committee were aware that that implementation of the guideline's previous recommendations had not been optimal and agreed that the recommendations should be strengthened to include ECTAS-accreditation and board level oversight of this, in order to address shortfalls in areas such as information provision and monitoring of adverse effects. The committee agreed that ECT should remain available as a treatment option and that it could be safe and effective if used in accordance with NICE recommendations.

						Our injuries are covered up and denied. We will not, and should not be expected to apologise for speaking the truth about our injuries and subsequent experiences. Neither should we be portrayed as scaremongers when we are simply acting as responsible members of the public in seeking to improve ECT unit standards across the UK. We want to prevent others suffering unnecessary harm.' Like others in our group, Dr Cunliffe has spent many years pursuing a complaint against the hospital which gave her ECT in breach of informed consent procedures, ECTAS standards and NICE guidelines. The hospital rejected the complaint and CQC refused to take any action. The ECT unit has since received a 'special commendation' from ECTAS for 'patient experience.' Our group is aware of 4 patients at the same hospital who have suffered life changing injuries. In every case, NICE Guidelines have been insufficient to protect vulnerable patients. In 2002 the Department of Health commissioned the SURE Patient Perspective study, which concluded among other things: 'The effects of damage to the memory are present in almost every aspect of people's lives. A language of frustration and humiliation is used to express how the simple tasks of daily living and social interaction become problematic following ECT…. When consumers complain of these difficulties to their doctors, they	

						are frequently told that they must be mistaken… There is no support available for people experiencing memory loss.. (some) consumers feel that their experience of ECT has been damaging and coercive.' This situation remains essentially unchanged, according to patients and carers who have contacted us. Thos who have received ECT are sceptical about the consultation; one has said: 'I do not hold out any hope whatsoever about the review of NICE Guidelines for the use of ECT. Psychiatry failed utterly to follow the 2003 Guidelines so…there seems little point in reviewing them.' We very much hope that this Draft Guideline will not be another missed opportunity to right these wrongs, and we hope the Committee will revisit section 1.13 accordingly.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

684	SH	UK ECT Improving Standards campaign group	Guideline	49	General	Although we welcome some parts of Section 1.13, we believe that overall it fails to address any of the urgent and longstanding concerns about the safety, efficacy and regulation of ECT. We are also very seriously concerned about the apparent abandonment of the requirement to produce proper evidence for this procedure, despite NICE's stated core principles and objectives. Moreover, we note that in 2003 the Final Decision by the Technology Appraisals and Guidance Information Services in relation to TA59: 'The clinical effectiveness and cost effectiveness of electroconvulsive therapy (ECT) for depressive illness, schizophrenia, catatonia and mania' was that 'The guidance will remain on the 'static guidance list'. In other words, no major research on this topic is due to be published within the next three to five years, and therefore updates are expected to be less frequent. We fail to see the appropriateness of this decision given that the need for research in this area is (as noted by NICE 2003 itself) so urgent.	Thank you for your comment. ECT was included as in intervention in a number of evidence reviews for this update of the depression guideline, but the committee were, like you, very disappointed that there was very little new evidence that allowed them to update their recommendations. While NICE actively encourages research in areas where the guideline development process has identified gaps in evidence, and works with the NIHR, it does not have control over the research that is funded or conducted. However, research recommendations relating to the indications and administration of ECT have been added back into the guideline to ensure these remain current topics where NICE encourages further research. A guideline cannot be updated if new research is not available and for that reason would remain on a 'static' list.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

685	SH	UK ECT Improving Standards campaign group	Guideline	49	General	We ask NICE to make a number of specific safety recommendations in order to meet NICE 2003's call for safer practice, as below. Use specified tests that have been demonstrated to be appropriate to assess for all potential cognitive and other damage to be administered after every ECT sessionDoctors to document patients' initial seizure threshold, electrical dose (Hertz, pulse width, pulse type, percentage of power electrode placement, medication, etc)An estimate of the pre-morbid cognition, motor function, auditory/visual processing, neuro vascular health and cardiac function to be established prior to onset of ECT. Doctors to document the length of time postictal suppression lasts, how long coma activity lasted, and how long muscle relaxants impaired breathing without ventilationPsychiatrists to be trained by neuropsychologists/neurologists about the effects of electrical field strengths and how to identify brain injuryECT clinics to use an evidence-based patient information leaflets that neither exaggerate efficacy, nor minimise or fail to mention adverse effects 6- and 12-month follow up assessments to be conducted for cognitive and other damage, and rehabilitation and compensation offered for any memory loss/brain damage identified. Clinics to inform patients, referrers, Trust managers and CQC, whether a clinic is accredited, and if not, why not. Clinics that	Thank you for your comment. The committee agreed that the safety procedures arou nd the administration of ECT needed updating, and agreed that the optimal way to do this was to advise that clinics providing ECT should be ECTAS-accredited and that this should be backed-up by board-level performance management. The committee agreed this would encompass the areas you have highlighted. The committee agreed that ECT should remain available as a treatment option and that it could be safe and effective if used in accordance with NICE recommendations.

						fail to meet Type 1 standards to be suspended until failures are rectified, or to be closedECTAS clinic reports to be made public, and easily accessible for patients and familiesSevere adverse effects, including deaths, to be reported to CQC and the MHRA	

686	SH	UK ECT Improving Standards campaign group	Guideline	49	General	We believe that in order to address the complexity of the issues, ECT should be a stand alone technology appraisal rather than a subsection of the Depression Guidelines. We also believe that in the ongoing absence of robust evidence about efficacy and safety, NICE should acknowledge that ECT should be placed in one of the three categories it identifies for such eventualities: 'Special Arrangements': 'The level of uncertainty about the efficacy or safety evidence is such that it is considered to be in the best interest of patients to recommend controlled investigation of the procedure under the scrutiny and protection of research ethics committees' 'Research Only': '……. the Committee recommends that the procedure should be carried out only in the context of formal research studies approved by a research ethics committee. This recommendation is normally made when at least 1 of the following is the case: the procedure is still considered to be experimental in nature; the level of uncertainty about the efficacy or safety evidence is such that it is considered to be in the best interest of patients to recommend controlled investigation of the procedure under the scrutiny and protection of research ethics committees; resolution of substantial uncertainties about its efficacy or safety would be fundamental to its routine use.' 'Do not use': 'When the evidence suggests that a	Thank you for your comment. The committee noted your suggestion that the ECT guidance should become a stand-alone technology appraisal, and also noted that this was how the initial review of ECT for depression was conducted in 2003. However, the incorporation of ECT into the NICE depression guideline in 2009, and then its updating again in 2022 has highlighted that there is very little new research being carried out in this area, and hence very little new evidence available for the committee to review. The committee discussed the possibility of removing the recommendations for ECT, as you suggest, but agreed that there was evidence of efficacy to justify its use in certain sub-groups of patients, and removing it as a therapeutic option may disadvantage some people with severe depression in whom it may be helpful. The committee agreed that ECT should remain available as a treatment option and that it could be safe and effective if used in accordance with NICE recommendations.

						procedure has no efficacy or poses unacceptable safety risks, the Committee recommends that it should not be used' https://www.nice.org.uk/process/pmg28/chapter/draft-recommendations Standard NICE processes, including a timeframe within which evidence should be produced, must then be set in place, and until then NICE should withdraw is recommendation of ECT as an NHS treatment until these serious failings have been remedied. Two other options available to NICE should be considered:Considering a second consultationIn exceptional circumstances, the CCP Director may consider the need for a further 4-week stakeholder consultation. This additional consultation may be required after the standard 6-week consultation has ended if either of the following criteria has been met:Information or data that would significantly alter the guideline has been omitted from the first draft.Evidence was misinterpreted in the first draft of the guideline and the amended interpretation significantly alters the guideline.Alternatively, we suggest the strategy employed with the recent guidelines on ME/CFS, in which a roundtable was convened 'to better understand the issues raised and determine how it can gain support for the guideline to ensure effective implementation' with the aid of 'an independent chair and…representatives from	

						patient organisations and charities, relevant professional societies and from NHS England and NHS Improvement, NICE and the guideline committee.'	

687	SH	UK ECT Improving Standards campaign group	Guideline	49	General	We are unclear whether ECTAS is now being proposed as part of the governance of ECT, despite ECTAS's statement that it does not have such a role. However, if this is the proposal, we note that the following criteria would need to be met: Carried out in a given time scale and reviewed and 100% achievedECTAS must redefine its aims and standards. It cannot be a body that ensures improvement. It must ensure at least the basics of NICE/ GMC/ Montgomery information for informed consent, validated testing designed by brain injury specialists and rehabilitation program designed by brain injury specialists.They must define a pathway for diagnosis and rehabilitation and support in the community.Have on its standards committee specialists trained in the bioscience of electrical injury and brain injury rehabilitation diagnostics specialists Commit to researching long-term consequences and rate of serious adverse effectsCollect data on injuries (prospective and retrospective) by a comprehensive review of patient notes. Identifying serious adverse events recognized by manufacturersFollow NICE requirements and report to the MHRA- must be regularly audited and reviewed.Core competencies- everyone in training must have a 3 month period attached to a neurorehabilitation ward. As part of ongoing professional training consultants must undergo	Thank you for your comment. The committee recognised that ECTAS is not a regulator of ECT services, but the committee agreed that advising ECTAS accreditation and board-level performance management can at least set a baseline standard for clinics administering ECT. The committee agreed that ECT should remain available as a treatment option and that it could be safe and effective if used in accordance with NICE recommendations.

						neurorehabilitation diagnosis and rehabilitation training.They must demonstrate a knowledge of the neurophysiology of ECT and delayed effects of electrical injury.They must develop defined and standardised protocols for stopping treatment.Injured patients must be assessed using a recognised quality of life disability questionnaireUpdate RCP ECT handbook to include manufacturing warnings, serious adverse effects, appropriate assessments, rehabilitation measures, delayed effects of electrical injury and ECT's neuropathology and histopathology information written by brain injury and electrical injury specialists. Must discuss patient adverse experiences, living with ECT brain damage and accessing appropriate assessments and rehabilitation.They must establish an external audit system comparable to the UK Spinal Registry. In which to get funding from CCG, ECT Clinics must submit data about long-term efficiency and injuries to an external ECT registry.No ECT clinics should receive funding unless they are participating members of the external ECT registry to ensure uniformity of care and improve standards through external governance.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

688	SH	UK ECT Improving Standards campaign group	Guideline	49	General	Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. Would implementation of any of the draft recommendations have significant cost implications? What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)In response to these questions, we assume that the possible steps we have outlined (placing ECT in a 'Special Arrangements/Research Only/Do not Use' category, and/or 'Considering a second consultation/Convening a round table discussion') would be supported and costed within NICE's usual procedures. We believe that a full and open commitment to establishing safe, appropriate and soundly evidence-based practice in this controversial area would do a great deal to re-establish the broken trust of many of our members, and help to ensure that future harms, both psychological and bodily, are avoided. We believe that NICE's commitment to equality must include equal treatment of patients. Following the IMMDS (Cumberlege) review into mesh, NICE commissioned an 'exceptional review' and has strengthened its guidance, including the of production of detailed guidance into the identification and treatment of patients injured by MESH. We believe that the same approach is	Thank you for your comment. The committee agreed that ECT should remain available as a treatment option and that it could be safe and effective if used in accordance with NICE recommendations.

						needed with regards to the injuries suffered by ECT recipients. We are grateful for the opportunity to comment on this Draft Guideline.	
689	SH	Healthwatch Bristol	Guideline	50	3	Section 1.13.3 'Discuss the use of ECT as a treatment option with depression, and reach a shared decision on its use based on their clinical needs and preferences, if they have capacity to give consent… Make sure valid, informed consent is given without pressure or coercion.'HealthWatch has received a number of comments indicating that coercion to have ECT treatment is happening: (Had ECT in 2018): I agreed to have ECT but was told if I didn't have it I would be forced as I was under section. I had already been traumatised by restrains, forced medications and periods in seclusion for 2 years up until this point. It's understandable I was scared. My parents were also	Thank you for your comment. The committee strengthened their recommendations on ECT to advise that informed consent should be obtained following a full discussion of the risks and benefits of ECT and that there should be no pressure or coercion. The committe also added the requirement that clinics providing ECT should be ECTAS-accredited and this should be subject to board-level performance management. The committee agreed that ECT should remain available as a treatment option and that it could be safe and effective if used in accordance with NICE recommendations..

						told if they didn't agree, my younger sister would be taken out of their care, despite no issues regarding their capability as parents. According to records I have kept (reports, minutes etc), the day prior to my mental capacity act assessment, the professionals involved in my care in hospital all decided I had no capacity to refuse treatment. Yet, the next day I was told I had capacity to decide, I believe this was because I agreed to undergo ECT. How could I have capacity and not at the same time? (Son had ECT in 2010). The psychiatrist categorically and adamantly stated that my son would be administered ECT. Other options were not explored and my son was forcefully subjected to several sessions of ECT.	
690	SH	British Psychological Society	Guideline	50	003-014	We support this recommendation to ensure informed consent for ECT if the patient is going to have it. However, as noted above, there are concerns as to whether true informed consent can be obtained if incorrect information is being supplied to patients.	Thank you for your comment. The committee added additional recommendations to advise that clinics providing ECT should be ECTAS-accredited as this accreditation requires a defined level of patient information to be provided as part of the consent process, which the committee hope will address this issue.
691	SH	Mind	Guideline	50	8	We agree with the recommendations on informed consent given without pressure or coercion. However, given the findings of audit (see comment 11) and the comments made in the 2003 TA, we think the guideline should make recommendations about how to assure this, or at least address this through implementation of the guideline.	Thank you for your comment. The committee added additional recommendations to advise that clinics providing ECT should be ECTAS-accredited as this accreditation requires a defined level of patient information to be provided as part of the consent process, and for

							the services provided to be audited, which the committee hope will address this issue.
692	SH	Mind	Guideline	50	24	We agree with the recommendation that clinics should be accredited by ECTAS, meet their standards and provide the required data. However, it is not appropriate for NICE to devolve prescribing advice to a voluntary quality improvement network (or any other body). There are gaps in these recommendations relating to clinical practice which need to be filled and which ECTAS should include in their standards (see comments below).	Thank you for your comment. The committee agreed that recommending ECTAS-accreditation can provide a baseline standard for clinics to reach but were aware that ECTAS does not have regulatory powers. The committee agreed that ECT should remain available as a treatment option and that it could be safe and effective if used in accordance with NICE recommendations.
693	SH	Mind	Guideline	50	24	There is a regulatory and data gap in relation to ECT that it is not ECTAS' role to fill. It is unacceptable that there is no national data collection about the use of such an invasive treatment and its outcomes and no clear regulatory role to oversee its use. We recommend that the relevant statutory and arms' length bodies consider how this gap can be effectively filled including ensuring that the MHRA and the yellow card scheme are used to address safety and effectiveness of treatment with ECT. It would be helpful to have a recommendation from NICE on what is required.	Thank you for your comment. The committee agreed that recommending ECTAS-accreditation can provide a baseline standard for clinics to reach but were aware that ECTAS does not have a regulatory role. The committee agreed that ECT should remain available as a treatment option and that it could be safe and effective if used in accordance with NICE recommendations.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

694	SH	Mind	Guideline	50	24	The guideline should make direct recommendations about safe dosage, frequency and duration of treatment, as in previous guidance, rather than only refer to ECTAS standards.	Thank you for your comment. The committee were aware that the ECTAS standards were developed with a wider range of ECT experts than were available on the guideline committee, and were updated on a regular basis, and therefore agreed that it was more appropriate to refer to these standards than create new recommendations.
695	SH	Mind	Guideline	50	24	The guideline should make direct recommendations about cognitive testing – the need for regular testing with appropriate, validated measures after each treatment and at follow-up.	Thank you for your comment. The committee were aware that detailed recommendations on cognitive testing were included in the ECTAS standards and therefore chose to recommend adherence to these rather than create new recommendations.
696	SH	Mind	Guideline	50	24	The guideline should include recommendations on how clinicians should respond to cognitive impairment.	Thank you for your comment. The committee were aware that detailed recommendations on cognitive testing were included in the ECTAS standards and therefore chose to recommend adherence to these rather than create new recommendations.

697	SH	Citizens Commission on Human Rights	Guideline	50	26	1.13.6 Line 26: The "ECT Accreditation Service (ECTAS) Standards for the administration of ECT" includes a chapter titled "Consent and information giving." It makes reference to the Royal College of Psychiatrists ECT Patient Information Leaflet as a provision for all patients regardless of their capacity to consent. The disclaimer in the leaflet states, "The content in this leaflet is provided for general information only. It is not intended to, and does not mount to advice which you should rely on. It is not in any way an alternative to specific advice. You must therefore obtain the relevant professional or specialist advice before taking, or refraining from, any action based on the information in this leaflet."The leaflet further states, "Rigorous scientific research has not found any evidence of physical brain damage to patients who have had ECT." Somatics, LLC's website and disclaimer specifically states: "In rare cases, patients may experience permanent memory loss or permanent brain damage." The Royal College of Psychiatrists leaflet is misleading and inaccurate.	Thank you for your comment. The committee noted your concerns about the ECTAS recommended patient information leaflet. The committee however agreed that ECT should remain available as a treatment option and that it could be safe and effective if used in accordance with NICE recommendations.

698	SH	UK ECT Improving Standards campaign group	Guideline	50	General	These subsections appear to be attempts to address the lack of standards for, or effective regulation of, the practice of ECT. However, welcome though this is, it will not be effective unless there is a body taking ultimate responsibility for ECT practice in all its aspects, whether administrative, clinical decision-making, training, or governance. This is an issue that we have pursued for some months without getting a satisfactory response. The role of the Care Quality Commission is, according to their website: 'We make sure health and social care services provide people with safe, effective, compassionate, high-quality care.' As the Committee will be aware, their duties include inspecting services and reporting on standards which must be met; protection from harmful treatment; ensuring informed consent; and ensuring effective governance. In an attempt to find out which body ultimately takes responsibility for the safe and effective practice of ECT, and has a duty to investigate breaches, the Shadow Minister for Mental Health, Dr Rosena Allin-Khan, asked two questions in Parliament on our behalf about who has overall responsibility for regulating electroconvulsive therapy; and what enforcement powers they have when breaches in guidance occurs:https://questions-statements.parliament.uk/written-questions/detail/2021-02-19/155287The reply	Thank you for your comment. The committee agree with your conclusions that the regulatory oversight of ECT is not clear: ECTAS-accreditation can set a baseline for good practice, and that is why the committee recommended board-level performance management of this. The committee agreed that ECT should remain available as a treatment option and that it could be safe and effective if used in accordance with NICE recommendations.

						from the Minister was: 'The Care Quality Commission (CQC) is responsible for assessing whether service providers are following the current standards and guidelines on electroconvulsive therapy (ECT), including those developed by the National Institute for Health and Care Excellence. If the CQC becomes aware of concerns about the use of ECT which may lead to potential regulatory breaches, the CQC may use its enforcement powers derived from the Health and Social Care Act 2008. The CQC's inspectors would review the risk and decide on the appropriate regulatory response, which may include enforcement action.'However, in practice this appears to be untrue. In response to our enquiries, Peter Wyman, Chairman of the CQC told us in a personal communication: 'ECT could be provided by a number of core services, but itself is not a core service in our structure. As such, we do not currently identify it as an aspect of services that must be checked on inspections, and about which data is routinely collated. As such, I am unable to provide the data you request: it could only be gathered through a manual trawl of all inspection reports. As these are published, it would be open to anyone to do this, but I would advise that the results are likely to be very limited.'The CQC also told us that 'CQC has no general investigatory power to address complaints (whether about	

						specific treatments or other matters.)' CQC does state that it has a role in relation to ECT given under the Mental Health Act, and told us: 'Whilst CQC has no general investigatory power to address complaints (whether about specific treatments or other matters), it does have a specific complaints remit to consider investigating the exercise of the powers or discharge of the duties under the Mental Health Act in respect of people made subject to those powers. That would include, for example, a complaint about the administration of ECT under the powers of the Mental Health Act.' On further enquiry by our group, this turns out to mean ensuring that the correct administrative procedures for getting a second opinion have been followed. Any other aspect – for example, the clinical appropriateness of the use of ECT, or the failure to adhere to NICE Guidelines – falls outside the CQC's remit.To summarise the situation in relation to the regulation of ECT:1 The ECTAS website states that 'ECTAS does not provide regulation of ECT'. 2 NICE has no powers to enforce the new Draft Guideline recommendation for clinics to be members of ECTAS.3 NICE guidelines are not legally binding and can be overridden by clinical judgement. 4 The CQC does not routinely inspect ECT clinics, since they do not count as a 'core service.' Moreover it has told us that in relation to ECT it has 'no general investigatory	

						power to address complaints, whether about specific treatments or other matters'. Thus, as several of our members have found, any concern raised by an individual can be designated as a 'complaint' and devolved back to the service itself, which is highly likely to dismiss it.5 In the rare instances that CQC does inspect an ECT clinic, they rely on data supplied by ECTAS itself. CQC uses the Health Quality Improvement Partnership (HQIP) to set criteria under which bodies are eligible to supply data to CQC's regulatory processes. These criteria include: 'The accreditation scheme is operated to ensure that the accreditation body and its assessors are impartial and independent of the service being accredited.' ECTAS does not, by this standard, qualify, since it is managed by the RCP's Centre for Quality Improvement. Impartiality is impossible given that it is RCP members who run ECT clinics, administer the treatment, and draw up ECTAS standards in the first place. Thus, at every stage of the regulatory process, doctors are 'marking their own homework.' Indeed, they are setting the homework in the first place, and defining the 'correct' answers. 6 CQC does not even take a view on the fact that clinics can be legally operating without being accredited by ECTAS and, therefore, potentially in breach of the most basic standards of safe and effective practice. Peter Wyman, CQC Chair, confirmed to us that	

						'services are not required, for example by NHS commissioning arrangement, to be part of ECTAS in order to provide the treatment'.7 The only area that CQC will admit to taking responsibility for, is the administrative process relating to treatment under the Mental Health Act. However, this does not include the quality of the clinical decision; as CQC told us: 'CQC does not have responsibility for, or power over, the independent medical opinions of SOADs appointed to review individual ECT treatment proposals. These doctors will be guided by their professional bodies and by NICE recommendations when making their decisions.'As noted above, ECTAS guidelines are not designed to address or overrule clinical decisions, although clinical decisions are expected to be in line with NICE guidelines; but NICE guidelines are not legally binding and can be overruled by clinical judgement; and however faulty or damaging such judgements are, there is no recourse to any higher authority, since complaints will simply be devolved back to the service which is alleged to be at fault. There is in theory the option of raising concerns with the relevant professional body, such as the GMC; the Minister for Mental Health told us: 'Professional regulators have a duty to investigate whether someone on their register is fit to practise if an allegation is made that they do not meet the required standards. Where necessary, the	

						regulator will take action to ensure public safety including restricting or removing a professionals' right to practise'. However, there appears to be no possible way in which a professional could be found at fault for the inappropriate use of ECT, since, as above, ECTAS standards do not address clinical decisions; NICE guidelines can be overruled by clinical judgement; and CQC defers to 'independent medical opinions…guided by their professional bodies'. The circle is thus complete. In practice, clinical decision-making in relation to ECT falls outside the regulatory remit of any service or body. Many of our members have spent years being passed from pillar to post, without finding any recognition or recourse even for harmful treatment that fell well outside NICE guidelines. This is exactly the same situation identified by the Cumberlege review, and the reason why we are calling for a similar review of ECT (the core themes in Cumberlege included 'No one is listening… We were never told… We do not know who to complain to' https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf).As they stand, these Draft Guidelines do nothing to change the situation in which ECT will continue to be in effect, unregulated; guidance will continues to be breached; damage will continue to be inflicted; and rehabilitation and redress for victims will continue	

						to be unavailable. We welcome the Developer's comments on the very serious failings in the regulatory processes, which we believe are totally unacceptable, and are at the heart of the many other concerns raised by and on behalf of harmed patients.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

699	SH	British Psychological Society	Guideline	51	003-005	Section 1.13.7While we welcome the recommendation that ECTAS standards should be monitored through board-level performance management (1.13.7), I do not think this goes nearly far enough in addressing the standards and governance of ECT practice. According to the ECTAS website, 'ECTAS is a voluntary network which uses a system of peer review …. ECTAS does not provide regulation of ECT'. I find it unacceptable that ECTAS standards remain voluntary, with 25% of ECT clinics currently unaccredited. The Care Quality Commission does not see ECT as a 'core service' and therefore does not routinely inspect them. CQC also states that it has no general investigatory power to address complaints about individual ECT treatment experiences or more general practice failures, except under a narrow range of circumstances where the Mental Health Act is involved. These draft guidelines do not address the very serious situation of a treatment option which is not regulated in any meaningful sense.	Thank you for your comment. The committee agree with your conclusions that the regulatory oversight of ECT is not clear: ECTAS-accreditation can set a baseline for good practice, and that is why the committee recommended board-level performance management of this. The committee agreed that ECT should remain available as a treatment option and that it could be safe and effective if used in accordance with NICE recommendations.
700	SH	Greater Manchester Mental Health Services	Guideline	51	6	Plateau of response is omitted as a criterion for stopping ECT	Thank you for your comment. The committee did not have any evidence on which to base a recommendation relating to a plateau of response for ECT so were unable to make this amendment.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

701	SH	Greater Manchester Mental Health Services	Guideline	51	10	IN Treatment Resistant Depression , continuation of same antidepressant molecules is associated with increased risk of relapse after response to acute course of ECT, few trials looking into this have not been reviewed , also the limitation in research evidence about trials with newer antidepressants has not been acknowledged.	Thank you for your comment. The committee included ECT as an intervention for the relapse prevention but did not identify any evidence relating to the use of antidepressants to prevent relapse after ECT. However, the committee will pass this to the NICE surveillance team who are responsible for ensuring guidelines are up to date to consider this for inclusion in a future update.
702	SH	Greater Manchester Mental Health Services	Guideline	51	15	rTMS , this is a missed opportunity to update the evidence base on rTMS and integrate the depression indication for the intervention. There has been plethora of research into effectiveness , refinement and increasing number of Trust are offering/considering offering the treatment ,moreover it has proliferated in independent sector so update is required.	Thank you for your comment. TMS was not included in the scope of this update as it was subject to a separate interventional procedure guideline, but the committee will pass this to the NICE surveillance team who are responsible for ensuring guidelines are up to date to consider this for inclusion in a future update.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

703	SH	LivaNova	Guideline	51	015 - 017	We would like to request that a hyperlinked reference to the Vagus Nerve Stimulation (VNS) Interventional Procedure Guidance (IPG 6791) be added as follows:“1.15 Vagus nerve stimulation for treatment-resistant depressionSee the NICE Interventional Procedure Guidance on Implanted vagus nerve stimulation for treatment-resistant depression”Rationale for request:Despite neither Transcranial magnetic stimulation (TMS) nor VNS for depression being included in the final scope2 or the evidence summary on chronic depression3, TMS was included in the draft guideline, but VNS was not.Our proposed wording is aligned with the draft wording for Transcranial magnetic stimulation (TMS) for depression.As NICE pathways (which currently include VNS4) are no longer being updated and will be removed in “spring 2022”5, it is important that VNS is included in the final guideline.References:Implanted vagus nerve stimulation for treatment-resistant depression (nice.org.uk)https://www.nice.org.uk/guidance/gid-cgwave0725/documents/final-scope Depression evidence review E (nice.org.uk)Step 4: Complex and severe depression in adults - NICE PathwaysWe are withdrawing our NICE Pathways service | NICE Pathways | Our programmes | What we do | About | NICE	Thank you for your comment. A link to the NICE interventional procedure guidance on VNS has now been included.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

704	SH	Janssen	Guideline	51	015-017	We would suggest that this recommendation should follow on from Section 1.9 Further line treatment for the same reason we gave in comment 12 for ECT. We also note that further detail is provided on the provision of ECT than on the provision of transcranial magnetic stimulation (TMS) in the guideline. We suggest further consideration of additional recommendations reflective of the recommendations for ECT in section 1.13, given that TMS is not without risk or safety concerns. There is also relatively limited scientific evidence based for TMS efficacy compared to other treatment options. The link to the NICE Interventional Procedure Guidance on Repetitive Transcranial Magnetic Stimulation for Depression does not provide the same level as detail as has been provided for other treatment options in the guideline e.g ECT, lithium and antipsychotics and therefore a consistent amount of detail should be considered.	Thank you for your comment.The committee discussed if the ECT recommendations would fit better at the end of the section on further-line treatment but agreed that as ECT may be used for some people earlier in the treatment pathway, it should remain as a stand-alone section of the guideline. The same consideration applies to the recommendations for TMS. TMS was not included in the scope of this update and so the committee were not able to make detailed recommendations on its use in line with those for ECT, lithium and antipsychotics.
705	SH	Voyage Care	Guideline	51	26	1.15.2 We feel Green Care should be added based on the positive impact reported by people with mental health problems who access nature including parks, the coast and wildlife.	Thank you for your comment. Nature-based interventions were not specified in any of the review protocols and thus specific benefits of these interventions as a treatment for depression have not been sought or reviewed. However, in response to stakeholder comments, the committee supported less intense 'move more' exercise for general wellbeing (although not as a treatment for depression) and made a

							new recommendation to reflect this. The recommendation also emphasised the benefits of outdoors activities.
706	SH	Institute of Health Visiting	Guideline	51	General	To include consideration of the care, safety and needs of any dependent children (including unborn babies)	Thank you for your comment. The committee agreed that the safeguarding issues relating to children of people with depression, or any mental health condition, would always be very important but this is covered in professional and statutory guidance and therefore is not restated in all NICE guidelines. Women with antenatal or postnatal depression were not included in the scope of this guideline and the committee agreed that treatment in these women would always need an individualised approach and the level of detail you suggest would not be appropriate to include in this guideline. However, a link to the NICE guideline on antenatal and postnatal mental health has been included in the section of the guideline on the delivery of treatments, to remind healthcare professionals to consider the care of these women separately.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

707	SH	Royal College of General Practitioners	Guideline	53	1	Rather than GP and practice nurse, can we request that the wording is changed to “primary care health care professional”. Increasingly, non GP members of the team are prescribing for patients in primary care and it is essential that the whole team is recognised in national clinical guidance.	Thank you for your comment. The wording has been changed to 'primary care healthcare professional' as you suggest
708	SH	Janssen	Guideline	53	001-011	We are supportive of further integrated services in mental health as outlined in section 1.15.3, especially for greater access and provision of mental health services in primary care. This increases the awareness and capacity of appropriate referral into secondary care from a primary care setting.	Thank you for your comment and support for this recommendation.
709	SH	British Psychological Society	Guideline	53	20	Rec 1.15.5 It is welcomed that the guidelines say:Commissioners and providers of mental health services should ensure pathways have the following in place for people with depression to promote access and increased uptake of services:services delivered in culturally appropriate or culturally adapted language and formats and, on the following page (54, line 2):procedures to support active involvement of families, partners and carers. Please list these points closer together, and integrate them, since one way of delivering psychological therapy in a culturally appropriate format is to actively involve families, partners and carers. For some groups this is a central way of facilitating their access to services. We request that behavioural couples therapy is also mentioned	Thank you for your comment. By linking these 2 sentences together, the recommendation implies that involvement of family and carers is only appropriate for culturally adapted services, whereas it may be appropriate for a wide variety of people, so they have been left as separate recommendations. Behavioural couples therapy is a specific intervention which is covered by separate recommendations elsewhere in the guideline, so that has not been added to these general access recommendations.

						here as one option. Suggested wording: Commissioners and providers of mental health services should ensure pathways have the following in place for people with depression to promote access and increased uptake of services:services delivered in culturally appropriate or culturally adapted language and formats. This may include procedures to support active involvement of families, partners and carers. Behavioural couples therapy may be a useful option to actively involve partners.	
710	SH	Tavistock Relationships	Guideline	53	20	Rec 1.15.5 It is welcomed that the guidelines say:Commissioners and providers of mental health services should ensure pathways have the following in place for people with depression to promote access and increased uptake of services:services delivered in culturally appropriate or culturally adapted language and formats and, on the following page (54, line 2), procedures to support active involvement of families, partners and carers. Please can these points be integrated since one way of delivering psychological therapy in a culturally appropriate format is to actively involve families, partners and carers? For some groups this is a central way of facilitating their access to services. We request that behavioural couples therapy is also mentioned here as one	Thank you for your comment. By linking these 2 sentences together, the recommendation implies that involvement of family and carers is only appropriate for culturally adapted services, whereas it may be appropriate for a wide variety of people, so they have been left as separate recommendations. Behavioural couples therapy is a specific intervention which is covered by separate recommendations elsewhere in the guideline, so that has not been added to these general access recommendations.

						option. Suggested wording: Commissioners and providers of mental health services should ensure pathways have the following in place for people with depression to promote access and increased uptake of services:services delivered in culturally appropriate or culturally adapted language and formats. This may include procedures to support active involvement of families, partners and carers. Behavioural couples therapy may be a useful option to actively involve partners.	

711	SH	Wellmind Health	Guideline	53	22	Rec 1.15.5 The inclusion of digital therapeutic (DTx) courses in treatment options would contribute to ensuring that pathways have services available outside normal working hours.	Thank you for your comment. The guideline recommends that people with depression are offered a choice about how all interventions will be delivered including options of face-to-face or remote delivery, and computerised CBT is included under self-help or self-help with support treatment options. However, the committee also discussed the importance of patient choice and problems associated with digital exclusion or digital poverty: some people may prefer a face-to-face intervention either because they are not comfortable using technology, because they lack the appropriate device or internet connection, lack a private and confidential space, or because of wider issues associated with difficulties in accessing services. The committee therefore recommended interventions be available via a range of different methods, and the methods of delivery should be guided by patient choice. The committee were aware that the digital therapeutic tool you are referring to (Be Mindful) has been evaluated by NICE as part of the digital therapies it assessed for inclusion in the IAPT programme, and has not been recommended for further practice evaluation, so the committee did not refer to it in the guideline.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

712	SH	Wellmind Health	Guideline	53	23	Rec 1.15.5 The inclusion of digital therapeutic (DTx) courses in treatment options would increase both the range of different methods to engage with and the delivery of treatments in addition to face-to-face meetings.	Thank you for your comment. The guideline recommends that people with depression are offered a choice about how all interventions will be delivered including options of face-to-face or remote delivery, and computerised CBT is included under self-help or self-help with support treatment options. However, the committee also discussed the importance of patient choice and problems associated with digital exclusion or digital poverty: some people may prefer a face-to-face intervention either because they are not comfortable using technology, because they lack the appropriate device or internet connection, lack a private and confidential space, or because of wider issues associated with difficulties in accessing services. The committee therefore recommended interventions be available via a range of different methods, and the methods of delivery should be guided by patient choice.
713	SH	Voyage Care	Guideline	53	27	1.15.5 We feel supported living should be specifically mentioned given the increase in demand for supported living services. The challenge is an increased risk of loneliness due to care packages in supported living can be limited to 30 minutes per day.	Thank you for your comment. The committee did not identify any evidence relating to the use supported living services to increase access to treatment for depression so this has not been added to the recommendation.

714	SH	Independent Age	Guideline	54	4	Rec 1.15.6 - We strongly welcome the specific inclusion of older people here. And would also make the point that there will be older people within these other groups who have difficulty accessing services such as older LGBT+ and older Black or Asian people. There are persistent issues with inequality of access to mental health treatment for people in later life. Older people have a low rate of access to talking therapies through the NHS in England (IAPT services). This is despite sustained evidence that older people have higher than average recovery rates. Analysis by the Department of Health in 2011 suggested that, based on demographics and the prevalence of common mental health problems among older people, people aged 65+ should make up an 'expected rate' of 12% of IAPT clients in England. However, despite welcome efforts to increase the number of older people accessing IAPT, the data consistently shows markedly lower levels of uptake. This is despite our ageing population which might mean we expect older people to make up more than 12% of clients in 2022. The most recent annual figures for the IAPT programme (covering 2020-21) show that people aged 65+ made up just 5% of referrals. Referral rates for people aged 80+ are particularly low. We recommend that the guidance signposts to further information about older people's access to mental health support. In	Thank you for your comment and for the information relating to lower than expected referral rates of older people to IAPT services. The committee identified older people as a group who may have difficulty accessing services but there was limited evidence on which to base recommendations to improve access for this age group, and the methods that were identified are included in these recommendations. It is not usual to refer from NICE guidelines to other non-NICE documents so although the committee agreed the IAPT guide was useful they were not able to refer to it directly.

						particular we recommend signposting to the 2021 refresh of the IAPT Older People's Positive Practice Guide[vi], a summary of which is also available in version 5 of the IAPT Manual.	
715	SH	We Are With You	Guideline	54	4	Reference to stigma could be helpfully included earlier in the guidance as it continues to be a significant barrier to treatment access and should be considered at the earliest point of contact. ****People who use drugs and alcohol continue to face stigma and should be included in the list of people who face difficulty in accessing help for mental health	Thank you for your comment. Stigma is mentioned in the first recommendation in the guideline, and some examples about how it can be overcome have now been included. The list of groups who may face difficulty in accessing services is not exhaustive and so the committee agreed not to add those who use drugs and alcohol to this list.
716	SH	British Psychological Society	Guideline	54	004-019	We support the recommendations on access.	Thank you for your comment and support for these recommendations.

717	SH	Voyage Care	Guideline	54	7	1.15.6 We feel people with a diagnosis of personality disorder can experience stigma when trying to access services and can be at risk of being excluded.	Thank you for your comment. The list of groups who may face difficulty in accessing services is not exhaustive and as there is a separate section of the guideline for people with depression and coexisting personality disorder, which now includes a recommendation to not withhold treatment for depression, the committee did not agree to add a recommendation here too.
718	SH	British Psychological Society	Guideline	54	10	Rec 1.15.6 People from Black, Asian and minority ethnic communities may particularly welcome being able to attend with their partners and we request that behavioural couples therapy is mentioned here as one option for addressing their needs.	Thank you for your comment. It is already recommended in this section that commissioners and providers of mental health services should promote access, and increased uptake and retention, by ensuring that pathways have in place: services delivered in culturally appropriate or culturally adapted language and formats; and procedures to support active involvement of families, partners and carers (if agreed by the person with depression). There are also recommendations in the choice of treatment section of the guideline that people with depression should be given the option to include family members or carers in the discussion of treatment options, and to attend (some or all of) treatment with a family member or friend. Behavioural couples therapy is a specific intervention which is covered by separate

							recommendations elsewhere in the guideline, so that has not been added to these general access recommendations.
719	SH	Tavistock Relationships	Guideline	54	10	Rec 1.15.6 People from Black, Asian and minority ethnic communities may particularly welcome being able to attend with their partners and we request that behavioural couples therapy is mentioned here as one option for addressing their needs.	Thank you for your comment. It is already recommended in this section that commissioners and providers of mental health services should promote access, and increased uptake and retention, by ensuring that pathways have in place: services delivered in culturally appropriate or culturally adapted language and formats; and procedures to support active involvement of families, partners and carers (if agreed by the person with depression). There are also recommendations in the choice of treatment section of the guideline that people with depression should be given the option to include family members or carers in the discussion of treatment options, and to attend (some or all of) treatment with a family member or friend. Behavioural couples therapy is a specific intervention which is covered by separate recommendations elsewhere in the guideline, so that has not been added to these general access recommendations.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

720	SH	The Mindfulness Initiative	Guideline	54	19	Although we recognise that this is a non-exhaustive list, we recommend adding:people who are homelesspeople who are from a lower socio-economic background or those with low social support[53]women[54]people managing long-term health conditions.This is particularly in line with your request to highlight any issues relating to COVID-19 that NICE should take into account when finalising the guidelines.	Thank you for your comment. The list of groups who may face difficulty in accessing services has been amended to include pregnant women (the committee were not aware otherwise that women face particular access issues), and those who are homeless. The committee agreed that as this is not an exhaustive list to include the other groups you suggest.
721	SH	Institute of Health Visiting	Guideline	54	General	Add parents/adults in perinatal period (pregnancy is a protected characteristic)	Thank you for your comment. There are a number of protected characteristics, but the committee were not aware that people in the perinatal period had specific needs relating to access and so have not added them to this list.
722	SH	British Psychological Society	Guideline	55	001-011	We support the recommendations about collaborative care and suggest this should include working with agencies that support people with environmental and social factors such as unemployment, discrimination,Y debt, domestic violence, exploitative employment practices, and other exploitative relationships.	Thank you for your comment. The committee has added that other agencies may also need to be involved in collaborative care.
723	SH	Royal College of Speech and Language Therapists'	Guideline	58	1	People with acquired cognitive impairments often have quite complex communication challenges, The RCSLT recommend that this is added to the Guideline.	Thank you for your comment. Communication has been added to the list of potential difficulties experienced by people with acquired cognitive impairments.
724	SH	Oxford Health NHS Foundation Trust	Guideline	59	26	The document refers to the term stepped care, but it is unclear how it is used as the tables do not support a stepped care model in terms of intensiveness of treatment. One section says	Thank you for your comment. The guideline section on treatment has been revised to clarify that stepped care principles should be utilised

						stepped care has been reviewed but then 1.15 still refers to a stepped care system.	when discussing choice of treatments with people with depression.
725	SH	Psychological Professions Network	Guideline	59	26	The guideline refers to stepped care, but the tables effectively abandon its use. This is out of line with the strong evidence from IAPT services that stepped care can deliver highly effective outcomes in practice. We would like to see the requirement to implement stepped care reinstated	Thank you for your comment. The guideline section on treatment has been revised to clarify that stepped care principles should be utilised when discussing choice of treatments with people with depression.
726	Individual	Individual 7	Guideline	60	8	There is a pressing need for more research into the efficacy of treatments in treatment-resistant depression.	Thank you for your comment. The committee did make a research recommendation on this topic: 'What are the relative benefits and harms of further-line psychological, psychosocial, pharmacological and physical treatments (alone or in combination), for adults with depression showing an inadequate response to an initial psychological treatment for the current episode? This research recommendation is listed in the guideline and further details are provided in appendix L of evidence review D.
727	SH	British Psychological Society	Guideline	60	012-015	We suggest a recommendation for research into what happens after someone has accessed appropriate services to address any social and environmental factors.	Thank you for your comment. The scope of this guideline update did not include specific interventions to address social and environmental factors in people who had accessed treatment, so the committee did not search for evidence on this topic. As a result, it is not possible to determine if there is a lack of evidence in this area, and so the committee did

							not make a research recommendation on this topic.
728	SH	Independent Age	Guideline	61	6	Rec 4 - We strongly welcome this research recommendation. Our Minds that matter report found that some people in later life find the combination of medication and talking therapy to be effective in treating or managing depression. Research on the effectiveness of these treatments for people aged 75+ specifically would be very welcome, as would research on other interventions such as social prescribing or sleep/diet interventions. Older people are not a homogenous group, despite regularly being grouped as aged 65+. This makes it challenging to explore age breakdowns beyond 65+, potentially masking differences across later life. We recommend that any research into treatment of chronic depression in those aged over 75 years includes a focus on subgroups of older people. This should include age breakdowns beyond 75+ (e.g. 65-74 vs 75-84, 85-90 etc.) and consideration of health inequalities among older people, including multiple inequalities such as income level, ethnicity, sex, disability and multimorbidity.	Thank you for your comment and support of this research recommendation. We have added the suggested sub-groups you suggest into the research recommendation modified PICO table in appendix L of evidence review E.

729	SH	The Mindfulness Initiative	Guideline	61	10	As well as looking at the most effective and cost-effective methods to promote increase assess to, and uptake of, treatments for people with depression who are under-served and under-represented in current services, we recommend further research is needed to understand:the barriers to accessing treatment for the different groups of people who are under-served[55] and under-represented, whether and what impact offering alternative treatments to anti-depressants and increasing person-centred treatment has on individuals who are under-represented or under-served in current services, andin relation to mindfulness, what models of mindfulness-based interventions are the most effective for underrepresented communities who have the highest risks of depression.	Thank you for your comment. The qualitative evidence review conducted on the barriers and facilitators to choice ('What are the facilitators and barriers that can enhance or inhibit choice of treatment for adults with depression? ') also identified a great deal of evidence on barriers to accessing treatment so the committee did not prioritise this area for further research. The committee did make a research recommendation about improving access to under-represented individuals: 'What are the most effective and cost-effective methods to promote increased access to, and uptake of, treatments for people with depression who are under-served and under-represented in current services?' This research recommendation is listed in the guideline and further details are provided in appendix L of evidence review H. This would include any methods to increase access, so if evidence on adapted models of mindfulness is available it would be captured by this research.
730	SH	Independent Age	Guideline	61	10	Rec 5 - We strongly welcome this research recommendation. We recommend that the research includes a focus on older people's access to appropriate mental health support and treatment, and the key barriers to these, both in terms of service design/accessibility/promotion and older people's attitudes/awareness/practical	Thank you for your comment. More details on this research rec are included in appendix L of evidence review H which explains that this includes older people (as well as other minority or under-represented groups).

						needs. The rate of access to NHSE's IAPT talking therapy programme for older people has remained consistently low for the past 10 years. As far as possible, research should look at the different experiences and challenges for subgroups of older people in relation to factors like age, ethnicity, sex and disability.	
731	SH	British Psychological Society	Guideline	61	010-013	This should include a recommendation to address the question of what is an adequate volume of service provision since provision level and access are closely related and current research evidence shows that capacity is insufficient.	Thank you for your comment. The committee did not search for evidence on adequate levels of service provision and its impact on access as part of their review on access. As a result, it is not possible to determine if there is a lack of evidence in this area, and so the committee did not make a research recommendation on this topic.
732	SH	Department for Environment, Food & Rural Affairs	Guideline	62	1	More research on how to use green social prescribing to treat depression would ensure the maximum benefits of this type of intervention can be gained. We would like to suggest this is therefore included as an additional 'other recommendation for research'.	Thank you for your comment. The committee did not search for evidence on green social prescribing as part of the scope for this guideline update. As a result, it is not possible to determine if there is a lack of evidence in this area, and so the committee did not make a research recommendation on this topic.
733	SH	Independent Age	Guideline	62	3	We welcome this recommendation. Such research should include a specific focus on the effectiveness of peer support among older people. Findings could inform the service offer of organisations like Independent Age.	Thank you for your comment. Subgroup analysis by age has been added to the modified PICO table for this research recommendation in appendix L of evidence review B.

734	SH	The Mindfulness Initiative	Guideline	62	8	As well as peer support, mindfulness has the benefit of being a non-stigmatising treatment option, that is used by individuals for non-clinical as well as clinical reasons. It can therefore play a key role in helping those with sub-clinical thresholds of depression, and in prevention more widely. Because mindfulness is not just seen as a therapeutic intervention, it has the scope to do this at a population level.We suggest therefore that the following research questions are added here:'Are community-based models of mindfulness an effective and cost-effective treatment in improving outcomes, including symptoms, personal functioning and quality of life in adults as a stand-alone treatment in people with less severe depression, or as an adjunct to other evidence-based treatments?'.'Are there group mindfulness interventions that reduce the chance of people with sub-threshold symptoms of depression going on to develop a first episode of clinical depression?'	Thank you for your comment. The committee made a research recommendation on peer support as very little evidence was found on peer support in the evidence reviews conducted for the guideline. In contrast, evidence was found for the use of mindfulness and it has been included as a recommended intervention, so the committee did not prioritise this area for further research.
735	SH	The Mindfulness Initiative	Guideline	62	General	In order to establish whether or not the treatment options being offered to people are effective, long-term data is needed. We recommend adding a research question looking at the long-term effects of an individual accessing each of the psychological and psychosocial interventions listed within the guidelines. In particular we note that the Public Health England 2019 review on dependence and	Thank you for your comment. Long-term evidence was included in the evidence reviews for this guideline update, and as utilised by the committee where available, and so long-term treatment was not prioritised by the committee as an area for further research.

						withdrawal associated with some prescribed medicine[56] found that nearly 1 million people had been taking them for at least three years, suggesting those with mild-to-moderate depression may have become dependent.	
736	SH	The Mindfulness Initiative	Guideline	63	1	There is limited evidence on the effectiveness of mindfulness-based interventions for the treatment of chronic depression – not because it isn't effective, but because there are not many studies. We recommend this as an area for research.	Thank you for your comment. The committee identified some evidence for mindfulness for chronic depression and so did not prioritise this as an area for further research.
737	SH	British Psychological Society	Guideline	63	005-007	We support the suggestion for research on social determinants of chronic depression and what can help.	Thank you for your comment and support of this recommendation.
738	SH	British Psychological Society	Guideline	63	015-018	The statement about the research finding that both healthcare professionals and people with depression would like time for meaningful discussion and to build trusting relationships for collaborative decision-making suggests a concerning issue in mental health services as currently constituted. Meaningful conversations and continuity of care should be routine and the absence of these is not only iatrogenic but causes waste. We suggest a recommendation for research on what enables such conversations to happen.	Thank you for your comment. The evidence showed that people value time for discussion and to build relationships but identified this as a positive experience for many people and not that this was always lacking, so the committee did not prioritise this for a research recommendation.

739	SH	British Psychological Society	Guideline	65	011-016	We note the admission here that the recommendation of lithium for depression was made based on “informal consensus” rather than evidence. We are concerned that NICE recommendation of this medication for depression has the potential to contribute to iatrogenic harm. Instead of recommending its use, NICE should be promoting great caution, further research, and the utmost effort to find or create more access to psychological and social therapies.	Thank you for your comment. This section of the guideline covers the practical aspects of prescribing, monitoring and stopping lithium. The practical advice contained in this section of the guideline is based on the committee's experience and the BNF, as this sort of practical information would not be identified in an evidence review. More detail on the indications for lithium are included in the later sections of the guideline on treatment for different types and severity of depression and there is no suggestion it should be prescribed without considering patient choice or in preference to psychological and social therapies where these would be more appropriate
740	SH	British Psychological Society	Guideline	65	021-027	We note the admission here that the recommendation of antipsychotics for depression was made based on “informal consensus” rather than evidence. We are concerned that NICE recommendation of these medications for depression has the potential to contribute to iatrogenic harm. Instead of recommending their use, NICE should be promoting great caution, further research, and the utmost effort to find or create more access to psychological and social therapies.	Thank you for your comment. This section of the guideline covers the practical aspects of prescribing, monitoring and stopping antipsychotics. More detail on the indications for antipsychotics are included in the later sections of the guideline on treatment for different types and severity of depression (which is based on evidence reviews) and there is no suggestion they should be prescribed in preference to psychological and social therapies where these would be more appropriate. The practical advice contained in this section of the guideline is based on the committee's experience, the BNF, and the NICE guideline on psychosis and schizophrenia,

							as this sort of practical information would not be identified in an evidence review.
741	SH	Oxford Health NHS Foundation Trust	Guideline	66	11	It is not clear where and how information on IAPT services was used as the descriptions of interventions given here do not match service delivery in the NHS.	Thank you for your comment. The recommended resource use was based on relevant information reported in the RCTs that informed the guideline NMA and economic analysis of treatments for a new episode of depression, supplemented by the committee's clinical experience on optimal delivery of interventions within the NHS. This information has now been added in Evidence review B, under Appendix N. However, the frequency and duration of sessions of psychological therapies has now been removed from the recommendations, to allow more flexibility in the delivery of interventions. In addition and in response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have

							been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice.

742	SH	Psychological Professions Network	Guideline	66	11	We suspect that the cost-effectiveness calculations have significantly under-estimated the cost-effectiveness of self-help with support, particularly by overlooking the high volume of IAPT service data that can inform this	Thank you for your comment. The committee drew on their knowledge of the IAPT dataset to inform recommendations and to re-structure treatment recommendations in response to stakeholder comments. To make decisions about the relative effectiveness of interventions, which informed the cost-effectiveness analysis, RCTs were prioritised in line with the NICE guidelines manual. To inform the guideline economic analysis, other epidemiological data were obtained from published longitudinal studies, as appropriate. Intervention resource use was obtained from the RCTs that informed the guideline NMA and the economic analysis, supplemented by the committee's expert opinion to reflect optimal routine practice in the UK. Other healthcare resource use associated with the management of depression was derived from a large cohort UK study. National UK unit costs were used. Therefore, the committee were confident that the guideline economic analysis used best quality and appropriate type of data for every model input parameter. It needs to be noted that in January 2020 NICE published a statement of intent signalling the ambition for the future use of wider sources of data and analytic methods (including sources commonly referred to as real-world data and evidence). To make decisions about the relative effectiveness

							of interventions, RCTs will continue to be prioritised in line with the NICE guidelines manual, in order to ensure that the populations treated with various interventions are equivalent. However it is possible that in the future, high-quality real-world datasets such as the IAPT dataset, could inform questions about access and engagement.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

743	SH	University of Nottingham	Guideline	66	24	"There was some evidence that counselling and STPP may be effective…" The term 'counselling' used here may cause confusion as there are many different forms of treatment which are referred to as counselling. The specific treatment referred to here is more often referred to in the research literature as "Counselling for Depression (CfD)" as for example in the treatment manual and competence framework cited elsewhere in the draft guideline (p013). The most precise and up to date label for the treatment is "Person-Centred Experiential Counselling for Depression" (PCE-CfD). It would aid clarity to refer to this treatment as PCE-CfD throughout the guideline. Use of the acronym PCE-CfD instead of "counselling" would more clearly distinguish this treatment from other psychological treatments.	Thank you for your comment. All the evidence for counselling that was included in the review for the treatment of a new episode of depression was non-directive counselling, and the committee therefore did not consider it appropriate to recommend specific interventions (for example, Counselling for Depression/Person-Centred Experiential Therapy [PCET]) as the evidence was not reviewed for these interventions. However, based on informal consensus, the committee agreed that counselling should use an empirically validated protocol developed specifically for depression and this was included in the recommendation.
744	SH	University of Nottingham	Guideline	68	9	"There was some evidence for the effectiveness of counselling and…" The term 'counselling' used here may cause confusion as there are many different forms of treatment which are referred to as counselling. The specific treatment referred to here is more often referred to in the research literature as "Counselling for Depression (CfD)" as for example in the treatment manual and competence framework cited elsewhere in the draft guideline (p013). The most precise and up to date label for the treatment is "Person-Centred Experiential Counselling for Depression" (PCE-CfD).	Thank you for your comment. All the evidence for counselling that was included in the review for the treatment of a new episode of depression was non-directive counselling, and the committee therefore did not consider it appropriate to recommend specific interventions (for example, Counselling for Depression/Person-Centred Experiential Therapy [PCET]) as the evidence was not reviewed for these interventions. However, based on informal consensus, the committee agreed that counselling should use an empirically validated

						It would aid clarity to refer to this treatment as PCE-CfD throughout the guideline. Use of the acronym PCE-CfD instead of “counselling” would more clearly distinguish this treatment from other psychological treatments.	protocol developed specifically for depression and this was included in the recommendation.

745	SH	University of Nottingham	Guideline	68	9	Overlooked the 2021 RCT showing equivalence between PCE and CBT (Lancet Psychiatry, 2021, Jun;8(6):487-499) also ignoring the MDS outcomes (Pybis et al. BMC Psychiatry (2017) 17:215), showing equivalence.	Thank you for your comment. The committee were aware of the Barkham et al. (2021) study, however, this study was published after the cut-off date for inclusion in the evidence review for this guideline, and did not meet the inclusion criteria according to the protocol (58% of the participants in this study were already receiving antidepressant medication and as such the study would not have met the protocol criteria for first-line treatment of a new episode of depression). Nevertheless, the committee considered this to be an important publication. The study concluded that counselling for depression (in this study called 'person-centred experiential therapy', PCET) is non-inferior to CBT at 6 months, but that PCET is inferior to CBT at 12 months. The committee discussed that the PCET used in this study was not the same as non-directive counselling (all the evidence for counselling that was included in the review for the treatment of a new episode of depression was non-directive counselling) and therefore this study does not provide evidence for the effectiveness of the type of counselling included in the evidence review. However, the committee considered that this study showed that PCET or counselling for depression may be effective, at least in the shorter term, but that CBT may be more beneficial in the longer term and therefore

							should usually be offered to patients as a preferred option. The committee therefore considered the findings of this study to be consistent with the recommendations made. The Pybis et al. (2017) study was not assessed for eligibility as it did not meet study design inclusion criteria, as outlined in the review protocol.

746	SH	EFT International	Guideline	68	015-019	Acupuncture and Acupoint Stimulation (eg by tapping with fingertips, as used in the Combined Somatic and Cognitive Therapy, Emotional Freedom Techniques (EFT)The committee are making a research recommendation on the use of acupuncture. In view of the evidence and comments below, we believe a research recommendation for EFT Tapping (which is extensively used in the western world) is also warranted.Although such studies do exist, within the evidence reviews no studies have been reviewed that show that either acupuncture by itself, or the form of "psychological acupuncture" sometimes referred to as Combined Somatic and Cognitive Therapy, or Emotional Freedom Techniques (EFT) may be effective for either mild to moderate or severe depression.There is evidence that acupuncture has shown significant effect sizes through imaging techniques.fMRI Imaging studies showed that the stimulation of certain points with needles reliably produced prominent decreases of activity in the amygdala, hippocampus and other subcortical areas. These areas of the brain are primarily associated with emotional responses and memory.Hui, K.K. et al, (2000) Acupuncture Modulates the Activity of the Limbic System and Subcortical Gray Structures of the Human Brain: Evidence from fMRI Studies in Normal Subjects. Human Brain Mapping	Thank you for your comment. The committee did not consider emotional freedom technique (EFT) to be an intervention that was in regular clinical use for the treatment of depression. Therefore these interventions were not specified in any of the review protocols and consequently the studies that you cite would not have met the inclusion criteria for the reviews. As such the evidence on emotional freedom technique (EFT) has not been appraised and the committee were not able to make any recommendations for the use of EFT. The number of research recommendations that the committee can develop is limited and unfortunately EFT was not prioritised for a research recommendation.

						2000;9(1):13-25 It may therefore be postulated that stimulation of certain acupuncture points, known as acupoints, would affect emotional responses. There are many studies that show this to be true of self-stimulation through tapping on these points. Nelms, J. and Castel, D.(2016) "A systematic review and meta-analysis of randomized and non-randomized trials of emotional freedom techniques (EFT) for the treatment of depression." Explore: The Journal of Science and Healing 12 (2016): 416-426. doi:10.1016/j.explore.2016.08.001. There is evidence through imaging studies that the amygdala and hippocampus will be deactivated through acupuncture. The following study showed extensive deactivation of the limbic-paralimbic-neocortical system. Fang, J. et al (2009) the Salient Characteristics of the Central Effects of Acupuncture Needling: Limbic-Paralimbic-Neocortical network modulationThere is evidence that the actual penetration of needles is not necessary for significant changes to take place. A double blind evaluation of penetrating versus non penetrating needles showed that there was no difference between the analgesic effects of the 2 conditions. Takacura, N. Yajima, H (2009) Analgesic effect of acupuncture needle penetration: A double blind crossover study. Open Medicine 2009 3(2): 54-61This indicates that acupuncture can be	

						effective with no needles involved. This is far more acceptable to patients presenting with psychological symptoms.Obviously, acupuncture itself cannot be self- administered. However, EFT can be easily taught and self- administered. Patients can then use it as an effective stress management technique, so that further presentations into mental health services can be avoided.EFT is used by some clinicians in the NHS, but whether patients are less likely to re-present into mental health after EFT has never been studied and should be considered as a research study.There is evidence that a form of psychological acupuncture, where acupuncture needles are substituted with a process that involves tapping with the fingertips on specific acupuncture points can be effective to reduce depression symptoms.Feinstein,D. (2012) Acupoint Stimulation in treating Psychological Disorders: Evidence of Efficacy. Review of General psychology doi:10.1037/a002802 This study explored18 RCTs, they all showed significant effect sizes.	

747	Individual	Individual 10	Guideline	69	15	This section of the guideline refers to 'some very limited evidence for the effectiveness of behavioural couples therapy for people with depression and who had problems in their relationship'. It is certainly the case that evaluating the efficacy and effectiveness of couple-based interventions for depression is fraught with methodological complications. However, there are some studies that should be taken into account in addition to the sole study that was considered in the development of these guidelines, such as:Baucom, D., Fischer, M., Worrell, M., Corrie, S., Belus, J., Molyva, E. and Boeding, S. (2018) Couple-based intervention for depression: an effectiveness study in the national health service in England. Family Process, 57: 275–92.Bodenman, G. et al. (2008). Effects of coping-oriented couple therapy on depression: a randomised controlled trial. Journal of Consulting and Clinical Psychology, 76, 944-954.Furthermore, couple-based interventions for depression are also effective for people who are in a non-distressed relationship (see Barbato, A. & D'Avanzo, B. (2020). The findings of a Cochrane Meta-Analysis of couple therapy in adult depression: Implications for research and clinical practice. Family Process, 59 (2), 1-15).Finally, there is also evidence for the effectiveness of other forms of couple therapy for depression, such as emotion-focused couple therapy and coping	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA). The Baucom et al. (2018) study was not appropriate for inclusion in the review as it was not a randomised controlled trial. Bodenmann 2008 was identified by the searches and assessed for eligibility, however it did not meet inclusion criteria as less than 80% of participants were receiving first-line treatment for depression (56% taking medication at baseline). This study is on the 'PA-Couple excluded studies' list of Supplement B1.

						oriented couple therapy (e.g. Barbato & D'Avanzo, 2020 as above).	

748	Individual	Individual 10	Guideline	69	15	This section of the guideline refers to 'some very limited evidence for the effectiveness of behavioural couples therapy for people with depression and who had problems in their relationship'. It is certainly the case that evaluating the efficacy and effectiveness of couple-based interventions for depression is fraught with methodological complications. However, there are some studies that should be taken into account in addition to the sole study that was considered in the development of these guidelines, such as:Baucom, D., Fischer, M., Worrell, M., Corrie, S., Belus, J., Molyva, E. and Boeding, S. (2018) Couple-based intervention for depression: an effectiveness study in the national health service in England. Family Process, 57: 275–92.Bodenman, G. et al. (2008). Effects of coping-oriented couple therapy on depression: a randomised controlled trial. Journal of Consulting and Clinical Psychology, 76, 944-954.Furthermore, couple-based interventions for depression are also effective for people who are in a non-distressed relationship (see Barbato, A. & D'Avanzo, B. (2020). The findings of a Cochrane Meta-Analysis of couple therapy in adult depression: Implications for research and clinical practice. Family Process, 59 (2), 1-15).Finally, there is also evidence for the effectiveness of other forms of couple therapy for depression, such as emotion-focused couple therapy and coping	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA). The Baucom et al. (2018) study was not appropriate for inclusion in the review as it was not a randomised controlled trial. Bodenmann 2008 was identified by the searches and assessed for eligibility, however it did not meet inclusion criteria as less than 80% of participants were receiving first-line treatment for depression (56% taking medication at baseline). This study is on the 'PA-Couple excluded studies' list of Supplement B1.

						oriented couple therapy (e.g. Barbato & D'Avanzo, 2020 as above).	
749	SH	British Psychological Society	Guideline	69	16	Evidence was only considered for the effectiveness of behavioural couples therapy for people with depression who also had problems in their relationship. Couple therapy for depression is a psychological therapy for depression and is in fact appropriate for people with depression with and without relationship problems. This incorrect assumption that couple therapy for depression is only or more suitable for a subgroup of people with depression has resulted in studies being excluded from the review. We request that the committee correct this error in the guidelines and	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA).

						include these studies in the evaluation of the evidence.	
750	SH	Tavistock Relationships	Guideline	69	16	Evidence was only considered for the effectiveness of behavioural couples therapy for people with depression who also had problems in their relationship. Couple therapy for depression is a psychological therapy for depression and is in fact appropriate for people with depression with and without relationship problems. The incorrect assumption that couple therapy for depression is only suitable for a subgroup of people with depression has resulted in several studies being excluded from the review. This is extremely concerning as this presumably contributed to a significant reduction in the amount of evidence for couples therapy being considered. We request that the committee correct this error in the guidelines as a matter of urgency and include these studies in the evaluation of the evidence.	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA).

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

751	SH	British Psychological Society	Guideline	73	017-018	We are concerned that the claim that there are only small and limited trials on psychological therapy for depression in personality disorder may lead to clinicians overlooking potentially helpful therapy, because many studies of psychological therapy for borderline personality disorder include measures of depression. An example of a randomised controlled trial is Bateman A, Fonagy P. (1999) Effectiveness of partial hospitalization in the treatment of borderline personality disorder: a randomized controlled trial. Am J Psychiatry, 156:1563-1569. We suggest modifying the search criteria so that important and robust trials of this nature are included and can inform recommendations, at least for borderline personality disorder (or emotionally unstable personality disorder).	Thank you for your comment. Bateman & Fonagy (1999) would not be eligible for inclusion as the intervention was targeted at the personality disorder rather than at the symptoms of depression. Evidence review F includes those with depression and a coexisting personality disorder but the target of the intervention and the primary outcome of interest is depression.
752	SH	NICE quality standards & indicators team	Guideline	78	10	We note that the CG90 appendix on assessing depression and its severity is no longer included. It would be helpful to explain why it is no longer included.	Thank you for your comment. The information on depression and its severity has been reinstated at the beginning of the guideline.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

753	SH	The Association of Clinical Psychologists UK	Guideline	049 – 051	General	The ECT section of the Draft Consultation Guidelines on Depression in Adults (section 1.13)needs radical revision in order to reiterate and uphold the unimplemented recommendations from the 2003 NICE Guidance on the Use of Electroconvulsive Therapy; and to take into account recent evidence on serious deficiencies in safety, effectiveness and regulation. As it stands, the ECT section of the draft is a clear breach of NICE's commitments to: Use evidence that is relevant, reliable and robust; propose new research questions and data collection to resolve uncertainties in the evidence; liaise with the research community to ensure they are addressed; take into account the advice and experience of people using services and their carers or advocates; and update recommendations in line with new evidence (https://www.nice.org.uk/about/who-we-are/our-principles). It also fails to demonstrate NICE's commitment to ensuring patient safety arising out of the recent Cumberlege review (https://www.nice.org.uk/about/what-we-do/our-programmes/patient-safety_ In line with NICE's principles of 'making decisions using a process that is transparent and contestable', we ask the Committee to rectify or justify the following serious omissions, as identified by the Campaign for an Independent Review of ECT:There is no	Thank you for your comment. The committee included ECT as an intervention in a number of evidence reviews and were disappointed by the lack of new evidence for ECT, which hampered their ability to update the ECT recommendations made in 2003 (and already updated once in 2009). The committee noted the limitations of the evidence for ECT for further-line treatment , both in terms of quantity and quality in the committee discussion of the evidence section. However, the committee were also aware that ECT may be beneficial for some people and that removing it as an option would be detrimental to some people with depression. The recommendations on ECT limit its use to very narrow circumstances (rapid responses, when other treatments have failed, patient preference). On this basis, the committee did not consider it appropriate to remove this recommendation, but did amend the wording to emphasise that ECT should generally not be used, and should only be considered in the limited circumstances described. The recommendation does not specify the use of ECT to prevent suicide, and an example is provided to clarify what is meant by life threatening. The committee discussed the fact that people need to be fully informed about the risks and

						statement about safe dosage, frequency or duration of treatment although NICE 2003 noted that '…. stimulus parameters impact on the safety and efficacy of the technique, and recent research needs to be augmented.' There is no statement about the need for regular cognitive testing, with appropriate measures, for adverse effects after every treatment and at follow up despite NICE 2003's requirement that 'the individual's cognitive function is monitored on an ongoing basis and at a minimum at the end of each course of treatment.' There are no recommendations on the provision of rehabilitation and compensation for memory loss/brain damage although NICE 2003 noted that 'a number of individuals find their memory loss extremely damaging and for them this negates any benefit from ECT'. NICE should also issue a call to routinely assess for all serious adverse effects, and should address the ethical issue of a doctor providing a treatment for which they have not studied the neuropathology or pathophysiology, including the bioscience of electrical dosing and the neuropathophysiology of electrical doses. Psychiatrists are thus unaware of potential adverse events and unqualified to provide long-term follow-up in such a situation. There is no statement about the failure to produce evidence-based patient information leaflets, as recommended by NICE 2003. A recent audit (Harrop et al, 2021)	benefits of ECT prior to its administration, and need to make an informed decision to have ECT. For these reasons, the committee stregthened the recommendations from the previous version of the guideline and added the requirement for clinics providing ECT to be ECTAS-accredited, with board level accountability for compliance with ECTAS standards. The committee were aware that ECTAS standards include detailed advice on monitoring and assessing cognitive impairment, and therefore chose to recommend adherence to these rather than create new recommendations. The committee have reiterated their call for more research into the place in therapy of ECT, and will also recommend to NICE that it explore doing future work on neuromodulatory techniques (and/or rapidly acting treatments) including ECT.

						shows that current leaflets contain numerous serious inaccuracies, confirming NICE 2003's concerns about informed consent: '….the potential for cognitive impairment following ECT may not be highlighted during the consent process.' This requirement is even more urgent in the light of the Montgomery (2015) ruling which requires even relatively rare risks to be mentioned. In line with the GMC 2020 informed consent guidelines, this would include informing patients about the risk of permanent brain damage and permanent memory loss as added to the instruction manual of Thymatron ECT machines in a regulatory update in 2018 (Somatics, 2018.) There is no comment on the huge regional variation in usage (up to 47-fold between different Trusts) raised in previous guidelines and documented in recent independent audits (Read et al, 2021) although this suggests serious failures in evidence-based decision-making. The failure to reiterate NICE 2003's recommendation that since many people are unaware of their rights and may be subject to both explicit and implicit coercion, '…..mechanisms to monitor and prevent this from occurring must be developed and implemented'.The failure to address NICE 2003's statement that 'RCTs….did not adequately capture the experience of service users' and that their testimony must be taken into account to balance findings from quantitative	

						studies. The failure to reiterate important limitations on practice cited in NICE 2003, including 'used only to achieve rapid and short-term improvement of severe symptoms after an adequate trial of other treatment options has proven ineffective and/or when the condition is considered to be potentially life-threatening'; 'Clinical status should be assessed following each ECT session and treatment should be stopped when a response has been achieved, or sooner if there is evidence of adverse effects' and 'Not recommended as a maintenance therapy in depressive illness.' The abandonment of the call for robust research into efficacy and safety made by NICE in 2003 and reiterated in 2009 and 2014. NICE 2003 noted: 'Further research is urgently required to examine the long term efficacy and safety of ECT… Of particular concern (was) the lack of long-term evidence regarding adverse effects on cognitive function….In addition to the use of appropriately validated psychometric scales, outcome measures should include user perspectives on the impact of ECT, the incidence and impact of important side effects such as cognitive functioning, and mortality….Further research into the mechanism of action of ECT is encouraged, because it may provide important information on aetiology and future treatment strategies.' The Royal College of Psychiatrists has	

						made no attempt to set up such a research programme in the intervening 19 years. The draft fails to cite a single placebo-controlled study justifying the use of ECT, or to refer to recent research reviews and independent audits finding little/no efficacy, major safety concerns and significant procedural/monitoring problems (Read et al, 2020). Reliance on adherence to the minimal standards of the ECT Accreditation Service (ECTAS) whose own website states 'ECTAS is a voluntary network which uses a system of peer review …. ECTAS does not provide regulation of ECT'. NICE has no powers to enforce the new recommendation for clinics to be members of ECTAS; NICE guidelines are not legally binding; and the Care Quality Commission does not routinely inspect ECT clinics, and has told us that in relation to ECT it has 'no general investigatory power to address complaints, whether about specific treatments or other matters'. As they stand, these draft guidelines do nothing to change the situation in which ECT will continue to be, in effect, unregulated. NICE 2003 noted that: 'The ongoing deficiencies in current practice were highlighted to the Committee, and the Committee strongly believed that action is required to ensure that appropriate standards of care are enforced whenever ECT is undertaken and that outcomes are continuously monitored.' No such action has	

						been taken, and as it stands, I believe that NICE should acknowledge that the practice of ECT should be placed in one of two categories it identifies for such eventualities: 'The level of uncertainty about the efficacy or safety evidence is such that it is considered to be in the best interest of patients to recommend controlled investigation of the procedure under the scrutiny and protection of research ethics committees' or 'When the evidence suggests that a procedure has no efficacy or poses unacceptable safety risks, the Committee recommends that it should not be used' https://www.nice.org.uk/process/pmg28/chapter/draft-recommendations We are aware that the Shadow Minister for Mental Health, Dr Rosena Allin- Khan, has asked questions in Parliament about the regulation of ECT on several occasions, and a number of MPs have also written to Health Secretaries to raise their concerns. Ongoing failure to address these concerns would represent a wilful neglect of patient safety, and a breach of NICE's own core commitment to evidence-based practice. The apparent abandonment of any attempt to require the gaps in the evidence to be filled is particularly disturbing. I trust that the committee will, even at this late stage, and in line with its own principles, reconsider. Harrop, C., Read, J., Geekie, J., Renton, J. (2021). How accurate are ECT patient information leaflets provided by mental health	

						services in England and the Royal College of Psychiatrists? An independent audit. Ethical Human Psychology and Psychiatry, doi: 10.1891/EHPP-D-21-00003Read, J., Kirsch, I., McGrath, L. (2020). Electroconvulsive Therapy for depression: A Review of the quality of ECT vs sham ECT trials and meta-analyses. Ethical Human Psychology and Psychiatry, doi:10.1891/EHPP-D-19-00014Read, J., Harrop, C., Geekie, J., Renton, J., & Cunliffe, S. (2021). A second independent auditof ECT in England, 2019: Usage, demographics, consent, and adherence to guidelines andlegislation. Psychology and Psychotherapy: Theory, Research and Practice. https://doi.org/10.1111/papt.12335Somatics L. Regulatory update to Thymatron System IV Instruction Manual. Somatics, LLC; 2018. http://www.thymatron.com/downloads/System_IV_Regulatory_Update.pdf	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

754	SH	Oxford Health NHS Foundation Trust	Guideline	331	Table 88	15 min interventions only are specificed for supported cCBT but not other low intensity interventions. Is there a conflation between the two? Problem solving has 30 mins.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.
755	SH	Psychological Professions Network	Guideline	331	Table 88	15 min interventions only for supported cCBT not other PWP interventions. Is there a conflation between the two? Problem solving has 30 mins	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the indication about the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions.
756	SH	Oxford Health NHS Foundation Trust	Guideline and Evidence Review B	General	General	The committee appears to lack appropriate expert input or membership from the IAPT workforce. This is a critical omission given firstly that IAPT services are a significant component of depression service provision in the UK, and secondly that expertise in understanding how to interpret evidence and make recommendations in relation to low and high intensity interventions for depression are likely only to be found in those with specific expertise in IAPT service provision.	Thank you for your comment. The committee included members who provided psychological services as part of the IAPT services, had been involved in the development of IAPT services originally or who commissioned IAPT services.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

757	SH	Mind	Guideline and Evidence Review B	023 - 031	General	As all treatments identified have been found to be both clinically effective and cost effective, removing rankings of treatments would better support patient choice and shared decision making, helping people to better identify the best treatments that will work for them.We recommend the removal of hierarchical ranking of treatments, and that treatment options are instead listed alphabetically.	Thank you for your comment. The committee listed the treatments in order of clinical and cost-effectiveness to guide treatment selection for people with depression and clinicians. The committee were aware that many people with depression express a preference for 'a talking therapy' but do not have a preference beyond that, so a certain degree of ordering will help in this situation. For people who do express a particular preference, the treatment of choice can be selected, without having to fail other treatments first.

758	SH	Psychological Professions Network	Guideline and Evidence Review B	General	General	The committee appears to lack input or membership from the IAPT workforce. This is unfortunate given that IAPT services are a significant component of depression service provision. As a result it appears that significant important evidence has been overlooked or misinterpreted, leading to flaws in the cost-effectiveness analysis and an incorrect hierarchy of interventions that mistakenly abandons stepped care. For the benefit of patients it is imperative that these flaws and mistakes are corrected to avoid the collapse of provision	Thank you for your comment. The committee included members who worked in or commissioned IAPT services and therefore were able to draw on their knowledge of these services. The committee drew on their knowledge of the IAPT dataset to inform recommendations and to re-structure treatment recommendations in response to stakeholder comments. Recommendations relating to the stepped care model have now been updated. To make decisions about the relative effectiveness of interventions, which informed the cost-effectiveness analysis, RCTs were prioritised in line with the NICE guidelines manual. For the guideline economic analysis, other epidemiological data were obtained from published longitudinal studies. Intervention resource use was obtained by the RCTs that informed the guideline NMA and the economic analysis, supplemented by the committee's expert opinion. Other healthcare resource use associated with the management of depression was derived from a large cohort UK study. National UK unit costs were used. Therefore, the committee were confident that the guideline economic analysis used best quality data for every model input parameter. It needs to be noted that in January 2020 NICE published a statement of intent signalling the ambition for

							the future use of wider sources of data and analytic methods (including sources commonly referred to as real-world data and evidence). To make decisions about the relative effectiveness of interventions, RCTs will continue to be prioritised in line with the NICE guidelines manual, in order to ensure that the populations treated with various interventions are equivalent. However it is possible that in the future, high-quality real-world datasets such as the IAPT dataset, could inform questions about access and engagement.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

759	SH	Janssen	Guideline, Evidence reviews	General	General	We thank NICE for the opportunity to comment on the update of NICE clinical guideline 90: Depression in adults: recognition and management. Overall, we are pleased to see that draft guideline is more accessible and structured in a more logical way from previous versions of the draft guideline, which we believe will be easier for relevant stakeholders to navigate and understand the recommendations within the guideline. We also welcome the publication of this draft guideline as it represents the chance to ensure parity of esteem between mental health and physical health as outlined in the Health and Social Care Act of 2012. Unfortunately, parity of esteem between mental health and physical health remains significant and COVID-19 is likely to have mad this worse (Marshall et al, 2020). The guideline is therefore an important piece in addressing parity of esteem and we hope that more frequent updates of the guideline in the future will allow for the latest evidence and interventions to be included more rapidly in the future. The recommendations in this guideline should support this desire for parity of esteem based on the evidence available, specifically to address the following points between physical and mental health:• equal access to the most effective and safest care and treatments • equal efforts to improve the quality of care • the allocation of time, effort and	Thank you for your comment and your support for the guideline structure and recommendations. The guideline recommends a range of evidence-based treatment options for depression, taking into account their risks, benefits and cost-effectiveness. Only interventions with adequate evidence of clinical and cost-effectiveness, supported by the committee's clinical expertise around service delivery and implementation issues within the NHS, were recommended. The guideline does not recommend any interventions with limited and/or poor evidence base. The vast majority of the recommended treatments are currently available in the NHS. Very few of the recommended interventions (for example group exercise, individual problem solving) are currently not available or have limited availability in routine practice, but the committee decided to recommend them based on the favouring available clinical and economic evidence. In response to stakeholder comments, the committee considered a number of practical issues around the waiting times of high intensity psychological interventions and implementation issues relating to the structure of IAPT services and has now updated recommendations for the

						resources on a basis proportionate with need • equal status within healthcare education and practice • equally high aspirations for service users• equal status in the measurement of health outcomesThe guideline does make some effort to address several of these points. In our response, however, we draw attention to areas where we believe that the guideline falls short of these principles. Fundamentally, we believe that it is important that clinicians and people with depression should have access to a range of treatment options given the heterogeneous nature of the condition. We believe that this give people with depression the best opportunity in escaping from a condition which has wide ranging effects not only on themselves, but their carers, the wider healthcare system through the impact on physical health, psychiatric emergency, and suicide, as well as wider society in general. Overall, we are supportive of the pragmatic way that the guideline committee have chosen treatment options, given the significant limitations in the evidence base when deciding between the most efficacious and tolerable treatments. It is welcomed that a wide range of options (both psychological and pharmacological) have been recommended within the draft guideline, however, we do note that for some interventions there is a limited and poor evidence base and therefore if the NHS is going to	treatment of a new episode of less severe depression guided by the principles of offering the least intrusive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice. The recommendations do not preclude people from receiving pharmacological interventions, as antidepressants are included in both Tables 1 and 2 (recommended treatments for less and more severe depression, respectively). For less severe depression (for which low intensity interventions can be offered first as step 2 of treatment according to updated recommendations), the committee agreed that as the evidence suggested that some psychological therapies might be more effective than antidepressants, and because antidepressants are associated with side effects and withdrawal effects, antidepressant medication should not be the default treatment, unless it was the person's preference. Training costs (in terms of qualification costs of low- and high-intensity therapists and additional training required for low-intensity therapists and for some therapies such as MBCT) have already been considered in the guideline economic modelling. As argued above, the vast majority of

						invest significantly in many of the recommended interventions that are not widely available currently then it is important that a more robust system of collecting and monitoring real world patient outcomes is put in place and recommended by NICE. As there is already significant variation at local level within mental health and the mixed availability and access to evidence based interventions across the country. It is acknowledged that the guideline has made a number of new recommendations in terms of referral to secondary care, patient decision making and the collection of clinical outcomes. This is welcomed, but we believe that the guideline committee could go further by recommending specific depression outcome measures like the PHQ-9, how often measures are taken and being stronger in the recommendation around when referrals should occur to secondary care services. The reality based on real world evidence is that patients are receiving multiple lines of suboptimal treatment in primary care before referral into secondary care services (Denee et al, 2021). We believe that transforming the treatment of depression into an efficient treatment pathway with appropriate evidence-based options at each stage of the patient journey is the single biggest intervention that can be done to improve depression treatment and outcomes in England	recommended interventions are already available in current routine practice, so they are not new or untested. Implementation issues relating to these interventions may be relevant regarding the scale of delivery. Where recommended treatments are currently not available or where their availability is limited, NICE will consider implementation issues when producing supporting tools for implementation of the guideline. Such treatments were recommended on the basis of their clinical and cost-effectiveness, as demonstrated by the available evidence. It is true that a separate evidence synthesis in the form of a NMA and economic modelling were not conducted for the review question on further-line treatment. A NMA in this area was not considered appropriate due to the high heterogeneity around the populations in the RCTs included in the review. However, evidence synthesis in the form of pairwise meta-analysis was carried out for this review. De-novo economic modelling was not prioritised for this area, due to time constraints and because other areas (treatment of a new episode, relapse prevention) were identified by the committee as higher priorities for economic modelling. The process of prioritisation was recorded in an

						and Wales. This starts with the uniform collection of patient outcomes across both primary and secondary care services and joined up integrated services that mean that patients can get the support that they require. Currently there is limited data collection, infrastructure, and mechanisms available compared to other physical heath therapeutic areas like oncology. The guideline has made important recommendations in this regard, but we believe that more could be included to ensure that this happens in practice and supports the gap between physical and mental health (Mitchel et al, 2017).In principle, we welcome the wider role for psychological and psychosocial treatments in treating depression. We are very conscious of the difficulties of adopting such wide ranging recommendations for these treatments currently in the NHS given the limited availability and evidence of such treatments, the lack of highly skilled individuals to give these treatments effectively and the long waiting times to access these treatments. Many people with depression already receive sub-optimal care in terms of timely referral to a secondary or tertiary care service. We are concerned that increased focus on psychological and psychosocial treatments will lead to more people in depression receiving inadequate or delayed treatment for a significant periods of time, risking their depression	economic plan, in line with NICE standard processes around guideline development as described in the NICE Guidelines Manual. The committee agreed that the area of further-line treatment needs to be considered for primary economic analysis in future guideline updates. It is noted, though, that this area is expected to require complex economic modelling, that may not be possible to capture all relevant sub-groups, as it includes a heterogeneous population that may follow very diverse treatment sequences and pathways. When formulating recommendations, the committee considered the existing clinical and economic evidence in the area of further-line treatment. As the economic evidence in this area was limited and of variant quality, the committee looked at the economic evidence on treatments for a new episode of depression only to check and confirm whether it supports recommendations for further-line treatment, as an intervention that is cost-effective in treating a new episode gives more confidence that it may also be cost-effective in further-line treatment of depression. The committee noted that routine outcome monitoring was used more in psychological therapy practice including in IAPT, than in

						becoming more severe and resistant. This is especially worrisome given that many patients on psychological and psychosocial waiting lists are not always monitored for clinical disease progression. Therefore, we believe that it is important that people with depression also have access to pharmacological treatments if they require them, especially if there are delays to accessing psychological and psychosocial treatments. We also note the significant investment in training and service set up for psychological and psychosocial treatments is not currently modelled in the economic evaluations. Many of these interventions are not widely available across the country and would need significant investment. We strongly suggest this is reviewed in the economic model given this has been a significant consideration of introduction for new pharmacological options (NICE ID1414). Without looking at the investment required for the NHS then this risks other potentially cost effective options being squeezed out at the margin and inappropriate recommendations being made in the guideline, especially when in comparison the evidence base for some of these psychological and psychosocial interventions is relatively poor. We also note that the pragmatism that has been applied to the limited evidence base by the guideline committee is not consistent with NICE technology committee	primary care or specialist mental health services. The committee agreed that the evidence on whether routine outcome monitoring improves outcomes was equivocal, but noted that it may be valued by people with depression. On this basis, the committee did not consider it appropriate to specify how often measures should be taken. However, in response to stakeholder comments the committee agreed to include the PHQ-9 as an example of a scale that might be used to measure depression symptoms, given that it is the scale most widely used in UK clinical practice. The committee agreed that the appropriate time to refer a person to specialist care services was highly variable, and did not feel able to stipulate this in a recommendation. However, the treatments that need to be initiated, managed and/or stopped in specialist mental health settings or after consulting a specialist are already specified in the guideline recommendations. The committee were aware of work emanating from the NHS long-term plan which suggested that care should be locality-based and integrated across all aspects of health and social care and so made recommendations (in the access section of

						for new pharmacological treatments and we strongly urge NICE to look at the consistency of their decision making given the strength and depth of evidence for new pharmacology options is significant greater to many of the interventions recommended in the guideline. Finally, we note that a separate evidence synthesis and appropriate economic modelling was not conducted for the further lines of treatment section of the guideline. We understand the rationale for the guideline committee taking this approach and generalising from the evidence for treatments for a new episode of depression to later lines of the treatment pathway given the challenges associated with the sparse evidence base, but we do note that the effectiveness of treatments is significantly determined by the number of previous failures, as demonstrated by the STAR*D study (Rush et al, 2006). We are concerned that this approach may not be reflective of identifying appropriate treatments for different places in the pathway, especially with a view to the future when new treatments are available that specifically target people with treatment resistant depression. We would ask NICE and the guideline committee to keep this in mind for future updates of the guideline so that an appropriate review based on the number of failed treatments can be conducted and appropriately modelled to look at the	the guideline) to advise this. The committee also agreed that in order to ensure that these pathways worked as intended it was necessary to monitor access, uptake and outcomes. The committee also recognised that mental health services for people with depression were delivered by a wide range of practitioners in a wide range of settings, but that integration between these services and settings was essential, and so made a recommendation to state this.

						sequencing of further lines of treatments in the pathway. Overall, we thank NICE for the opportunity to comment on the guideline and we are supportive of the guideline being published given the significant delay in development and believe that the recommendations are important step in improving the care of patients with depression withing the NHS in England and Wales and addressing the parity of esteem between physical and mental health. Below we provided specific comments on the section of the guideline.	

760	SH	EMDRIA	Guideline, evidence reviews B and D	General	General	EMDR has a robust evidence base for the treatment of depression in the context of PTSD. Hence it is one of the two recommended first-line treatments in the NICE (2018) PTSD guidelines. As a trauma-focused therapy, EMDR targets the dysfunctional 'unprocessed' memories and mental representations of stressful life events that are thought to drive psychological symptoms. Given the substantial relationship between the onset of major depression and experiences of adverse life events including trauma, it is plausible that EMDR may also be effective in treating depression, particularly where there are clear relationships between symptoms and adverse experiences. The emerging evidence base for treating depression with EMDR is relatively small but promising. Hence, we were pleased at the committee's decision to include EMDR (for depression, not PTSD) in the review protocol. However, we identified significant issues in how the EMDR trial evidence was treated in the review, and we think this was potentially key to EMDR not being included as a 'consider' option, particularly as a further-line treatment for those where depression relates to negative life events or experiences of adversity. We think that people with treatment-resistant depression, who have experienced stressful or traumatic life events, could benefit from evidence-based psychotherapies such as	Thank you for your comment. In response to your other comments, a specific supplementary search has been run for EMDR. However, no eligible studies were identified, apart from the Ostacoli 2018 study that was already included in this review. The excluded studies lists of Supplement B and Supplement D have now been updated with the additional studies which were identified, and the reason for exclusion. The committee decided not to recommend EMDR for further-line treatment as there was only data from a single study, the effects on remission (at endpoint and 6-month follow-up) were not statistically significant, and the trial was not sufficiently powered to conclude non-inferiority compared to CBT.

						EMDR, that target aversive memories. We think that if all the relevant EMDR trial data had also been included in the NMA, that is reasonably likely that EMDR would also receive a recommendation as an alternative, further line, treatment for this group.	
761	Individual	Individual 9	Guidelines	General	General	Why has stepped care been removed?	Thank you for your comment. In response to stakeholder comments, in particular around implementation issues in the context of IAPT, some changes have been made to the tables of interventions for the treatment of a new episode of depression guided by the principles of offering the least intrusive and least resource intensive intervention first, reflecting clinical and cost effectiveness, and reinforcing patient choice.

762	Individual	Individual 9	Guidelines	26	Table 1	Guided self-help to be delivered in 15 minutes, guided self-help on a one to one basis shouldn't be delivered in 15 minutes, has this time frame been derived from CCBT literature only.Why have studies on guided self-help like the COBRA trial not been included.	Thank you for your comment. The committee agreed that PWPs may need more time and flexibility to fulfil their role and responsibilities, including assessment and discussing treatment options. Therefore, the duration of sessions has now been removed from the recommendations, to allow flexibility and ensure effective delivery of low intensity interventions. The COBRA trial was excluded from the NMA because it did not meet inclusion criteria for a new episode of depression. This is because <80% of the study sample received first-line treatment for a new episode of depression. This was a requirement of the review protocol in order to create a homogenous dataset. Nevertheless, the committee used their knowledge of pragmatic trials such as the COBRA trial when interpreting the evidence from the systematic review and making recommendations.
763	Individual	Individual 11	Guidelines	51	8	Saying ECT should finish if remission seems to rule out maintenance ECT? My daughter relapsed within4 weeks when ECT was stopped suddenly.	Thank you for your comment. The committee did not find any evidence to suggest ECT maintenance treatment was effective and so were unable to make recommendations to state this.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

764	Individual	Individual 11	Guidelines	55	13	1.15.9 would seem to exclude patienst from accessing secondary care if they 'just' have severe depression. Is this the aim. My daughter would be excluded from consultant cate despite having severe , life limiting depression. See unemployment is give as a reason for being able to access services, but is that because it I a marker of seveity or because they want to give you employment advice?	Thank you for your comment. Severe life-limiting depression would be a criteria for referral to specialist mental health services and this is covered in the earlier section of the guideline on risk assessment and management and in the following section of the guideline on crisis care. Unemployment is included here as an example of a factor that can contribute to depression and which complicates the assessment and successful treatment of depression.
765	SH	British Beauty Council	Guidelines	61	1	Recommendations for research: "3. Further-line treatment" proposes the following research – "What are the relative benefits and harms of further-line psychological, psychosocial, pharmacological and physical treatments (alone or in combination), for adults with depression showing an inadequate response to an initial psychological treatment for the current episode?" Physical interventions referenced in the research are acupuncture, electroconvulsive therapy, exercise, yoga, and light therapy (for depression, not SAD)." We propose that touch therapy be included within the definition of physical treatments in order to expand on the existing body of evidence in respect of these treatments for helping to manage and reduce the symptoms associated with poor mental health. As yet, NICE, whilst acknowledging that existing research has shown positive results, has not supported touch	Thank you for your comment. The committee did not consider touch therapies to be interventions that were in regular clinical use for the treatment of depression. Therefore these interventions were not specified in any of the review protocols, the evidence has not been appraised, and the committee were not able to make any recommendations on the use of touch therapies. The number of research recommendations that the committee can develop is limited and unfortunately touch therapies were not prioritised for a research recommendation.

						and massage, aromatherapy and reflexology as a therapies for mental health, citing potential flaws with the research methodologies carried out outside of the UK. This is an ideal opportunity to expand on this. If the proposed research was expanded to explore the benefits or potential harms of a range of touch therapies as a means of combatting, preventing and avoiding a relapse of depression we are confident these lines of treatment could be offered to patients with positive results.Given the potential benefits directly from personal care services to the UK economy and health and wellbeing, we would recommend further research be carried out in the UK to replicate the benefits seen elsewhere.	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

766	SH	UK Spa Association	Guidelines	61	1	Recommendations for research: "3. Further-line treatment" proposes the following research – "What are the relative benefits and harms of further-line psychological, psychosocial, pharmacological and physical treatments (alone or in combination), for adults with depression showing an inadequate response to an initial psychological treatment for the current episode?" Physical interventions referenced in the research are acupuncture, electroconvulsive therapy, exercise, yoga, and light therapy (for depression, not SAD)." We propose that touch therapy be included within the definition of physical treatments in order to expand on the existing body of evidence in respect of these treatments for helping to manage and reduce the symptoms associated with poor mental health. As yet, NICE, whilst acknowledging that existing research has shown positive results, has not supported touch and massage, aromatherapy and reflexology as a therapies for mental health, citing potential flaws with the research methodologies carried out outside of the UK. This is an ideal opportunity to expand on this. If the proposed research was expanded to explore the benefits or potential harms of a range of touch therapies as a means of combatting, preventing and avoiding a relapse of depression we are confident these lines of treatment could be offered to patients with	Thank you for your comment. The committee did not consider touch therapies to be interventions that were in regular clinical use for the treatment of depression. Therefore these interventions were not specified in any of the review protocols, the evidence has not been appraised, and the committee were not able to make any recommendations on the use of touch therapies. The number of research recommendations that the committee can develop is limited and unfortunately touch therapies were not prioritised for a research recommendation.

						positive results.Given the potential benefits directly from personal care services to the UK economy and health and wellbeing, we would recommend further research be carried out in the UK to replicate the benefits seen elsewhere.	
767	SH	Psychotherapy & Counselling Union	Methods	11	5	Omission of non-RCT dataExcessive weight is still given to randomised controlled trials (RCTs), and consequently other high-quality data is ignored, including the huge volume of data available from the national Improving Access to Psychological Therapies (IAPT) programme (e.g. Hepgul et al., 2016, https://bmcpsychiatry.biomedcentral.com/track/pdf/10.1186/s12888-016-0736-6.pdf). This may be partly an issue for the consultation on NICE guideline development, but the current guideline development manual (NICE, 2014, pp. 106-110) still allows for flexibility in this area.	Thank you for your comment. When making recommendations, the committee interpreted the RCT evidence in light of their knowledge of the clinical context (including drawing on their knowledge of the IAPT dataset) so that the 'reality' for people experiencing depression was taken into consideration. In response to stakeholder comments, the committee have re-structured treatment recommendations in order to take into account implementation factors. In January 2020 NICE published a statement of intent signalling the ambition for the future use of wider sources of data and analytic methods

							(including sources commonly referred to as real-world data and evidence). To make decisions about the relative effectiveness of interventions, RCTs will continue to be prioritised in line with the NICE guidelines manual, in order to ensure that the populations treated with various interventions are equivalent. However it is possible that in the future, high-quality real-world datasets such as the IAPT dataset, could inform questions about access and engagement.
768	SH	Olly's Future Suicide Prevention Charity	Question 1	General	General	We believe that many of the changes included in this draft guidance are needed, however it may take time for practitioners to adjust to routinely offering patients the new range of treatments and resist the default option of prescribing antidepressants. Equally, we believe that care must be taken when alternative therapies to anti-depressants are chosen by patients to ensure that waiting lists do not become excessively long. Currently, there are some concern in the literature regarding waiting times (Mind) and how many patients on waiting lists are resorting to crisis care (Royal College of Psychiatrists, 2020). Long waiting times for treatment leaves people vulnerable to becoming more unwell and risks patients feeling forgotten about or side lined. As anti-depressants are available further down the treatment list, then	Thank you for your comment. The committee were keen to ensure that the evidence-based treatments they recommended were available, as you suggest, and so have added a new recommendation for commissioners about the timely availability of NICE-recommended treatments.

						other therapies need to be made more available quicker.	
769	SH	Royal College of Speech and Language Therapists'	Question 2	Question 2	Question 2	Response to question two: What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)The RCSLT recommend that communication needs, and supporting communication, must be taken into account throughout the Guideline. Approximately 60% of people accessing mental health services have communication difficulties. At present the Guideline could be significantly improved in how it recognises and supports people with communication needs. Supporting communication enables people to express their wishes and preferences, to participate in decisions about their care and treatment and to engage in psychological interventions. Unsupported communication is a barrier to a person expressing their health needs. it results in in inaccurate risk assessments and a barrier to accessing and engaging in rehabilitation and psychological programmes, which are often	Thank you for your comment. Your separate comments about communication needs have been addressed individually, and changes made to the guideline in a number of places to address them.

						delivered verbally and are thus reliant on people's language skills. The NICE guideline on "Rehabilitation for adults with complex psychosis and related severe mental health conditions" recognises that communication difficulties create a barrier for people with complex mental health, and support and resources are required to ensure effective engagement.This Guideline needs to be improved on its links between communication needs and mental health and how people can be better supported.. Reference: Walsh, I., Regan, J., Sowman, R., Parsons, B. and McKay, A.P., 2007. A needs analysis for the provision of a speech and language therapy service to adults with mental health disorders. Irish journal of psychological medicine, 24(3), pp.89-93Walsh I. Language and Communication in Schizophrenia. 2004. Jenny France (ed) Communication and Mental Illness. (pp 351-pp 400) Jessica Kingsley PublishersBryan K. Psychiatric disorders and Communication. 2014. Louise Cummings (ed) Handbook of Communication Disorders. (pp. 300-318) Cambridge: Cambridge University Press	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

770	Individual	Individual 9	Staff and contributors	General	General	Why isn't there a representative for low intensity/ PWP been involved in the committee?	Thank you for your comment. The committee included members who provided psychological services as part of the IAPT services, had been involved in the development of IAPT services originally or who commissioned IAPT services, but you are correct that no PWP was included on the committee, and this may be considered by NICE as an option for future updates of this guideline.
771	Individual	Individual 4	Supplement 1 Methods	5	023 - 025	This states that recognition and assessment were not included in this update. But NICE recommendations in CG90 (2009) were diagnosis specific. Treatment without a precise knowledge of what is being treated is likely to be fruitless. The Proposed Guidance de facto rubber stamps the current practice in IAPT of delivering an intended depression treatment on the basis of an elevated PHQ9 score, notwithstanding that this latter could have arisen in the context of a wide variety of disorders including adjustment disorder, PTSD, panic disorder etc. There is nothing in the Guidance to orientate the clinician to the appropriate disorders and treatment protocols. The Guidance takes little account of the common comorbidities of depression.	Thank you for your comment. The guideline includes a number of recommendations on assessment which are designed to ensure that a full assessment of need is undertaken and decisions on treatment are not made solely on the basis of a score on a depression scale. The guideline also includes specific recommendations about the treatment of depression in people with an anxiety disorder, or acquired cognitive impairment, or those with depression and a coexisting personality disorder.

772	SH	Institute of Psychoanalysis	Supplement 1: Methods	29	General	The Supplement 1: Methods document outlines the methodology that underpins the development of this guideline. Under the heading 'validation process' on p.29 it states: "This guideline was subject to a 6-week public consultation and feedback process. All comments received from registered stakeholders were responded to in writing and posted on the NICE website at publication."Whilst we acknowledge that stakeholder involvement is indeed an important part of the validation process of the methodologies used in NICE guideline in general, we would like to emphasise that it cannot be the only process. Surely all RCTs and systematic reviews require a protocol that describes their methods and analysis plans including the rationale before a study begins. This common practice ensures adherence to ethical and scientific standards can be assessed and monitored, and as such validated adequately (e.g., Tetzlaff et al, 2012). Not having a transparent, clearly defined and peer-reviewed protocol can lead to inflated effect sizes (Gelman and Carlin, 2014) and type I errors (Luck and Gaspelin, 2017), risk researcher allegiance, which has been demonstrated to significantly affect the results of meta-analyses (Munder et al., 2013) and contribute to low replication rates of psychological studies (Open Science Collaboration, 2015). Failing to define inclusion/exclusion criteria prior to	Thank you for your comment. At the start of this latest update of the guideline, review protocols were agreed with the committee, and were registered on PROSPERO in October 2019. Changes had been made to previous versions based on stakeholder consultation comments. For example, stakeholder consultation on the 2016 version of the guideline raised concerns about the non-validated thresholds on which studies were categorised into less or more severe depression populations, and inconsistencies in thresholds across different scales. As detailed in the methods and process section of Evidence review B, an anchor point of 16 on the PHQ-9 was selected as the cut-off between less severe and more severe depression, on the basis of alignment with the clinical judgement of the committee and eligibility criteria in the included studies. Published standardization of depression measurement crosswalk tables (Carmody 2006; Rush 2003; Uher 2008; Wahl 2014) were used in order to 'read-across' different symptom severity scales that were used in different studies. These thresholds were outlined in the protocol that was registered on PROSPERO prior to the update of the data analyses for this latest iteration of the guideline.

						analysing the data or failing to disclose changes to inclusion/exclusion criteria is a key source of questionable research practices (Baldwin and Goldberg, 2021).Throughout the different iterations of this draft guideline, various aspects of the methodology have been changed, some of them without the provision of a transparent rationale, making it impossible to rule out various problems and biases, including those mentioned above. An example would be the threshold for defining whether a study should contribute to the review of less severe or the review of more severe depression. This was amended in this third draft to the PHQ-9 anchor point and was changed from 18 to 16 without any explanation provided.	

773	Individual	Individual 10	Supplement B1	Excluded studies page	General	A number of couple therapy outcome studies were excluded for questionable reasons and should be reconsidered. For example, the Bodenman (2008) study was excluded as 25% participants had dysthymia. However, the mean BDI score of participants at the start of therapy was 24-26 (in the moderate range for depression).The Leff (2000) study was excluded because of the high drop-out rate in the medication arm of treatment (56.8%). However, the drop-out rate in the couple therapy condition was only 15% and the patients in this group showed significant improvements on the BDI post-treatment and at follow-up. This suggests couple therapy is an effective treatment for depression, and furthermore that is it more acceptable than medication.	Thank you for your comment. As outlined in the review protocol for Evidence review B, trials were excluded where more than 20% of the population have chronic depression (chronic depression defined as depression for at least 2 years, or persistent subthreshold symptoms [dysthymia], or double depression [an acute episode of major depressive disorder superimposed on dysthymia]). The exclusion of Bodenman (2008) is in line with stipulations of the review protocol that aimed to create a homogenous data set. The Leff (2000) study was not excluded based on drop-out, although there is a note in Supplement B that this study was excluded in the 2004 NICE depression guideline with the reason for exclusion provided as '>50% drop out in one arm'. Leff (2000) was excluded in this update of the guideline because there was no assessment at endpoint (first assessment at 1-year).

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

774	Individual	Individual 10	Supplement B1	Excluded studies page	General	A number of couple therapy outcome studies were excluded for questionable reasons and should be reconsidered. For example, the Bodenman (2008) study was excluded as 25% participants had dysthymia. However, the mean BDI score of participants at the start of therapy was 24-26 (in the moderate range for depression).The Leff (2000) study was excluded because of the high drop-out rate in the medication arm of treatment (56.8%). However, the drop-out rate in the couple therapy condition was only 15% and the patients in this group showed significant improvements on the BDI post-treatment and at follow-up. This suggests couple therapy is an effective treatment for depression, and furthermore that is it more acceptable than medication.	Thank you for your comment. As outlined in the review protocol for Evidence review B, trials were excluded where more than 20% of the population have chronic depression (chronic depression defined as depression for at least 2 years, or persistent subthreshold symptoms [dysthymia], or double depression [an acute episode of major depressive disorder superimposed on dysthymia]). The exclusion of Bodenman (2008) is in line with stipulations of the review protocol that aimed to create a homogenous data set. The Leff (2000) study was not excluded based on drop-out, although there is a note in Supplement B that this study was excluded in the 2004 NICE depression guideline with the reason for exclusion provided as '>50% drop out in one arm'. Leff (2000) was excluded in this update of the guideline because there was no assessment at endpoint (first assessment at 1-year).

775	Individual	Individual 5	Supplement B3	General	General	Whilst the Jordan et al study is referenced in Evidence Review B it is not presented in supplement B3.	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. Metacognitive therapy (MCT) was included in the class of cognitive and cognitive behavioural therapies (as was CBT). Jordan 2014 was included in the NMA that informed the recommendations. However, because the study included a within-class comparison it is not included in the forest plots, and is not mentioned in the text as the within-class comparison of MCT versus CBT, was not regarded by the committee as a critical comparison.

776	Individual	Individual 5	Supplement B3	General	General	B3 should be enlarged with the inclusion of Callesen et al 2020 and Jordan et al 2014.	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. Metacognitive therapy (MCT) was included in the class of cognitive and cognitive behavioural therapies (as was CBT). Jordan 2014 was included in the NMA that informed the recommendations. However, because the study included a within-class comparison it is not included in the forest plots, and is not mentioned in the text as the within-class comparison of MCT versus CBT, was not regarded by the committee as a critical comparison.

							Callesen et al. (2020) was identified by the searches but did not meet inclusion criteria as less than 80% of participants were receiving first-line treatment (35% receiving psychiatric medication at baseline). This study is in the excluded studies list of Supplement B1.

777	SH	Greater Manchester Mental Health Services	Supplement B3	General	General	Whilst the Jordan et al study is referenced in Evidence Review B it is not presented in supplement B3.	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. Metacognitive therapy (MCT) was included in the class of cognitive and cognitive behavioural therapies (as was CBT). Jordan 2014 was included in the NMA that informed the recommendations. However, because the study included a within-class comparison it is not included in the forest plots, and is not mentioned in the text as the within-class comparison of MCT versus CBT, was not regarded by the committee as a critical comparison.

778	SH	Greater Manchester Mental Health Services	Supplement B3	General	General	B3 should be enlarged with the inclusion of Callesen et al 2020 and Jordan et al 2014.	Thank you for your comment. Due to the large number of interventions included in this review, comparing all pairs of interventions individually within the network meta-analysis (NMA) or in the pairwise meta-analyses would not be feasible and would require particularly complex consideration and interpretation of the evidence. Moreover, some interventions included in the systematic review had been tested on small numbers of participants and their effects were characterised by considerable uncertainty. For these reasons, the analyses utilised class models: each class consisted of interventions with a similar mode of action or similar treatment components or approaches, so that interventions within a class were expected to have similar (but not necessarily identical) effects. Metacognitive therapy (MCT) was included in the class of cognitive and cognitive behavioural therapies (as was CBT). Jordan 2014 was included in the NMA that informed the recommendations. However, because the study included a within-class comparison it is not included in the forest plots, and is not mentioned in the text as the within-class comparison of MCT versus CBT, was not regarded by the committee as a critical comparison.

							Callesen et al. (2020) was identified by the searches but did not meet inclusion criteria as less than 80% of participants were receiving first-line treatment (35% receiving psychiatric medication at baseline). This study is in the excluded studies list of Supplement B1.

779	SH	UK ECT Improving Standards campaign group	Supplements	Tables A1	Tables A1	None of the papers informally submitted to the committee by Professor John Read, at the invitation of Dr Paul Chrisp (NICE Director of the Centre for Guidelines) and Clifford Middleton (NICE commissioning manager for the depression update) are to be found in any of the Clinical Evidence Table Supplements. The papers include:HARROP, C., et al. (2021). How accurate are ECT patient information leaflets provided by mental health services in England and the Royal College of Psychiatrists? An independent audit. Ethical Human Psychology and Psychiatry, 23, 5-24.PELTZMAN, T. et al. (2020). Effects of Electroconvulsive Therapy on short-term suicide mortality in a risk-matched patient population. Journal of ECT, 36(3), 187-192READ, J., et al. (2021). A second independent audit of ECT in England: Usage, demographics, consent, and adherence to guidelines and legislation in 2019. Psychology and Psychotherapy: Theory, Research and Practice, 94, 603-619.READ, J., et al. (2019). Electroconvulsive Therapy for depression: A Review of the quality of ECT vs sham ECT trials and meta-analyses. Ethical Human Psychiatry and Psychology, 21, 64-103.READ, J., et al. (2018). An audit of ECT in England 2011-2015: Usage, demographics, and adherence to guidelines and legislation. Psychology and Psychotherapy: Theory, Research and Practice, 91, 263-277READ, J., &	Thank you for your comment. The committee discussed the care and considerations that need to be taken into account when delivering ECT, such as informing people of the risks and benefits, obtaining consent, monitoring cognitive function and stopping ECT. The committee amended the existing recommendations on these topics but agreed that there are now recognised up to date standards produced by the Royal College of Psychiatrists, which provide guidance on how a safe and effective ECT service should be delivered, in the context of an ECT accreditation service (ECTAS). The committee added a recommendation, and subsequently strengthened this recommendation in response to stakeholder comments, that clinics should only provide ECT if they are ECTAS-accredited, provide ECT in accordance with ECTAS standards, and submit data (including outcomes) on each course of acute and maintenance ECT they deliver as needed for the ECTAS minimum dataset. There is also a recommendation that trusts which provide ECT services should ensure compliance with the ECTAS standards for administering ECT through board-level performance management. The committee did not review the audit evidence for ECT (such as the papers cited:

						BENTALL, R. (2010). The effectiveness of electroconvulsive therapy: A literature review. Epidemiology and Psychiatric Sciences, 19, 333-347.Other important papers not listed in the draft guidance: On assessing memory loss and offering rehabilitation:Robertson, H and Pryor, R (2006) (Memory and cognitive effects of ECT: informing and assessing patientsAdvances in Psychiatric Treatment 12, 228–238Lomas, M, Rickard, V, Fraser Milton, F, Savage, S, Weir, A & Zeman, A (2021): Electroconvulsive therapy related autobiographical amnesia: a review and case report, Cognitive Neuropsychiatry https://doi.org/10.1080/13546805.2021.1871889 Mangaoang, M. A., & Lucey, J. V. (2007). Cognitive rehabilitation: assessment and treatment of persistent memory impairments following ECT. Advances in Psychiatric Treatment, 13(2), 90-100.On mortality risk: DUMA, A., et al. (2019). Major adverse cardiac events and mortality associated with Electroconvulsive Therapy: A systematic review and meta-analysis. Anesthesiology, 130,(1), 83-91.On ECT and preventing suicide:"Suicide mortality was significantly higher among patients who received ECT (RR, 5.71) [during 2 years following index mental health encounter]. Peltzman T, Gottlieb DJ, Shiner B, Riblet N, Watts B V. Electroconvulsive Therapy in Veterans Health Administration	Harrop et al. 2021; Read et al. 2018, 2021), or non-RCT evidence for benefits or harms (such as, Peltzman et al. 2020; Robertson & Pryor, 2006; Lomas et al. 2021; Mangaoang & Lucey, 2007; Duma et al. 2019; Tsai et al. 2021) as this was outside the scope of this update. However, the committee were aware that the ECTAS standards were developed with a wider range of ECT experts than were available on the guideline committee, and were updated on a regular basis, and therefore agreed that it was more appropriate to refer to these standards than create new recommendations. As specified in the scope, the experience of care section from the 2009 guideline was not included in this update. It was therefore not possible to include qualitative studies on the experience of treatment (although a new qualitative review question on patient choice was added to this update). Recent meta-analyses on the effectiveness of ECT including those included in Read 2019 (Janicak 1985; Kho 2003; Mutz 2019; Pagnin 2004; UK ECT Review Group 2003) have been checked for additional relevant eligible studies. Read 2019 is listed in the excluded studies of Supplement D (further-line treatment) as it is not

						Hospitals: Prevalence, Patterns of Use, and Patient Characteristics. J ECT. 2020;36(2):130-136. doi:10.1097/YCT.0000000000000635"The RR of a suicide attempt in the year or year prior was more than 16 times greater among individuals who received ECT compared with those who did who did not. (Peltzman T, Shiner B, Watts B V. Effects of Electroconvulsive Therapy on Short-Term Suicide Mortality in a Risk-Matched Patient Population. J ECT. 2020;36(3):187-192. doi:10.1097/YCT.0000000000000665)Homeless US veterans who did not receive ECT had less suicidal ideation than matched groups of US veterans: (TSAI, J. et al. 2021. Effects of Electroconvulsive Therapy on suicidal behavior and emergency department use among homeless veterans: a propensity score-matched study. Journal of Clinical Psychiatry, 82(6), 21m13935.)On patient perspectives:Rose D, Fleischmann P, Wykes T, Lees e M, Bindman J. Patients' perspectives on electroconvulsive therapy: systematic review BMJ 2003; 326 :1363 doi:10.1136/bmj.326.7403.1363Johnstone, L (1999) Adverse psychological effects of ECT. Journal of Mental Health, 8, 1, 69-85.Wells K, Hancock N, Honey A. The experience of living after ECT: a qualitative meta-synthesis. J Ment Health. 2021 Aug;30(4):526-540. doi: 10.1080/09638237.2020.1739244. Epub 2020 Mar	eligible for inclusion in its entirety (but has been checked for relevant additional primary studies). Read et al. (2010) had not been previously identified but in response to your comment, it has been checked for additional eligible studies and no new studies have been identified for inclusion. The committee noted the limitations of the evidence for ECT for further-line treatment, both in terms of quantity and quality in the committee discussion of the evidence section. However, the committee were also aware that ECT may be beneficial for some people and that removing it as an option would be detrimental to some people with depression. The recommendations on ECT limit its use (to when a rapid response is needed, when other treatments have failed, or based on patient preference). On this basis, the committee did not consider it appropriate to remove this recommendation, but did amend the wording to emphasise that ECT should generally not be used, and should only be considered in the limited circumstances described. The committee have reiterated their call for more research into the place in therapy of ECT, and will also recommend to NICE that it explore

						18. PMID: 32186223.On brain injury and electrical injury:Abbott CC, Quinn D, Miller J, et al. Electroconvulsive Therapy Pulse Amplitude and Clinical Outcomes. Am J Geriatr Psychiatry. 2021;29(2):166-178. doi:10.1016/j.jagp.2020.06.008)Fosse, R., Read, J. (2013). Electroconvulsive treatment: Hypotheses about mechanisms of action. Frontiers in Psychiatry, 4, 94-103.Omalu B, Hansen S, Williams E, et al. Traumatic Brain Injury Advisory Board Meeting Minutes.; 2019. https://www.dor.ca.gov/Content/DorIncludes/documents/TBI/TBI Full Committee Meeting Minutes 8-26-19.docx ****Kirstein L, Ottosson J-O. Experimental studies of electroencephalographic changes following electroconvulsive therapy: the role of the electrical stimulation and of the seizure studied by variation of stimulus modification by lidocaine of seizure discharge. Acta Psychiatr Scand Suppl. 1960;35(145):49-67. https://pubmed.ncbi.nlm.nih.gov/14409401/Enns M, Peeling J, Sutherland GR. Hippocampal neurons are damaged by caffeine-augmented electroshock seizures. Biol Psychiatry. 1996;40(7):642-647. doi:10.1016/0006-3223(95)00450-5Castleman KR. Expert Report on Electroconvulsive Therapy (Castleman Exibit C). Riera v Somatics, LLC; 2018.Garcia PA, Rossmeisl JH, Neal RE, et al. Intracranial nonthermal	doing future work on neuromodulatory techniques (and/or rapidly acting treatments) including ECT.

						irreversible electroporation: In vivo analysis. J Membr Biol. 2010;236(1):127-136. doi:10.1007/s00232-010-9284-zHancock SP. Acquired Channelopathies Secondary to Repetitive High Energy Field “Low-Voltage” Electrical Injury.; 2020. doi:10.13140/RG.2.2.15825.15207 https://www.researchgate.net/publication/347440178_Acquired_Channelopathies_Secondary_to_Repetitive_High_Energy_Field_Low-Voltage_Electrical_InjuryBarichello T, Bonatto F, Agostinho FR, et al. Structure-related oxidative damage in rat brain after acute and chronic electroshock. Neurochem Res. 2004;29(9):1749-1753. doi:10.1023/B:NERE.0000035811.06277.b3Abbott CC, Quinn D, Miller J, et al. Electroconvulsive Therapy Pulse Amplitude and Clinical Outcomes. Am J Geriatr Psychiatry. 2021;29(2):166-178. doi:10.1016/j.jagp.2020.06.008	

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

780	SH	LivaNova	Supplements Methods	5	27	Despite Transcranial magnetic stimulation (TMS) for depression being stated as "not included in the scope of this update"1, it is included in the draft guideline, whereas Vagus Nerve stimulation (VNS) is not. No rationale is provided for this. We request that a hyperlinked reference to the VNS Interventional Procedure Guidance (IPG 6792) be added. Reference:https://www.nice.org.uk/guidance/GID-CGWAVE0725/documents/supporting-documentation-6 Implanted vagus nerve stimulation for treatment-resistant depression (nice.org.uk)	Thank you for your comment. A link to the NICE interventional procedure guidance on VNS has now been included.
781	SH	EMDRIA	Supporting documentation B1 / Evidence review B	General	General	In Evidence review B (Supporting documentation B1) – first line treatment - no EMDR trials were included. 6 papers are listed as excluded : at least 3 relate to a systematic review (Carletto 2017) which was not in itself included as it has some non-RCT data. The excluded papers are:Gauhar (2016) excluded as n<10 for waitlist for analysis (sample size too small) .Hase (2018) has been excluded because of inclusion criteria "current psychopharmacological antidepressant treatment" – "excluded as considered further line treatment" – but this was not then included in the further line review.Jahanfar (2020) – excluded because "no depression outcomes reported", "baseline severity cannot be categorised.Song(b) 2007 – from Carletto (2017) – data cannot be extracted from	Thank you for your comment. In response to your comment, the Yan 2021 systematic review has been checked to ascertain whether sufficient information is reported to enable inclusion of the non-English language paper Song (2007). However, it is still not possible to include Song (2007) as baseline severity cannot be categorised as this data is not available in Yan (2021). Yan 2021 has been added to the excluded studies list of Supplement B1.

						review – excluded because non English language paper. We think that, for the reasons below, the following papers should have been included in the review under first line treatments, and this would have contributed to the trial evidence supporting EMDR as a potential first line treatment:Song (2007) – N=64. This was excluded as non-English and data cannot be obtained from an existing review (Carletto, 2017) – the data is available in the more recent Yan et al (2021) meta-analysis.	
782	SH	EMDRIA	Supporting documentation B1, B2 and D	General	General	The evidence base for EMDR in depression is summarised in three recent positive systematic reviews: Dominguez et al (2020), Carletto et al (2021), Yan et al (2021). None of these recent reviews is mentioned in the evidence reviews or supporting documentation. Some of the evidence in these reviews would not meet the NICE search protocol criteria, however we would like to draw the committee's attention to these reviews, as they do not appear to have been considered in the NMA's and do not appear in the excel spreadsheets.	Thank you for your comment. In response to your other comments, a specific supplementary search has been run for EMDR. However, no eligible studies were identified, apart from the Ostacoli 2018 study that was already included in the further-line treatment review. The excluded studies list of Supplement B1 (and Supplement D) have now been updated with the additional studies which were identified, and the reason for exclusion. The systematic reviews mentioned in your comment (Dominguez 2020; Carletto 2021; Yan 2021) were identified by this supplementary search. These reviews have been checked for additional eligible studies (no new studies were identified), and have now been added to the excluded studies list of Supplement B1.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

783	SH	EMDRIA	Supporting documentation D1	General	General	In Supporting documentation D1, 3 EMDR trials are listed as excluded:Dominguez (2020) excluded because depression measure – DASS - outside protocol.Hase (2018) From NMA excludes (2016-2019 search). TAU arm all received antidepressants but also received inpatient treatment with a psychodynamic or behavioral group therapy (participation twice or 90 min per week) and a standard individual therapy – comparison not of interest.Minelli (2019) excluded because the control used was a "Trauma focused therapy" (trauma focused CBT) as comparison. We think that, for the reasons below, the following trials should have been included in the review under further line treatments, and this would have contributed to the trial evidence supporting EMDR as a potential further line treatment:Dominguez (2020) RCT n=49. This trial investigated augmenting a ten-day CBT-based group intervention for depression with 3 sessions of EMDR. This trial included both TAU and an active control arm, and has 6 week follow-up data. It was excluded because it used the DASS as a depression measure, which was outside the NICE protocol (although a reliable and valid measure). However the trial also used the SCID5 structured clinical interview to determine depression diagnostic status – 80% met criteria at entry. At 6 weeks 14% of the EMDR group met criteria, vs 47% for active	Thank you for your comment. As mentioned in your comment, the Dominguez (2020) study was assessed for eligibility and was excluded as the outcome measure was outside the protocol stipulations. Unfortunately, it is not possible to include it based on a diagnostic status measure as this cannot be classified as remission (the only potentially relevant outcome outlined in the protocol) as not all participants met criteria for a diagnosis of depression at baseline and it is not clear how many of those who did meet criteria for diagnosis at baseline, lost this diagnosis at endpoint. Hase (2018) was considered for inclusion but did not include a comparison of interest. As outlined in the review protocol, for the further-line treatment review interventions were categorised into the following categories: dose escalation; switching strategies; augmentation strategies (including augmenting the antidepressant with another antidepressant, augmenting the antidepressant with a non-antidepressant agent and augmenting the antidepressant with a psychological/psychosocial/physical intervention). Although TAU in Hase (2018) included all participants receiving antidepressants, this study could not be

						control and 67% for TAU. We think this trial potentially falls within the further line review protocol when considering this data.Hase (2018) n=30 was excluded from the first line review it was considered a further line trial (as the participants were all taking antidepressants), However it was not then considered in further line evidence: EMDR+TAU vs TAU, it uses BDI-II and SCL 90 as symptom measures, BDI-II scores placed the participants in the severe range (BDI-II 24 mean > 22): 50% of the 14 patients who received EMDR + TAU showed a complete remission at the end of treatment. We think this trial potentially falls within the further line review protocol when considering this data.Minelli (2019) n=32 was excluded because the comparator condition was trauma-focused CBT. This is an active control and meets the review criteria for the control arm – ie a type of CBT – so was incorrectly excluded in our view. The paper investigated applying trauma focused treatment models to depression, but nevertheless treating depression rather than PTSD. We think this trial should be included in the further line evidence, as the participant sample all had previous unsuccessful treatments including with medication.	categorised as EMDR augmenting antidepressant treatment (versus antidepressant treatment only) as TAU also included inpatient treatment with a psychodynamic or behavioral group therapy (participation twice or 90 min per week) and a standard individual therapy. The committee did not consider trauma-focused CBT to be an intervention of interest, and this was the reason for exclusion of Minelli (2019).

784	SH	Institute of Health Visiting	Visual Summary	General	General	There is now a direction of move to more personalised and individualised care. https://www.england.nhs.uk/personalisedcare/https://www.longtermplan.nhs.uk/areas-of-work/personalised-care/Both visual summaries imply a single direction of travel for treatment and care options. The iHV would advise strengthening the option of personalised care within this summary to include a holistic assessment, taking a partnership approach as well as a coproduced plan of care with the patient. The inclusion of a 'start arrow' implies a 'rating' of one treatment against another with the options at the end of the cycle possibly deemed as more intensive than those at the start. Formulation may not necessitate the order of steps recommended in the visual circle. If the visual summary states you can only choose one option at a time, this limits choice for the patient who may want to try SSRI antidepressants alongside another treatment option for example. The iHV would suggest taking out the arrow to demonstrate a more personalised approach.The visual should also include:Peer supportFamilyRelationship counselling and peer support should be an option…The term physical activity should be used rather than exercise. Physical activity does not need to be limited to only a group option – individual physical activity should be an option also.https://www.nhs.uk/better-	Thank you for your comment. The visual summary is designed to supplement and not replace the tables of interventions included in the guideline. These are arranged in order of effectiveness and cost-effectiveness and there is a 'direction of travel' with treatments further on in the circle being less effective and less cost-effective. The visual summary is to aid discussions and shared decision-making between clinicians and people with depression and it is made clear that patient preference should also be taken into consideration when making an individualised choice of treatment. The visual summary makes it clear that people starting a first-line treatment for depression can start at any point in the circle and do not have to fail earlier treatments to pass to a later treatment. The tables of interventions and the visual aid include treatments that were shown by the evidence to be effective and cost-effective, and so interventions for which there was not good evidence were not included. For example, the evidence for effectiveness was for structured group exercise and that is why that is included (although an additonal recommendation for less structured physical activity has now been added to the guideline, based on the committee's expertise and stakeholder feedback). The visual is in plain English, and more details of the

						health/get-active/Social groupsIf used with a patient – the visual needs to be plain English with definitions of what the treatment options mean.The second visual for severe depression should also have an option for mothers in the perinatal period to be admitted to a mother and baby unit as a first line treatment option because the onset and deterioration of mental health is very rapid in the perinatal period. https://www.rcpsych.ac.uk/docs/default-source/improving-care/nccmh/perinatal/nccmh-the-perinatal-mental-health-care-pathways-full-implementation-guidance.pdf?sfvrsn=73c19277_2	treatment options are included in the tables. Women with antenatal or postnatal depression were not included in the scope of this guideline and no evidence for treatment in this group was examined so interventions for this group cannot be added to the treatment tables or visual summary. However, a link to the NICE guideline on antenatal and postnatal mental health has been included in the section of the guideline on the delivery of treatments, to remind healthcare professionals to consider the care of these women separately.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

785	SH	Practice Plus Group	Visual Summary	General	General	This is presented as a circle and yet it is a linear model so there is no sense in it being a circle as one doesn't move from the last step back to the first.	Thank you for your comment. The visual summary does not create a complete circle and the interventions are arranged in order of effectiveness and cost-effectiveness, and represent first-line treatment so there is no expectation that people would move around the listed treatments in a step-wise fashion.
786	SH	UK Mindfulness Centres Collaboration	visual summary	General	General	We like the visual summary but do not support the idea of moving round the circle when 'people have no preferences' for three reasons: 1) in our view people with sufficient information and explanation will always have preferences; 2) we are not convinced that there is sufficiently robust evidence to reliably rank the interventions according to effectiveness; 3) the ranking does not take into account 'fit' between the user and the intervention.An additional point is that the circle includes interventions which are at different levels within IAPT provision. For example, guided self-help is at step 2 whereas 1:1 CBT and MBCT are at step 3. This does not fit well with the idea of moving around the circle.	Thank you for your comment. The committee were aware that there may be people who express a preference for 'talking therapy' compared to 'medication' and the table of interventions and the visual summary are designed to aid discussion, take into account people's preferences and facilitate shared decision-making. There is evidence of a differential in the effectiveness and cost-effectiveness of the interventions included to justify their order, but there is also a recognition that people have to use a treatment that is suitable for them, and hence people can start with any treatment and do not have to fail a treatment to try another treatment. The guideline recommendations have been revised to recognise that in practice, it may be appropriate to start people with less severe depression on guided self-help initially, before considering step 3 interventions such as CBT.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

787	SH	LivaNova	Visual Summary	General	General	Given the removal of NICE Pathways1, which currently list Vagus Nerve Stimulation (VNS) under "step 4: complex and severe depression in adults"2, we request clarification on what is to replace this and, if this is to be the visual summary included as part of this draft consultation3, we would request that this is extended to include further stepped treatments to reflect these pathways. Rationale: If the visual summaries that form part of this draft consultation are to replace these pathways, the one for "more severe depression" 3 is much more simplistic as it only focuses on 1st Line treatments. This is not reflective of the available treatment options listed in the current NICE pathway2. We would therefore request that this is extended in line with the current "NICE Pathway", which includes VNS2. References: We are withdrawing our NICE Pathways service | NICE Pathways | Our programmes | What we do | About | NICEStep 4: Complex and severe depression in adults - NICE PathwaysDepression in adults: choosing a first-line treatment for more severe depression (nice.org.uk)	Thank you for your comment. You are correct that NICE pathways are being withdrawn. However, these were intended to guide users to different aspects of NICE guidance and not designed as treatment pathways. However, in response to stakeholder comments, a link to the NICE interventional procedure guidance on Implanted vagus nerve stimulation for treatment-resistant depression has now been included in the depression guideline. The visual summaries (which are now available for first-line and further-line treatment) are not meant to replace the NICE pathways or to act as a treatment pathway, but are meant to assist discussion and shared decision-making about treatment options.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

788	SH	Association for Dance Movement Psychotherapy UK, British Association of Art Therapists, British Association of Music Therapists and the British Association of Dramatherapists	Visual summary	General	General	These diagrams are very user-friendly. They should include all the arts therapies, given the wealth of evidence for their utility and acceptability, and the need to maximise patient choice.	Thank you for your comment. The visual summaries include all the first-line treatments for less and more severe depression for which evidence of effectiveness and cost-effectiveness was identified and this did not include arts therapies. Art therapy was included in the review protocols for these review questions. However, no eligible studies of art therapy for first-line treatment were identified (only 1 study on art therapy for further-line treatment is included). The committee considered the evidence too limited to make a recommendation.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

789	SH	Sport England	Visual summary	General	General	We feel a ranking approach of intervention options on the treatment wheel undermines true patient choice. We are concerned how a patient will be informed of exercise as a treatment option, particularly should they have no preference or limited understanding of what could be available.We feel the starting point for treatment options should not be the most cost-effective interventions. We suggest a method that starts with understanding patient needs through appropriate questioning and responding with the most relevant treatment option/s would be useful.Evidence suggests that exercise could be a particularly attractive treatment option for those intrinsically motivated by sport and physical activity or have had a previous positive experience of this. There is a strong positive association between internal, motivations and activity levels. For the total population, internal motivations are amongst the biggest drivers of behaviour, with enjoyment being the biggest driver for how active individuals are. For example, 82% of those people who strongly agree that they find exercise enjoyable are active, compared to 65% of those who just agree and 28% of those who strongly disagree (Active Lives Adult Survey. Understanding Behaviour, Sport England, 2019)	Thank you for your comment. The visual summary is designed to supplement the tables of interventions included in the guideline and is arranged in order of effectiveness and cost-effectiveness. Cost-effectiveness is important to the NHS to optimise the use of scarce resources. The visual summary is to aid discussions and shared decision-making between clinicians and people with depression and it is made clear that patient preference should also be taken into consideration when making an individualised choice of treatment. However, the visual summary makes it clear that people starting a first-line treatment for depression can start at any point in the circle and do not have to fail earlier treatments to pass to a later treatment. The tables of interventions and the visual aid include treatments that were shown by the evidence to be effective and cost-effective, and so interventions for which there was not good evidence were not included. For example, the evidence for effectiveness was for structured group exercise and that is why that is included (although an additonal recommendation for less structured physical activity has now been added to the guideline, based on the committee's expertise and stakeholder feedback).

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

790	SH	The Mindfulness Initiative	Visual summary	Gene ral	Gener al	We recommend that rather than ranking treatments, they are presented in a patient information leaflet, with short summaries of each particular type of treatment. This would help overcome the challenges of people not understanding or being told about all the treatment options available to them.The words 'or meditation' should be removed from the reference to 'Group mindfulness or meditation' to avoid conflating different options for people in a way which is likely to lead to decreased effectiveness, confusion, and potential harm from the perspective of the individual choosing which treatment they would like to access.	Thank you for your comment. The visual summary is designed to supplement the tables of interventions included in the guideline, which include more detail about the treatments available. The visual summary is to aid discussions and shared decision-making between clinicians and people with depression and it is made clear that patient preference should also be taken into consideration when making an individualised choice of treatment. Meditation has not been removed from the combined intervention as the data for mindfulness interventions such as mindfulness-based cognitive therapy and more meditation-focused interventions were analysed together.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

791	SH	British Psychological Society	Visual summary	General	General	We suggest the recommendations for less severe depression should include choices of arts therapies, arts on prescription, compassion-focused therapy and yoga, given the evidence listed below: Blomdahl et al. (2018). A manual-based phenomenological art therapy for individuals diagnosed with moderate to severe depression (PATd): A randomized controlled study. Psychiatric Rehabilittion Journal, 41(3), 169-182; Choi et al. (2020). The effects of combining art psychotherapy with pharmacotherapy in treating major depressive disorder: Randomized control study. The Arts in Psychotherapy, 70, ArtID 101689; Ciasca et al. (2018). Art therapy as an adjuvant treatment for depression in elderly women: A randomized controlled trial. Brazilian Journal of Psychiatry, 40(3), 256-263; Nan & Ho (2017). Effects of clay art therapy on adults outpatients with major depressive disorder: A randomized controlled trial. Journal of Affective Disorders, 217, 237-245; Thyme et al. (2007). The outcome of short-term psychodynamic art therapy compared to short-term psychodynamic verbal therapy for depressed women. Psychoanalytic Psychotherapy, 21(3), 250-264. Arts on prescription: All Party Parliamentary Group on Arts, Health and Wellbeing (2017) Creative health: The arts for health and wellbeing, https://www.culturehealthandwellbeing.org.uk/ap	Thank you for your comment. Art therapy was an intervention of interest and is listed in the review protocols. Blomdahl 2018 was identified by the searches but is not included as baseline severity could not be categorised (outcome measure outside protocol MADRS-self-report).This study is listed under excluded studies in Supplement B1. Choi et al. (2020) was not identified by the searches. However, in response to your comment the study has been assessed for eligibility for the further-line treatment review (as all participants receiving pharmacological treatment). However, it does not meet inclusion criteria as participants were not randomised at the point of non-response. This study has now been added to the excluded studies list of Supplement D. Ciasca 2018 was identified by the searches but is not included as the outcome measure is outside protocol (GDS-15). This study is listed under excluded studies in Supplement D. Nan 2017 is included in the further-line treatment review. However, this was the only included study for art therapy, and the

						pg-inquiry/Publications/Creative_Health_Inquiry_Report_2017_-_Second_Edition.pdf Compassion focused therapy: Craig, C. (2020) Compassion focused therapy: a systematic review of its effectiveness and acceptability in clinical populations. Expert Review of Neurotherapeutics, 20(4) ISSN: 1473-7175 Online ISSN: 1744-8360 Prathikanti S, Rivera R, Cochran A, Tungol JG, Fayazmanesh N & Weinmann E (2017). Treating major depression with yoga: A prospective, randomized, controlled pilot trial. PLOS ONE, March 16, https://doi.org/10.1371/journal.pone.0173869	committee considered the evidence too limited to make a recommendation. Thyme 2007 was identified by the searches but is not included in the first-line treatment review as less than 80% of partipants had non-chronic depression (64% diagnosed with dysthymic disorder). This study is listed under excluded studies in Supplement B1. The Arts on prescription: All Party Parliamentary Group on Arts, Health and Wellbeing (2017) citation was not considered by the committee as it does not meet study design eligibility criteria. The committee did not consider compassion focused therapy to be an intervention that is in regular clinical use for the treatment of depression. Therefore these interventions were not specified in any of the review protocols and consequently the systematic review that you cite (Craig 2020) would not have met the inclusion criteria for the reviews. As such the evidence on compassion focused therapy has not been appraised and the committee were not able to make any recommendations. Yoga was an intervention of interest and is listed in the review protocols. Prathikanti 2017 is

							included in the NMA for the first-line treatment of less severe depression. However, the committee considered the evidence too limited to make a recommendation for yoga.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

792	SH	British Psychological Society	Visual summary	General	General	We suggest the recommendations for more severe depression should include choices of arts therapies, arts on prescription and compassion-focused therapy, given the evidence listed below: Blomdahl et al. (2018). A manual-based phenomenological art therapy for individuals diagnosed with moderate to severe depression (PATd): A randomized controlled study. Psychiatric Rehabilittion Journal, 41(3), 169-182; Choi et al. (2020). The effects of combining art psychotherapy with pharmacotherapy in treating major depressive disorder: Randomized control study. The Arts in Psychotherapy, 70, ArtID 101689; Ciasca et al. (2018). Art therapy as an adjuvant treatment for depression in elderly women: A randomized controlled trial. Brazilian Journal of Psychiatry, 40(3), 256-263; Nan & Ho (2017). Effects of clay art therapy on adults outpatients with major depressive disorder: A randomized controlled trial. Journal of Affective Disorders, 217, 237-245; Thyme et al. (2007). The outcome of short-term psychodynamic art therapy compared to short-term psychodynamic verbal therapy for depressed women. Psychoanalytic Psychotherapy, 21(3), 250-264. Arts on prescription: All Party Parliamentary Group on Arts, Health and Wellbeing (2017) Creative health: The arts for health and wellbeing, https://www.culturehealthandwellbeing.org.uk/ap	Thank you for your comment. Art therapy was an intervention of interest and is listed in the review protocols. Blomdahl 2018 was identified by the searches but is not included as baseline severity could not be categorised (outcome measure outside protocol MADRS-self-report).This study is listed under excluded studies in Supplement B1. Choi et al. (2020) was not identified by the searches. However, in response to your comment the study has been assessed for eligibility for the further-line treatment review (as all participants receiving pharmacological treatment). However, it does not meet inclusion criteria as participants were not randomised at the point of non-response. This study has now been added to the excluded studies list of Supplement D. Ciasca 2018 was identified by the searches but is not included as the outcome measure is outside protocol (GDS-15). This study is listed under excluded studies in Supplement D. Nan 2017 is included in the further-line treatment review. However, this was the only included study for art therapy, and the

						pg-inquiry/Publications/Creative_Health_Inquiry_Report_2017_-_Second_Edition.pdf Compassion focused therapy: Craig, C. (2020) Compassion focused therapy: a systematic review of its effectiveness and acceptability in clinical populations. Expert Review of Neurotherapeutics, 20(4) ISSN: 1473-7175 Online ISSN: 1744-8360	committee considered the evidence too limited to make a recommendation. Thyme 2007 was identified by the searches but is not included in the first-line treatment review as less than 80% of partipants had non-chronic depression (64% diagnosed with dysthymic disorder). This study is listed under excluded studies in Supplement B1. The Arts on prescription: All Party Parliamentary Group on Arts, Health and Wellbeing (2017) citation was not considered by the committee as it does not meet study design eligibility criteria. The committee did not consider compassion focused therapy to be an intervention that is in regular clinical use for the treatment of depression. Therefore these interventions were not specified in any of the review protocols and consequently the systematic review that you cite (Craig 2020) would not have met the inclusion criteria for the reviews. As such the evidence on compassion focused therapy has not been appraised and the committee were not able to make any recommendations. Yoga was an intervention of interest and is listed in the review protocols. Prathikanti 2017 is

							included in the NMA for the first-line treatment of less severe depression. However, the committee considered the evidence too limited to make a recommendation for yoga.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

793	Individual	Individual 10	Visual summary	1	General	Please consider including couple therapy for depression in this summary of first line treatments for more severe depression. There is robust evidence that is an effective treatment for depression for people who are in either distressed or non-distressed relationships.	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA). The committee did not consider it appropriate to include behavioural couples therapy in the tables or visual summaries of treatment options in the guideline as the evidence and recommendation for behavioural couples therapy was for a subgroup of people with depression, unlike the other interventions listed in these tables/visual summaries.
794	Individual	Individual 10	Visual summary	1	General	Please consider including couple therapy for depression in this summary of first line treatments for more severe depression. There is robust evidence that is an effective treatment for depression for people who are in either distressed or non-distressed relationships.	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA). The committee did not consider it appropriate to include behavioural couples therapy in the tables or visual summaries of

							treatment options in the guideline as the evidence and recommendation for behavioural couples therapy was for a subgroup of people with depression, unlike the other interventions listed in these tables/visual summaries.
795	SH	Insight Healthcare	Visual Summary	1	General	We are concerned about the evidence base singling out counselling as the only therapeutic intervention that is recommended after anti-depressants for low to moderate depression. There is a significant piece of research by BACP suggesting it is equally as effective as CBT for depression.	Thank you for your comment. Counselling was found to less cost-effective in the large network meta-analysis than other treatment options and that is reflected by its place in the treatment choices table.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

796	SH	UK University Mindfulness Centres	Visual summary	27	Table 1	We suggest that it is not possible to directly compare the effectiveness of different interventions without head-to-head trials, which are generally lacking, and therefore placing interventions in order of effectiveness is not meaningful. We appreciate that Network Meta-Analysis attempts to address this issue however there are substantial differences in trial quality (which is inversely associated with effect size), population and setting in the studies contributing to the decision wheel and comparing interventions by effect size is not reliable. As an alternative we suggest that the interventions listed on the decision wheel are presented as a list of options with equal weighting and that service users are supported to make an informed choice from this list. To facilitate this, we wonder if the committee might consider publishing a document providing a brief description of each intervention for service users. If this is something that the committee would like to consider, we would be happy to help draft a section describing MBCT.	Thank you for your comment. NMA was the main method used to synthesise evidence on pharmacological, psychological, physical and combined interventions in order to allow simultaneous estimation of the relative effectiveness, acceptability and tolerability across all treatments for a new episode of less severe or more severe depression. This is in line with the NICE Guidelines Manual, according to which "when multiple competing options are being appraised, a network meta-analysis should be considered". An important advantage of NMA over pairwise meta-analysis is that it allows estimation of effect between treatments that have not been directly compared in a head-to-head comparison, via indirect comparisons. This is essential in order to estimate the relative effectiveness of all pairs of treatments assessed in the review. It also allows simultaneous comparison of the effects and ranking of all treatments. This approach was also necessary in order to inform the economic model so as to concurrently assess the relative cost-effectiveness across the whole range of effective treatments for a new episode of depression. The committee acknowledged that there were differences in trial quality, but noted that these would also impact on the results of pairwise

							meta-analysis, if this was selected as the primary method of analysis, as these limitations characterise the dataset rather than the type of analysis employed. The committee considered the limitations in the evidence base when making recommendations. Moreover, in the context of the NMA, a number of sensitivity analyses were conducted, to assess the robustness of the results under potential bias and issues with transitivity: bias-adjusted analyses were undertaken, which assessed potential bias associated with small study size. In addition, in response analyses, the impact of excluding (small) studies with <15 participants in any arm, as well as studies with contribution to the residual deviance of >5 points, was examined (the latter were excluded in this sensitivity analysis because differences of >5 points were considered important and suggested misfit - Spiegelhalter et al., Journal of the Royal Statistical Society 2002; B 64,583-616). This resulted in several classes and interventions being excluded from analysis as these were only informed by very small studies. Although the random effects NMA model was a better fit for these data and heterogeneity was considerably lower, there were no substantial changes in treatment efficacy. Moreover, for the SMD outcome, a non-pharmacological subgroup of

							the overall dataset was analysed separately as a further sensitivity analysis, to explore whether transitivity issues between pharmacological and non-pharmacological trials might have impacted on the results of the NMA. Finally, for the SMD outcome, a sub-group analysis including only studies at low risk of bias for the attrition domain in the RoB tool has now been conducted and described in Evidence review B. The committee took into account the results of these additional analyses when making recommendations. When assessing clinical effectiveness, the committee considered the results of the NMA, the volume of the evidence base of each treatment, and the results of pairwise meta-analysis. The committee also considered the cost-effectiveness results and other factors such as availability of treatments and the structure of IAPT services. Interventions are arranged in Tables 1 and 2 of the guideline in the suggested order in which options should be considered, based on the committee's interpretation of their clinical and cost effectiveness and consideration of implementation factors. However, this is not a rigid hierarchy, all treatments included in Tables 1 and 2 can be used as first-line treatments, and it may be appropriate to recommend an

							intervention from lower down in the table where this best matches the person's preferences and clinical needs. The committee were aware of the need to provide a wide range of interventions to take into account individual needs and allow patient choice. However, the committee did not consider it appropriate to provide a list of options with equal weighting as this would not accurately reflect the evidence base (which suggested differences in clinical and cost-effectiveness across interventions), nor serve as a guide to choice for those who do not have pre-existing preferences. The visual summary is intended to be used in conjunction with the Tables in the guideline which contain details of each intervention (including MBCT), and so these have not been repeated in the visual summary.

797	Individual	Individual 4	Visual Summary – Less severe	General	General	This suggests that for the less severe depression beginning discussion with depressed clients by asking them to consider group interventions. No account has been taken of what happens in routine practice when group treatments are offered, see Scott and Stradling (1990) and detailed further on Group CBT (2011) published by Routledge. There is an inherent obstacle to overcome in discussing group interventions at the start of contact and the marketing of group interventions is by no means easy. However, the hurdles can be negotiated to a degree by offering a blend of individual and group CBT, weighted to the latter. Without due care, the marketing of group interventions at the outset could simply be alienating. The Proposed Guidance makes no distinction between efficacy trials and effectiveness studies, it is the latter that have salience for implementation. The Guidance is a product of a top-down analysis of studies, rather than a bottom-up process in which clients are asked whether treatment made a difference they care about and the questions are posed in the setting of a non-research centre.	Thank you for your comment. Group interventions were likely to be a more cost-effective option for the treatment of less severe depression compared to individual therapies and so were recommended in preference to individual therapy, but if group therapy is not preferred, then the visual summary makes it clear that individual therapy can be an option. The guideline was developed by taking into consideration the clinical and cost-effectiveness evidence, patient choice, and the views of lay members and stakeholders.

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

798	Individual	Individual 10	Visual summary – less severe depression	1	General	Please consider including couple therapy for depression in this summary of first line treatments for less severe depression. There is robust evidence that is an effective treatment for depression for people who are in either distressed or non-distressed relationships.	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA). The committee did not consider it appropriate to include behavioural couples therapy in the tables or visual summaries of treatment options in the guideline as the evidence and recommendation for behavioural couples therapy was for a subgroup of people with depression, unlike the other interventions listed in these tables/visual summaries.
799	Individual	Individual 10	Visual summary – less severe depression	1	General	Please consider including couple therapy for depression in this summary of first line treatments for less severe depression. There is robust evidence that is an effective treatment for depression for people who are in either distressed or non-distressed relationships.	Thank you for your comment. As pre-specified in the review protocol, the committee identified couple interventions, including behavioural couples therapy, as interventions that would be more appropriate for subgroups of adults with depression (for people with problems in the relationship with their partner) and as such these interventions were considered only in pairwise comparisons (and not included in the NMA). The committee did not consider it appropriate to include behavioural couples therapy in the tables or visual summaries of

Depression in adults: treatment and management
Consultation on draft guideline - Stakeholder comments table

23 November 2021 - 12 January 2022

							treatment options in the guideline as the evidence and recommendation for behavioural couples therapy was for a subgroup of people with depression, unlike the other interventions listed in these tables/visual summaries.