NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical Technologies Evaluation Programme

Digitally enabled therapies for adults with depression
Final scope

November 2022

1 Introduction

The topic has been identified by NICE for consideration for early value assessment (EVA). The objective of EVA is to identify promising technologies in health and social care where there is greatest need and enable earlier conditional access while informing further evidence generation. The evidence developed will demonstrate if the expected benefits of the technologies are realised and inform a final NICE evaluation and decision on the routine use of the technology in the NHS.

NICE's topic selection oversight panel ratified digitally enabled therapies for depression in adults as potentially suitable for an EVA by the medical technologies evaluation programme (MTEP).

A list of abbreviations is provided in appendix A.

2 Description of the technologies

This section describes the properties of the digital technologies based on information provided to NICE by manufacturers and experts and information available in the public domain. NICE has not carried out an independent evaluation of this description.

2.1 Purpose of the medical technologies

Depressive disorders are very common and are among the leading causes of disability worldwide. In people aged 18 to 44 years, depression is the leading cause of disability and premature death (NICE clinical knowledge summary, 2022).

Improving and widening services for mental health is a commitment of the NHS (NHS Long Term Plan). The Five Year Forward View for Mental Health and Long Term Plan states that IAPT services need to increase access to support so at least 25% of people (or 1.5 million) with common mental health conditions access services each year and that 75% of people need to access treatment within a 6 week waiting time by 2020/21.

In the annual report on the use of Improving access to psychological therapies (IAPT) services in England 2021/22, there were 1.81 million referrals to IAPT services between April 2021 to March 2022. Of these, only 37% completed a course of treatment showing a substantial gap between the number of people referred and the number of people starting treatment (House of Commons library 2021, Nuffield Trust 2022). This may be for many reasons including IAPT therapies not being suitable for a person's level of risk or impairment. Waiting times for NHS psychological therapy vary from 4 days to 86 days in different parts of England (House of Commons library 2021).

Digitally enabled therapies are a treatment option for adults with depression. They can be delivered online or through apps and allow people to self-manage their mental health condition with varying levels of practitioner support. These therapies generally include modules for the person to work through in their own time. Some can also monitor a person's progress through self-report questionnaires.

Digitally enabled therapies may offer greater flexibility, more choice and self-management through remote interventions. They may also help to increase access and reduce waiting lists by improving productivity in care provision. For example, therapist time may be saved as much of the clinical content is presented through digital self-study modules, backed up by weekly remote discussions with the therapist.

2.2 Product properties

NICE's clinical guideline on depression in adults: treatment and management states that guided self-help may include materials based on structured CBT, problem solving, psychoeducation and behavioural activation delivered face-

to-face or by telephone or online. It can be delivered with support from a trained practitioner who facilitates the self-help intervention, encourages completion and reviews progress and outcomes and usually consists of 6 to 8 structured regular sessions.

This scope focuses on digitally enabled therapies for treating and managing depression in adults. Digitally enabled therapies are products that deliver a substantial portion of therapy through its content but are designed to be used with practitioner or therapist support. The draft IAPT assessment criteria for digitally enabled therapies defines this as technology use based on practitioner or therapist review of a patient's progress along with regular (weekly or biweekly) interactions with the patient about their progress. The assistance will also help people deepen their understanding of the intervention materials, support them in setting goals and provide advice on real world assignment.

For this EVA, NICE will consider digitally enabled therapies that:

- are intended for use by adults
- deliver a therapeutic intervention in line with NICE guidelines that can be used in IAPT services with practitioner or therapist support
- deliver a substantial portion of the therapy through the technology rather than being platforms to support teletherapy
- meet the standards within the digital technology assessment criteria (DTAC), including the criteria to have a CE or UKCA mark where required. Products may also be considered if they are actively working towards required CE or UKCA mark and meet all other standards within the DTAC.
- are available for use in the NHS.

Technologies included in this EVA are also expected to complete the IAPT Digitally Enabled Therapies (DET) assessment criteria at an appropriate point. This includes validation of clinical content in line with NICE guidelines and light-touch assessment of clinical effectiveness, to ensure the product meets baseline standards for use in IAPT. The status of each product against the IAPT DET assessment criteria will be included in the EVA.

In total, 6 digitally enabled therapies for adults with depression are included in the scope. The final list of included technologies may be subject to change.

Space from Depression (SilverCloud):

Space from Depression is an online CBT programme for adults with low mood and depression. It aims to teach users skills and strategies to manage depression. The programme comprises of modules that contain quizzes, videos, information, personal stories, interactive activities, homework suggestions and summaries. In addition, the interventions incorporate mindfulness tools and resources, positive psychology, and motivational interviewing techniques. It can be used as a supported or a self-guided programme within IAPT services. Practitioners or therapists can guide people through the programme using built-in messaging within the platform. SilverCloud recommends that all programmes are used with a supporter who regularly reviews progress, provides feedback and unlocks content. Silvercloud has other programmes which can be used for a range of other mental health conditions, including a programme for anxiety and depression combined. However, experts state that the programmes for individual indications are primarily used in IAPT services. SilverCloud has screening tools incorporated into the programme, including the PHQ-9, which can be used to flag risk and send risk alert emails to the user's supporter or relevant members of the care team. Programmes can be accessed at any time using any smartphone, tablet, or computer.

Minddistrict (Minddistrict):

Minddistrict is an online CBT programme intended for treating psychological health conditions, including mild-to-moderate depression. It has a catalogue of modules, diaries, and questionnaires that can be combined and edited to suit the needs of each person. These include modules on mindfulness and self-help short courses that support everyday issues. Minddistrict can be used as a standalone self-help tool or in a therapist-guided model of care, which allows practitioners to use video calling within the platform. The company state that the IAPT depression module has been designed to treat mild-to-

moderate depression in adults. This consists of 7 sessions that are usually completed in 6 weeks. In this IAPT version, the Minimum Data Set is included in the module, with the PHQ-9 questionnaire included to allow services to automatically collect outcomes. The technology can be accessed via a web browser and there is also a smartphone app.

Beating the blues (365 Health Solutions Ltd.):

Beating the Blues is an online CBT program for individuals with mild to moderate depression and anxiety. Each of the 8 sessions comprise 3 or 4 modules each taking 10 to 15 minutes to complete. The sessions contain both reading material and practical hands-on tools and lasts 8 to 12 weeks. It can be used according to the user's preferences with any computer, laptop, smartphone or tablet with internet access.

Deprexis (Ethypharm Digital Therapy):

Deprexis is a web-based program based on elements from CBT intended to help those with unipolar depression or depressive disorders. It is intended to be used as a supplement to care-as-usual. Deprexis integrates 10 modules on topics related to depression. During these modules, the technology adapts its approach according to the needs and preferences of the user. Worksheets, exercises, audio sequences, short texts and illustrations are also available to in order to guide people through the program. It can be used according to the user's preferences with any computer, laptop, smartphone or tablet with internet access. Progress can be tracked using the PHQ-9 questionnaire and moodcheck (to monitor mood). These questionnaires (in addition to progression charts) can then be downloaded to be shared with a healthcare professional.

Wysa (Wysa Ltd.):

Wysa is an artificial intelligence-based app for people with mild to moderate depression and anxiety. It has a collection of CBT-based self-help programmes that are designed to be used with practitioner or therapist support. This includes a web-based therapist companion portal that lets

practitioners and therapists review a person's engagement and recommend programmes. Wysa has an AI-guided chatbot that uses natural language processing to encourage self-reflection and help users engage with the mental health tools. It has built in mental health assessment which collects outcome data such as the PHQ-9 questionnaire. Wysa includes a risk alert system and pathway that provides grounding exercises, a crisis care plan and crisis numbers for emergency support. In addition to the patient app, Wysa also has a web-based AI-supported e-triage tool that collects data based on questions from the referral form for IAPT services.

Iona Mind (Iona Mind):

Iona Mind is an app-based CBT programme for people with depression or generalised anxiety disorder. It is designed to be used alongside therapist support. It creates personalised support plans to help people achieve their mental health goals through guided exercises and insight into their patterns of thinking. It uses machine learning to anticipate and adapt the programme to a person's needs. Progress can be tracked using screening measures such PHQ-9. It also monitors mood and goal progression. The app additionally has functionality to identify crisis events and provide signposting.

Perspectives (Koa Health):

Perspectives is an app-based CBT programme adults with depression. It is designed to be used alongside therapist support. This includes a web-based admin portal that lets practitioners and therapists review a person's progress. The technology has in-app messaging (asynchronous messaging) for people to communicate with their healthcare provider between follow up appointments. Progress can be tracked using screening measures such as PHQ-9.

3 Target conditions

The target population for this assessment is adults with depression.

Depression is a common mental health problem which can present with a variety of different symptoms. It is characterised by the absence of a positive affect (a loss of interest and enjoyment in ordinary things and experiences), low mood and a range of associated emotional, cognitive, physical and behavioural symptoms.

In ICD-11, depression is defined as the presence of depressed mood or diminished interest in activities occurring most of the day, nearly every day, for at least 2 weeks, accompanied by other symptoms such as:

- reduced ability to concentrate and sustain attention or marked indecisiveness
- beliefs of low self-worth or excessive or inappropriate guilt
- hopelessness about the future
- recurrent thoughts of death or suicidal ideation or evidence of attempted suicide
- significantly disrupted sleep or excessive sleep
- significant changes in appetite or weight
- psychomotor agitation or retardation
- reduced energy or fatigue

Depression severity exists along a continuum and is composed of 3 elements:

- symptoms (which may vary in frequency and intensity)
- duration of the disorder
- the impact on personal and social functioning.

Depression has traditionally been grouped in 4 categories: subthreshold, mild, moderate and severe. NICE's clinical guideline on depression in adults: treatment and management has categorised new episodes of depression as less severe or more severe depression, based on the available evidence on the classification. Less severe depression includes subthreshold and mild depression, and more severe depression encompasses moderate and severe depression.

NICE's clinical guideline on depression in adults: treatment and management states that each year 6% of adults in England will experience an episode of depression and more than 15% of people will experience an episode of depression over the course of their lifetime. For many people the episode will not be severe, but for more than 20% the depression will be more severe and have a significant impact on their daily lives. Recurrence rates are high: there is a 50% chance of recurrence after a first episode, rising to 70% and 90% after a second or third episode, respectively. Women are between 1.5 and 2.5 times more likely to be diagnosed with depression than men. However, although men are less likely to be diagnosed with depression, they are more likely to die by suicide, have higher levels of substance misuse and are less likely to seek help than women. Depression can have a major detrimental effect on a person's personal, social and work life. This places a heavy burden on the person and their carers and dependents, as well as placing considerable demands on the healthcare system. Depression is the leading cause of suicide, accounting for two-thirds of all deaths by suicide.

3.1 Care pathway

NICE's clinical guideline on depression in adults: treatment and management recommends considering a number of factors when considering treatment including:

- assessment of need
- any physical health problems
- any coexisting mental health problems
- factors that would make the person most likely to engage with treatment
- previous treatment history
- barriers to the delivery of treatments because of any disabilities, language or communication difficulties

It also recommends matching the choice of treatment to meet the needs and preferences of the person with depression and use the least intrusive and

most resource efficient treatment that is appropriate for their clinical needs, or one that has worked for them in the past.

For all people with depression having treatment:

- review how well the treatment is working with the person between 2 and 4 weeks after starting treatment
- monitor and evaluate treatment concordance
- monitor for side effects and harms of treatment
- monitor suicidal ideation, particularly in the early weeks of treatment
- consider routine outcome monitoring (using appropriate validated sessional outcome measures, for example PHQ-9) and follow up.

Less severe depression:

The guideline recommends discussing treatment options with people with a new episode of less severe depression and matching their choice of treatment to their clinical needs and preferences. All treatments listed below can be used as first-line treatments, but it is recommended to consider the least intrusive and least resource intensive treatment first (guided self-help):

- Guided self-help
- Group cognitive behavioural therapy (CBT)
- Group behavioural activation (BA)
- Individual CBT
- Individual BA
- Group exercise
- Group mindfulness and meditation
- Interpersonal psychotherapy
- Selective serotonin reuptake inhibitors
- Counselling
- Short-term psychodynamic psychotherapy

The list is arranged in order of the guideline committee's consensus on the average effectiveness and cost effectiveness of the treatments in adults with

less severe depression, with the most effective and cost effective listed at the top. Factors which may promote implementation, such as the use of least intrusive treatments first, have also been taken into account. If a less intrusive treatment has not worked then treatment can then be stepped up to offer other treatment options.

More severe depression:

The guideline recommends discussing treatment options with people with a new episode of less severe depression and matching their choice of treatment to their clinical needs and preferences. All treatments listed below can be used as first-line treatments:

- Combination of individual CBT and an antidepressant
- Individual CBT
- Individual BA
- Antidepressant medication
- Individual problem-solving
- Counselling
- Short-term psychodynamic psychotherapy
- Interpersonal psychotherapy
- Guided self-help
- Group exercise

The list is arranged in order of the guideline committee's consensus on the average effectiveness and cost effectiveness of the treatments (as well as consideration of implementation factors) with the most effective and cost effective listed at the top, but the committee agreed that choice of therapy should be a personalised decision and that some people may prefer to use a treatment further down the list and that this is a valid choice.

The guideline committee note that although guided self-help can be a treatment option for people with severe depression, other treatment choices with more therapist contact should be carefully considered first.

The guideline also states that commissioners and providers of mental health services should consider using models such as stepped care or matched care for organising the delivery of care and treatment of people with depression. The Improving Access to Psychological Therapies (IAPT) programme offers a range of NICE-recommended therapies for depression in line with a stepped-care model, when appropriately indicated. Currently, digitally enabled therapies are primarily used in step 2 of the IAPT programme and are delivered by psychological wellbeing practitioners.

As guided self-help was not listed as a treatment option for preventing relapse, further-line treatment, chronic depressive symptoms, depression in people with a diagnosis of personality disorder or psychotic depression, these are not discussed in this scope.

Potential place of digitally enabled therapies in the care pathway

NICE's clinical guideline on depression in adults: treatment and management recommends guided self-help as an option for treating both less severe and more severe episodes of depression. It should be considered first for most people with less severe depression as it is the least intrusive and least resource intensive treatment for less severe depression. However, guided self-help may not be as appropriate for more severe depression and other treatment choices with more therapist contact should be considered first. The guideline describes guided self-help as less resource intensive for IAPT services to deliver and is likely to be available for people in a timely fashion without the need for a long time on a waiting list.

The IAPT programme was developed to organise and improve the delivery of, and access to, evidence-based psychological therapies within the NHS. It provides support for adults with depression and anxiety disorders. NICE-recommended therapies are delivered by a single clinician, with or without concurrent pharmacological treatment, which is typically managed by the GP.

Here, digitally enabled therapies being considered in an IAPT setting, after an IAPT assessment. Although anyone with depression can be offered a digitally enabled therapy, depression severity, patient preference and risk need to be

considered. These technologies are more likely to be appropriate for those with sub-threshold to moderate depression.

3.2 Patient issues and preferences

Digitally enabled therapies are delivered via mobile phones, tablets, or computers and can therefore be accessed remotely. As there is an increased demand for treatment for depression, but limited capacity within IAPT services, digitally enabled therapies can be used to increase capacity and support because they tend to require less clinical time than alternatives. Digital CBT provides more treatment options, flexible access, greater privacy and anonymity, and increased convenience. They may be particularly appealing to regular users of digital technologies such as smartphones and tablets. However, not everyone who regularly uses digital technologies may prefer this option. Digitally enabled therapies may also allow people to better self-manage their mental health and be more involved in treatment decisions.

Some people may choose not to use digitally enabled therapies and may prefer clinician led treatment, either face-to-face or teletherapy. There may be some concerns about the level of support provided in a digitally enabled therapy and concerns around data security and quality control. People have the right to make informed decisions about their care, including the use of digitally enabled therapies.

The Ofcom Adults' Media Use and Attitudes report states that 6% of households (around 1.7 million) did not have access to the internet at home in December 2021 (Ofcom report, 2022). The groups more likely not to have internet access at home are those aged 75 and over (26%), those in a lower socioeconomic household classification (DE social grade; 14%) and those who are most financially vulnerable (10%). This digital exclusion was due to having no internet at home or elsewhere, a lack the digital skills or confidence to navigate the online environment safely and knowledgeably and being able to afford access to the internet. Digital exclusion would need to be considered when offering access to digital therapies. In addition to this, 21% of internet users access the internet exclusively via a smartphone (Ofcom report, 2022).

There may be concerns around whether technologies are accessible whilst using a smart phone as this may prevent uptake or retention on this therapy option.

4 Comparator

Digitally enabled therapies would be offered as an alternative to existing psychological interventions in IAPT services. Comparators should be based on the other options offered in IAPT services to adults with depression, according to NICE's clinical guideline on depression in adults: treatment and management.

However, comparators in the evidence may not reflect standard care in IAPT services because studies often use waitlist controls rather than psychological interventions. The evidence review may therefore also need to include studies comparing digitally enabled therapies with waitlist, active or attentional controls to determine efficacy and an absence of harm.

5 Scope of the assessment

Table 1 Scope of the assessment

Populations	Adults with depression who have been referred to IAPT services.
Interventions (proposed technologies)	Digitally enabled therapies for facilitating guided self-help in people with depression. These technologies have been designed to be used with support by healthcare professionals: • Beating the Blues • Minddistrict • Space from Depression • Wysa • Deprexis • Iona Mind • Perspectives
Comparator	Standard care according to NICE's clinical guideline on depression in adults: treatment and management The recommended treatment options for less severe depression include: • Guided self-help

	• Group cognitive behavioural therapy (CBT) • Group behavioural activation (BA) • Individual CBT • Individual BA • Group exercise • Group mindfulness and meditation • Interpersonal psychotherapy • Selective serotonin reuptake inhibitors • Counselling • Short-term psychodynamic psychotherapy For more severe depression include: • Combination of individual CBT and an antidepressant • Individual CBT • Individual BA • Antidepressant medication • Individual problem-solving • Counselling • Short-term psychodynamic psychotherapy • Interpersonal psychotherapy • Guided self-help • Group exercise
Healthcare setting	Improving access to psychological therapies (IAPT) services
Outcomes	Intermediate measures for consideration may include: • Patient choice and preferences • Treatment satisfaction and engagement • Intervention adherence and completion • Referral to treatment time • Assessment to treatment time • Intervention-related adverse events • Inaccessibility to intervention (digital inequalities) • Rates of attrition (dropouts) and engagement
	Clinical outcomes for consideration may include: • Change in depression symptoms • Change in other psychological symptoms • Global functioning and work and social adjustment Service level clinical outcomes: • Rates of reliable recovery

	• Rates of reliable improvement • Rates of reliable deterioration • Rates of relapse (including relapse rate and time from remission to relapse)
	Patient-reported outcomes for consideration may include: • Health-related quality of life • Patient experience
	Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration may include: • Costs of the technologies • Cost of other resource use (e.g., associated with managing depression, adverse events, or complications): o GP or IAPT appointments o Medication o Healthcare professional grade and time
Time horizon	The time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.

6 Other issues for consideration

Characteristics of digital technologies

- The digital CBT technologies included in the scope are heterogeneous in terms of delivery mode (computer, app). Two of the technologies (Wysa and Iona Mind) use AI in addition to therapist support.

- Technologies included in this EVA will complete the IAPT DET assessment criteria. This includes validation of clinical content in line with NICE guidelines and assessment of clinical effectiveness. Passing this assessment will be a requirement to proceed to evidence generation stage of the EVA.

Population

- Most technologies are for mild to moderate depression. This spans NICE's clinical guideline on depression in adults definition of less (subthreshold and mild) and more severe (moderate and severe) which have different recommendations. This would need to be a consideration during the evidence review.

- People with depression may also have other mental health problems such as anxiety. IAPT services offer disorder-specific treatments based on a person's main presenting problem. For digitally enabled therapies, this would mean offering a person treatment for a depression rather than a combined programme targeting both depression and anxiety.

Evidence

- This assessment will look across a range of evidence types including RCTs, real world evidence and benchmarking against NHS Digital published metrics. Evidence considered will include evidence of clinical effectiveness, comparative outcomes to alternative treatments offered in IAPT for the relevant clinical condition and absence of harm.

- The amount and level of evidence for each of the technologies varies. Many of the identified technologies have RCT data. Some research studies were conducted in an NHS setting while others were done outside of the UK. Comparators also vary but most often include waitlist control. Study populations are also heterogenous and include people with depression or depression and anxiety. It is likely that the different technologies will require different levels of additional evidence.

- This assessment will evaluate the clinical and potential cost effectiveness of digitally enabled therapies as an alternative to standard care in IAPT services. This will include evaluating whether digitally enabled therapies have equal or superior outcomes to alternative treatments offered in IAPT services for adults with depression.

Care pathway

- Digitally enabled therapies can be used at different points in the care pathway depending on their therapeutic content. This should align with NICE guidelines and should be supported or delivered by healthcare professionals who are appropriately trained in delivering the specific therapy. Treatment selection should be guided by healthcare professional assessment, patient risk, and patient choice.

7 Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Depression is more common in women than in men. Women, people from a White British background or in midlife are more likely than others to receive treatment for a common mental health disorder. Increasing social deprivation is associated with higher prevalence rates of depressive symptoms.

Digital therapies are delivered through a mobile phone, tablet, or computer. People will need regular access to a device with internet access to use the technologies. Additional support and resources may therefore be needed for people who are unfamiliar with digital technologies, do not have access to smart devices. People with visual, hearing, or cognitive impairment; problems with manual dexterity; a learning disability; or who are unable to read or understand health-related information (including people who cannot read English) may need additional support to use digital therapies. Some people would benefit from digitally enabled therapies in languages other than English. People's ethnic, religious, and cultural background may affect their views of mental health problems and interventions. Healthcare professionals should discuss the language and cultural content of digitally enabled therapies with patients before use.

Age, sex, disability, race, and religion or belief are protected characteristics under the Equality Act 2010.

8 Potential implementation issues

Training

Training is required to facilitate these digitally enabled therapies. Technologies offer training for supporters (such as psychological wellbeing practitioners), are mostly in the form of self-directed training. Time needs to be allocated for the completion of training and supporters need a good understanding of the content available in each technology in order to

appropriately offer modules or resources. The language used in some technologies may not match those used in other therapies, so training may be needed to learn the differences in language use.

Cost

Costs may differ between technologies. Smaller service areas may have higher costs per user due to not needing as many licences for the technology. Digitally enabled therapies may be chosen based on the balance between costs and expected outcomes.

Risk of harm

Digitally enabled therapies must be able to identify potential risks for patients. Initial assessment is important to ensure people get the right care at the right level. Some digitally enabled therapies have inbuilt processes to flag the need for more intervention. This is important to consider when choosing digitally enabled therapies.

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Appendix A Abbreviations

AI	Artificial intelligence
EVA	Early value assessment
CBT	Cognitive behavioural therapy
MTEP	Medical technologies evaluation programme
IAPT	Improving access to psychological therapies
PHQ-9	Patient health questionnaire-9
DET	Digitally enabled therapies
DTAC	Digital technology assessment criteria