NICE National Institute for Health and Care Excellence

Behaviour change: digital and mobile health interventions

Consultation on draft guideline - Stakeholder comments table
24/01/2020 to 06/03/2020

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Action on Smoking and Health (ASH)	Guideline	General	General	ASH endorses Cancer Research UK's response to this consultation, which has been drawn on in the development of this response. ASH's response to this consultation will be restricted in scope to the use of digital and mobile interventions for smoking. ASH welcomes the proposed guidelines that digital and mobile health interventions be considered as a supplement, not a replacement, to existing services. This message reflects and communicates the evidence base for digital and mobile interventions for smoking, which is currently limited. The evidence base for smoking cessation interventions and services, including behavioural support, brief interventions and pharmacotherapy, is strong and well established, as acknowledge by NICE guidance.[i] Someone who smokes is 3 times more likely to quit with the combination of behavioural support and pharmacotherapy provided by stop smoking services.[ii] It is important that commissioners are made explicitly aware of this and that digital and mobile interventions should not supplant or be given precedence over these well-evidenced interventions. Recommendations 1.2.2, 1.3.4 and 1.5 are welcomed in the guidelines for making this explicit.	Thank you for your comment, and the support for the recommendations highlighted in the comment. Weak recommendations were made for digital and mobile health interventions so it is clear that they are options, and not necessities for behaviour change. The committee understood that for some people, a digital or mobile health intervention may help with their health behaviours, but that it would not suit everyone. In addition, the vast majority of people who choose to use a digital or mobile health interventions should use them as an adjunct to existing services the person may use. As detailed in the rationale for section 1.3, a small minority of people may benefit from only using a digital or mobile intervention, but this should only be decided on individual circumstances and if existing services are not suitable for the person and their lifestyle. The committee considered the suggestion for explicitly excluding interventions developed or funded by the tobacco industry and agreed it was an important recommendation to make. It also agrees with Developing NICE guidelines: the manual and is in line with WHO policy on tobacco products. Section 1.5 now includes the recommendation "Do not offer digital and mobile health interventions that are funded or developed by the tobacco industry."

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				However, digital and mobile interventions have the potential to more widely communicate available support, to improve access to existing evidence-based support and to work as a supplement to existing, evidence-based support. Seeing these services commissioned as an addition to established and evidence-based interventions could therefore be a welcome measure. It is important that only evidenced and established mobile and digital interventions capable of appropriately meeting local needs in an equitable way are commissioned and developed – ASH welcomes the provisions made to ensure this in the draft guideline. As mentioned below (comment 5), the guideline should include an explicit reference to excluding the tobacco industry in the development and commissioning of mobile and digital interventions, in line with the UK's legal obligation under Article 5.3 of the World Health Organization Framework Convention on Tobacco Control.	
Action on Smoking and Health (ASH)	Guideline	004 - 005	018 - 009	ASH welcomes the recommendation that intended users should be involved in the development of interventions from the earliest possible stage. This is particularly important for ensuring digital and mobile interventions have an equity positive impact, as evidenced by the intervention StopAdvisor which is one of the few	Thank you for your comment. Involving users from specific groups may improve outcomes in that group. This is why there are recommendations to encourage innovation and

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				examples of a digital intervention for smoking cessation having an equity positive impact (having a greater positive effect among participants from low socio-economic status (SES) groups than among participants in high SES groups).[iii] The development of the StopAdvisor intervention specifically involved input from disadvantaged smokers and the intervention was tailored to have a greater impact among smokers from low SES groups. That the intervention was successful in its aim demonstrates the importance of involving the intended users in the development process.	development of interventions that are for specific populations. The StopAdvisor intervention is tested in Brown 2014, which is included in evidence review 1: smoking.
Action on Smoking and Health (ASH)	Guideline	005	010 - 025	As above, ASH welcomes the explicit statement that digital and mobile health interventions be commissioned "as a supplement to existing services, not as a replacement". ASH also welcomes the recommendation to ensure any commissioned interventions meets current frameworks, as Cancer Research UK states in its response, this will help to build the evidence base and allow the most clinically effective options to emerge, ensuring a convergence to best practice nationally in the use of digital and mobile interventions, as opposed to a disparate and fragmented landscape of varying interventions.	Thank you for your comment. The committee agrees with the comment and that the recommended frameworks should be followed.

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				Particularly important is the recommendation made in 1.2.5 (lines 24-25) that expert sources be checked for existing interventions before new interventions are commissioned or developed. Stop smoking services across England are already using and have developed mobile apps to support services, we should be building on the evidence and examples already available. If followed, this recommendation, in addition to recommendation 1.1.2 and 1.1.3 (page 4, lines 7-15), should prevent misallocation of resources and direct commissioners to existing interventions, thereby buoying the evidence base and contributing to a more uniform digital and mobile intervention commissioning landscape, as described above.	
Action on Smoking and Health (ASH)	Guideline	006	005 - 012	ASH strongly supports this recommendation. There is a lack of evidence on the equity impact of digital interventions, however, where an equity impact assessment has been possible, results have been variably positive and negative.[iv] Examples of factors which can contribute to the positive equity impact of studies include matching support to the user's reading level (a consideration acknowledged in the draft guideline),[v] demonstrating that a failure to give consideration to equity impact can exacerbate inequalities or that, on a more positive reading, giving adequate consideration to equity impact has the potential to reduce inequalities.	Thank you for your comment. It is one of NICE's aims to mitigate inequalities in any guidance it produces. The committee agreed that not only should interventions be accessible to as many people as possible, there will be situations where an intervention cannot serve every group. Which is one reason why they recommended using an expert source that lists many different interventions, with each one catering for a few groups instead of recommending one intervention that caters to all, which may be difficult to design. In this way, inequalities could be reduced because there will be interventions available that are tailored to different groups. Commissioners have been asked to consider equity of access, such as sensory

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				Digital interventions clearly can have an equity positive impact, most clearly demonstrated for smoking cessation support by a study of the internet-based intervention StopAdvisor.[iii] It's also clear that digital and mobile interventions can be targeted for greater uptake among groups where smoking rates are particularly high and additional support is required, as demonstrated by Tommy's Baby Buddy app where young women are over-represented in the user population (where support is most needed).[vi] As, therefore, we know it makes a difference, it is important that equity impact be given high priority in decisions regarding the commissioning of support to ensure already wide inequalities in smoking rates and health are eliminated, not exacerbated. As rightly noted by Cancer Research UK, commissioners should always endeavour to ensure that digital and mobile-based interventions are as universally accessible as possible (linguistically or otherwise), available at no cost to the user and, where possible, do not require extended internet connection.	impairments and literacy, when conducting impact assessments. If multiple interventions need to be chosen to cover these, the EIA for the guideline says that multiple interventions can be commissioned to maximise access. StopAdvisor is assessed in the study by Brown et al. 2014, which is included in evidence review 1: smoking.
Action on Smoking and Health (ASH)	Guideline	007	001 - 010	ASH strongly recommends the guidance include the requirement for digital and mobile interventions commissioned or developed by local services and authorities to be completely independent of the tobacco industry.	Thank you for your comment. The UK Government is a signatory and party to the WHO Framework Convention on Tobacco Control (FCTC). As an Arm's Length Body of Government, NICE has an obligation under Article 5.3 of the FCTC to protect

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				As a signatory to the World Health Organization Framework Convention on Tobacco Control (FCTC) the UK has a legal obligation to meet all articles of the convention, including Article 5.3 which requires that "in setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law".[vii] The tobacco industry has frequently tried to influence the tobacco control work of local authorities in England, and clearly has an interest in public consumption of its own digital interventions and applications, as demonstrated by Philip Morris' 'Hold My Light' website,[viii] which encourages users to create profiles and switch to its heated-tobacco IQOS product. It is important that in commissioning and developing mobile and digital interventions intended to support people who smoke to quit, the tobacco industry is not allowed any space for influence, directly or indirectly, to ensure that the public health aims of these interventions are not corrupted by or supplanted for commercial ones.	public health policies from the commercial and other vested interests of the tobacco industry. We have added a recommendation that reads "Do not offer digital and mobile health interventions that are funded by the tobacco industry."
AGILE	Guideline	General	General	Questions asked to consider in the consultation process:	Thank you for your comment. The NICE evidence standards framework for digital health interventions recommended in 1.1.1 says

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				Q1 - Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. Opportunity for digital tech to inform public health interventions and whole system commissioning decisions via big data at population level has potential for greatest impact but challenging in context of IG/GDPR consent etc. An example of how this could be impactful at a population level could be the opportunity to monitor smoking, physical activity levels and/or evaluate using QOL measures over time would provide longitudinal data which could aid risk stratification and decision making as to where to target/allocate resources to address ill health. Q2 - Would implementation of any of the draft recommendations have significant cost implications? Yes, across the board if the need is to design new technologies – we already know there is significant investment in research and tech companies to develop innovation and tools to support population health (I'd be interested to know how much) and yet this evidence coming out in this guideline is limited and suggests inappropriate investment in the wrong digital tech (ie over and above reputable /endorsed tools) and/or the evaluation of these technologies is poor and/or spread and scale up is limited by costs/IT platform capability (e..g cant host	interventions should be designed to allow continual outcome data retrieval from consenting users. It also says that developers need to measure the economic impact and effectiveness of these interventions. After reviewing consultation comments, recommendations have been added asking developers to use the NICE evidence standards framework for digital technologies evidence standards framework to test how effective and engaging it is for a wide range of people from the target population and to use feedback from testing and after releasing the intervention to continually improve the intervention The committee considered expert testimony that said there was a lot of innovation and development of new digital and mobile health technologies. But, issues arose with insufficient testing of products that makes it difficult to know which products and components of products are effective. This is why the committee made recommendations in section 1.1 that would guide developers when making and testing new products. This should expand the evidence base and the understanding of how these products work, without increasing the expenditure of designing products too greatly. The NHS Apps Library is recommended as a resource for digital interventions in the guideline (recommendation 1.3.3).

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				multiple users at once to support population level scale up). Q3 - What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) I think a repository of the 'reputable/recommended national resources would be useful and would support spread of effectively evaluated high quality tools – scope for these to be adapted to local needs would cheaper than starting from scratch, I think examples which draw on how co-production has resulted in the output of an effective technology also meaningful And examples which reflect the different approaches to design and co-production which might be taken for different populations e.g. LD versus MCI versus visual impairment versus hard to reach groups/IT literacy issues Need to draw out role for asset-based community design in implementation of these technologies e.g. use of community/VSC and peers to support upskilling populations to use digital tech.	
AGILE	Guideline	General	General	The COM-B behaviour change model referred to in the guideline but nil else. Is there a reason for this? What about the theoretical domains framework (TDF) as wouldn't this framework be instrumental in informing the design of a behaviour change technology i.e. if can understand the barriers to change in context of	Thank you for your comment. The COM-B model was used to inform related guideline Behaviour

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				the behaviour, then can target these using the evidence based interventions most appropriate to the barrier(s) identified i.e. information alone is not sufficient to change behaviour. Information/evidence on the TDF and/or other frameworks for BC and examples showing how they can be used to support the development of effective and tested digital technologies could add value.	change: individual approaches (PH49), to which this guideline is aligned. Data was extracted for each study on the Behaviour Change Technique Taxonomy listed in the reference below. Michie et al, The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions, Annals of Behavioral Medicine, Volume 46, Issue 1, August 2013, Pages 81–95, https://doi.org/10.1007/s12160-013-9486-6"
AGILE	Guideline	005	001 - 009	User acceptability – need examples to reflect the need to use different approaches for different populations, e.g, teenagers versus older people. Particularly need to consider user acceptability in the older population considering many are not IT literate and/or may not have access to digital technologies to allow these to be used to support behaviour change (as is alluded to in the commissioning section on page 6, lines 5-12. Is there a section which explores the evidence base and recommendations or future research needs in order to better optimise digital technology use with older people?	Thank you for your comment. User testing for all groups to get their views and experiences is important. Our literature searches did not find any evidence specifically looking at use of digital interventions in older people. Expert testimony described to the committee that older people generally use these interventions as well as or better than younger people. The committee discussed and agreed that specific recommendations would not be developed for older age groups. The committee made a research recommendations around engaging people who do not traditionally engage with these type of interventions, on the most effective components and combinations of components of digital and mobile health intervention, and on the sustainability of behaviour change over the long-term. These research

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					recommendations include age as a specific consideration. The recommendations note that when discussing the interventions with individuals the factors that may contribute to digital exclusion, such as digital and other literacy, possible costs and opportunity for change should be discussed.
AGILE	Guideline	005	016 - 017	Commissioning digital technologies – examples of needs assessment tools for different populations could be useful. 'Joint Strategic Needs Assessments' are referred to later (pg 14) – if this is what is being referred to as the 'needs assessment' within this section, then need to be consistent with language used	Thank you for your comment. The committee decided not to use the term 'Joint Strategic Needs Assessment' in the recommendation itself as the terminology may change in the near future, and instead used "needs assessment" which will cover this and other similar assessments.
AGILE	Guideline	006	021	what about capability & capacity of the health care professional in supporting the user to learn how to use a chosen digital platform i.e. if recommending one from a reputable source, do HCPs have the skills, IT equipment and access and more importantly time to show users how to use. Can we make links/draw on evidence on services/commissioners should be tapping into community assets/VSC to support people to use these tools i.e. right care right place right professional??	Thank you for your comment. NICE is not recommending specific digital interventions in this guideline. The referrer should discuss with the person which factors an intervention should contain and the person should find interventions themselves using expert sources. This is because digital intervention content changes frequently, and a suitable intervention may not be suitable in future as it removes a factor or component which is suitable to them. The training of healthcare professionals is outside of the scope of this guideline. Professional bodies usually have a leading role in identifying training needs for their healthcare professionals unless

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					something specific is identified during the development of the guideline.
AGILE	Guideline	007 - 008	General	Diet and physical activity – not sure having these two behaviours together is appropriate. Linked to obesity but not necessarily to mental health/self regulation around eating disorders and over exercise which are the examples used. Could diet be a section in its own right; and also physical activity – as having together suggests the two need to be targeted in combination and this may not be appropriate or feasible. Opportunity exists to support those with abnormal eating disorders/behaviours via unique digital technologies and which may face very different populations; and a physical activity technology might also require a standalone approach +/- could be more straightforward (i.e. be designed at population level relate to national physical activity (PA) guidelines etc.). They (diet and PA) are listed as separate entities later in the guideline on page 21 lines 28-29: I feel this should be reflected in the recommendations section also.	Thank you for your comment. This guideline was developed as an addition to the behaviour change: individual approaches guideline (PH49). To keep these guidelines aligned, diet and physical activity were kept in one review, as in PH49. Many of the interventions considered reported both diet and physical activity outcomes. Therefore, it would be difficult to obtain separate conclusions from the studies for the two behaviours. However, the committee did make one recommendation about not recommending self-monitoring interventions to people with a history of or at risk at developing disordered eating.
AGILE	Guideline	008	003 - 005 - General	'Advise the person that an intervention they interact with multiple times may be better than a one-off intervention, but a one-off intervention is better than no intervention at all' - would this advice not apply to all behaviours and be a function of a digital technology designed to	Thank you for your comment. We found limited evidence for alcohol consumption that interventions people interact with multiple times are more effective at behaviour change than one-off interventions. We did not find this evidence for the other behaviours.

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				address diet, PA, smoking and alcohol consumption?	
AGILE	Guideline	010	024 - 026	Is it worth expanding to give examples of underserved groups e.g. older populations, those with MCI/LD etc.?	Thank you for your comment. The full details of the research recommendation can be found in evidence review 1: smoking. These examples are considered for this research recommendation.
AGILE	Guideline	011	General	Research recommendations – how can digital technologies inform population health improvement i.e. could anonymised data from the software packages contribute to big data and capture health related information to aid population health understanding, stratification and analysis e.g. risk factors for ill health identified to support upstream targeting and early intervention e.g. preventative/proactive frailty systems of care? Or to identify barriers to behaviour change in populations which could, be used to inform local/national policy or commissioning e.g. access to leisure facilities/environment; cost of healthy food etc. Also, is there a research need to identify how digital technology can be used effectively to address social norms, health literacy and the influence of peers etc. e.g. interactive peer support functionality/motivational support and/or buddying etc.?	Thank you for your comment. The NICE evidence standards framework for digital health technologies, recommended in 1.1.1, specifies that outcome data should be collected after the intervention has been released to continually assess the effectiveness of the intervention. Social support is considered in the protocol for research recommendation 2: What components and characteristics of digital and mobile interventions are most effective, separately and combined, to achieve behaviour change? under behaviour change techniques.
AGILE	Guideline	012	General – 001 - 002	'They agreed that more collaboration between developers, stakeholders and potential users would be likely to produce more applicable and	Thank you for your comment. The NICE evidence standards framework outlines how digital interventions should be developed and is

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				engaging interventions' – I feel this recommendation needs to be made more explicit and be emphasised at the offset and directed to all inc developers, commissioners, HCPs and users of any technology. Are there examples of how this has been done effectively/good practice in relation to co-production of digital technologies that can be hyperlinked or a resource bank be signposted to? There is an example but it is very superficial/headlines only – not what was actually undertaken to achieve co-production of an effective end product	recommended in 1.1.1. It can also be used by commissioners, referrers and users to assess if a product is of good quality. The NHS Apps Library is cited as an expert source in 1.3.3. In the framework, tables 3 onwards show minimum evidence standards interventions should adhere to in order to be classified as either tier, 1, 2, 3a or 3b interventions. Involving relevant clinical or social care professionals in the development of the interventions is a minimum evidence standard for tier 1 interventions, which is the lowest tier. Interventions must meet all standards in a tier before being considered for a higher tier meaning all interventions wishing to be considered as good quality interventions must have clinical or social care professional input in development. As the framework goes into detail about digital health interventions should contain and how they should be tested and is linked to in the recommendation.
AGILE	Guideline	014	004 – 007 General	'They agreed that these new technologies should cater for groups and issues that are not covered by existing behaviour change services. For example, by targeting people with learning disabilities, hearing, vision, mobility requirements, neurodevelopmental disorders or cancer' – need to state not an exhaustive list. Other examples could be cognitive impairment, anxiety, depression etc. etc.	Thank you for your comment. We have included the examples you have provided into the guideline. We have kept "for example" to illustrate that this is not an exhaustive list.

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Asthma UK and British Lung Foundation Partnership	Guideline	008	008 - 014	It is important to make clear to health care professionals that digital and mobile health interventions that might help with smoking cessation should only be offered as an addition to other types of evidence-based stop smoking support, as outlined in NG92 (stop smoking interventions and services). It could be helpful to link through to the NG92 guideline in the smoking section of this guideline to make sure that it can be easily accessed by people supporting smokers to quit.	Thank you for your comment. The wording for these recommendations has now been changed to reflect that digital and mobile health are recommended as an adjunct to existing services. The committee have also amended the wording of recommendation 1.5.1 so it says that effectiveness of these interventions is variable. Though the overall effect estimate of the smoking evidence shows in favour of smoking cessation, there is considerable heterogeneity between and within the studies. In addition, most studies did not compare with current usual care. Many studies have very wide confidence intervals that cross the line of no effect. Therefore, it is reasonable to suggest that these interventions would be beneficial to some people and should be made available as an option for behaviour change alongside existing services.
Asthma UK and British Lung Foundation Partnership	Guideline	022	007 - 008	Is there no evidence or basis for digital or mobile health interventions to help support someone who has recently quit smoking? Could digital and mobile tools be equally useful in not just helping people quit but also as a tool to help keep someone motivated and prevent them relapsing?	Thank you for your comment. This could be the case but this guideline is looking at people who would benefit from changing their behaviours and does not cover people who have recently changed their behaviours and want to maintain the change, for example for people who have recently quit smoking. Interventions that are purely to maintain people's behaviour change is out of scope for this guideline.
Asthma UK and British Lung Foundation Partnership	Supporting documentation - Methods	General	General	We believe the inclusion criteria for digital interventions should exclude any products created by the tobacco industry. Health care professionals and people who smoke should not	Thank you for your comment. The consultation process for this guideline is in line with developing NICE guidelines: the manual and the WHO policy on tobacco. A recommendation

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				be recommended products that are owned by the tobacco industry.	against using interventions made or funded by the tobacco industry has been added.
Breaking Free Group	Guideline	004	011 - 015	Recommendation 1.1.3 states that BCTs should be used in reporting and designing interventions, however this contradicts the advice made in the smoking guidance (see our comments in point 19 above).	"Thank you for your comment. The committee noted that BCTs are often not well reported in studies. This is one reason why they recommended developers follow the NICE evidence standards framework for digital interventions. It says developers should use BCTs and report them well when designing and testing interventions. BCTs were not reported well enough for recommendations to be made on their use, but the committee used their expertise and related NICE guidance to recommend interventions should be designed with specific BCTs included. The BCTs highlighted in 1.1.3 should be considered when designing interventions of all behaviours covered in the guideline, including smoking. The smoking section of this guideline does not mention BCTs because there was no evidence that showed other BCTs should be considered as well as those in 1.1.3. This does not mean that they should not be considered for smoking cessation interventions. The BCTs which are mentioned in this guideline result from a theory of how people change behaviour, and not any component associated with bringing about behaviour change. A taxonomy of the specific techniques can be found here: Michie et al, The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered

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					Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions, Annals of Behavioral Medicine, Volume 46, Issue 1, August 2013, Pages 81–95, https://doi.org/10.1007/s12160-013-9486-6"
Breaking Free Group	Guideline	005	008	Please clarify what 'wide range' relates to i.e. sample size calculations may be helpful, or are the committee referring to wider groups within the population such as low SES or vulnerable adults?	Thank you for your comment. A wide range of people means people with different needs, views and experiences. This is likely to include assessing which subgroups exist within the target population and ensuring these are considered by recruiting people from each of these subgroups during development.
Breaking Free Group	Guideline	006	005	Within recommendations 1.2.7, commissioners should also consider data sharing. They should ensure that their service users are protected by interventions being GDPR compliant. Also, commissioners should consider whether they are given anonymised access to data to explore efficacy and engagement with the intervention.	Thank you for your comment. The NICE evidence standards framework for digital health interventions recommended in 1.1.1 says interventions should be designed to allow continual outcome data retrieval from consenting users. It also says that developers need to measure the economic impact and effectiveness of these interventions. GDPR compliance is now a legal requirement for all bodies that handle data.
Breaking Free Group	Guideline	007	002 - 003	Is ORCHA another example of an expert source?	Thank you for your comment. The committee were concerned about the lack of transparency in ORCHA's review process and did not decide to recommend it.
Breaking Free Group	Guideline	007	015 - 022	This guideline does not consider whether interventions could be used in tandem i.e. digital alongside face-to-face support. Although not the purpose of the evidence reviews, several suggestions and assumptions are made about	Thank you for your comment. This guideline assessed interventions that had minimal healthcare professional input and where the professional was not delivering the intervention themselves. The evidence of effectiveness was variable. It was not possible to deduce which digital

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				digital vs offline, none of which reflect the combined utility of these in real world practice.	and mobile health interventions were effective and in whom. But the committee were aware that other, well-established interventions should not be replaced with digital. As a result, the committee recommended that digital interventions should be an adjunct not a replacement for existing services.
Breaking Free Group	Guideline	008	009 – 011	We disagree with the committee's conclusion that it is not clear whether digital and mobile smoking interventions are effective – at multiple points in the evidence review the committee conclude that there was in facct evidence that such interventions, regardless of modality, can be effective at up to at least 6-months follow-up, and for some interventions, at 12-months follow-up (see our comments in points 14, 15, 16 and 20 above).	Thank you for your comment. After revisiting the evidence, the wording for these recommendations has now been changed to reflect that people should be referred to these interventions as an adjunct to existing services. The committee have also amended the wording of recommendation 1.5.1 so it says that effectiveness of these interventions is variable. Though the overall effect estimate of the smoking evidence shows in favour of smoking cessation, there is considerable heterogeneity between and within the studies. Many studies have very wide confidence intervals that cross the line of no effect. In addition, most studies did not compare with current usual care. Therefore, it is reasonable to suggest that these interventions would be beneficial to some people and should be made available as an option for behaviour change alongside existing services.
Breaking Free Group	Guideline	008	012 – 014	We disagree with the committee's conclusion that text message interventions may be more effective than other digital and mobile interventions, as the evidence review states that text message interventions only have evidence of effectiveness for up to 6-months follow-up, whereas other digital and mobile interventions	Thank you for your comment. The committee discussed that text messages may be more effective than mixed and internet-based interventions at 6 months. Internet-based interventions were not found to be more effective than other interventions at 12 months. They recommended text messages over mixed

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				such as mixed interventions, have evidence of effectiveness for up to 12-months follow-up (see our comment in point 17 above).	interventions as it would be simpler intervention to implement and would likely have less of a resource impact. They also discussed the benefit of regular reminders sent by text as these are seen as more personal and can be sent at times of the day most useful to the person.
Breaking Free Group	Guideline	008	019	Recommendation 1.6.2. states that a motivational assessment should be used to determine the most appropriate intervention for a service user. This does not seem appropriate in real-world settings as it assumes that Healthcare Professionals will have substantial knowledge and information around a wide range of potentially suitable digital interventions in order to make a referral. Furthermore, in the smoking evidence review it was acknowledged that access to alcohol apps may be more self-directed which would therefore indicate an assumption that Healthcare Professional referral may not be necessary for this audience.	Thank you for your comment. Though there was evidence to suggest how motivated someone is influences behaviour change, this recommendation has been removed from the guideline. This is because there was no suitable tool NICE could recommend for conducting the motivational assessment. There was also no evidence on how the outcome of the motivational assessment should be used to inform care.
Breaking Free Group	Guideline	013	022 – 024	The committee conclude that there is poor evidence that digital and mobile interventions can be effective, although this contradicts the fact that some of the evidence reviews (e.g. for smoking) conclude that some interventions can be effective at up to 12-months follow-up. Additionally, the committee state here that the reviews did not allow conclusions to be made as to whether digital and mobile interventions could be more effective than usual care. However, this	Thank you for your comment. The committee noted that the evidence was variable and inconsistent, that some interventions would be effective, and some people would experience positive outcomes using digital or mobile health interventions. However, from the evidence it was not possible to deduce which components this would be as each intervention included in the reviews contained many different combinations of components, which made it difficult to isolate which

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				should not influence decisions as to whether digital and mobile interventions can be effective or not in the draft guidance, as the aim of this evidence review were simple to determine if components and characteristics of digital and mobile interventions could be effective. The evidence reviews' aims did not state that it was intended to determine if digital and mobile interventions were more or less effective than usual care. Especially as some studies may not have used face-to-face services as a comparator, this further challenges the assumptions of this statement. Furthermore, as mentioned previously, this assumption may also not reflect real-world settings where online and offline support may be used in tandem, and is often found to have preferential outcomes compared to either in isolation.	were driving behaviour change. This included non-digital components in the comparator arms. To make this point clear the committee have changed the wording in this recommendation noting that there is variability in effectiveness, not uncertainty.
Breaking Free Group	Guideline	015	005 – 006	See our comment in point 32 below We disagree with the committee's conclusion that it is not clear whether digital and mobile smoking interventions are effective – at multiple points in the evidence review the committee conclude that there was in facct evidence that such interventions, regardless of modality, can be effective at up to at least 6-months follow-up, and for some interventions, at 12-months follow-up (see our comments in points 14, 15, 16 and 20 above).	Thank you for your comment. After revisiting the evidence, the wording for these recommendations has now been changed to reflect that these interventions should be referred as an adjunct to existing services. The committee have also amended the wording of recommendation 1.5.1 so it says that effectiveness of these interventions is variable. Though the overall effect estimate of the smoking evidence shows in favour of smoking cessation, there is considerable heterogeneity between and within the studies. Many studies have very wide confidence intervals that cross the line of

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					no effect. In addition, most studies did not compare with current usual care. Therefore, it is reasonable to suggest that these interventions would be beneficial to some people and should be made available as an option for behaviour change alongside existing services.
Breaking Free Group	Guideline	015 016	026 - 029, 001 - 002	The committee state that digital interventions may lead to limited interaction with healthcare professionals however the example used seems to be just in relation to sexual health, and it is an overgeneralisation that this is the case, especially when, as discussed previously, online and offline resources are likely to be used in tandem in real-world settings.	Thank you for your comment. The example given is to illustrate how people may isolate others from face-to-face care and can be used for other behaviours. We agree that there may be a number of possibilities around how the interventions could be used, the example given does not exclude other possibilities and a exhaustive is not possible. To demonstrate a potential harm of more digital and mobile health interventions being developed, the committee wanted to make people aware that even though they can be used in tandem with other interventions, they could be found and used by people without a consultation with a healthcare professional.
Breaking Free Group	Guideline	017	018 – 019	The committee conclude here that there was evidence that digital and mobile interventions can help people stop smoking. However, this directly contradicts the conclusion the committee state earlier in the draft guidance on page 9 – 11 that it was not clear whether digital and mobile smoking interventions could be effective (see our comment in point 32 above).	Thank you for your comment. After revisiting the evidence, the wording for these recommendations has now been changed to reflect that these interventions should be referred as an adjunct to existing services. The committee have also amended the wording of recommendation 1.5.1 so it says that effectiveness of these interventions are variable. Though the overall effect estimate of the smoking evidence shows in favour of smoking

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					cessation, there is considerable heterogeneity between and within the studies. Many studies have very wide confidence intervals that cross the line of no effect. In addition, most studies did not compare with current usual care. Therefore, it is reasonable to suggest that these interventions would be beneficial to some people and should be made available as an option for behaviour change alongside existing services.
Breaking Free Group	Guideline	018	025	Please define what an 'excessive drinker' is. This phrase is not usually used as standard terminology around alcohol consumption.	Thank you for your comment. We have changed the term to "hazardous drinkers".
Breaking Free Group	Evidence review - smoking	005		In relation to the primary outcomes, setting a quit date may also be an appropriate measure of engagement to consider in relation to the Russell Standard: https://www.ncsct.co.uk/usr/pub/assessing-smoking-cessation-performance-in-nhs-stop-smoking-services-the-russell-standard-clinical.pdf	Thank you for your comment. Setting a quit date is a good measure of engagement and is considered under number of logins/visits and self-reported interaction with the intervention.
Breaking Free Group	Evidence review - smoking	021	008 – 009	If access to the intervention stopped at 6-months this may be why longer follow up found the intervention to be ineffective. However, this methodology lacks ecological validity as in real-world settings, access to digital and mobile interventions can be ongoing without necessarily having an end point. This is particularly important for supporting ongoing smoking cessation as lapses over time are common.	Thank you for your comment. As access to digital and mobile health interventions are ongoing, the committee decided that longer follow-up times would be more illuminating than short follow-up periods and provide some indication of sustained behaviour change. The committee wanted to see whether or not digital or mobile health interventions have a prolonged, not just a novel, effect on behaviour. How long people have access to the interventions is detailed in the TIDieR checklist of the evidence

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					tables, in Appendix F. All but one study gives participants access for at least the follow-up period.
Breaking Free Group	Evidence review - smoking	021	012 - 030	For the studies listed within this section, please state the follow-up periods that the analyses are reporting on.	Thank you for your comment. The follow-up periods have now been added.
Breaking Free Group	Evidence review - smoking	022	036 – 040	The committee state here that it can be assumed that when someone drops out of a smoking intervention study, they can be assumed to have resumed smoking. The literature that suggests this should be provided here as it cannot necessarily be assumed that dropping out of a study means people have resumed smoking. This is especially relevant as the committee go onto say that drop out in diet or physical activity intervention studies can be attributed to participants having successfully achieved behaviour change and so have no incentive to stay in the study. In a commentary on attrition within smoking cessation apps (Webb, T. L. (2009). Commentary on Shahab & McEwen (2009): Understanding and preventing attrition in online smoking cessation interventions: a self-regulatory perspective. *Addiction*, *104*(11), 1805-1806), the author argues that attrition may also be due to poor goal setting and monitoring, and low motivation caused by the intervention itself. Later, on page 28 (lines 24-26) experts also acknowledge that there is limited evidence on what can lead to disengagement. Therefore this is also contradictory to the committee's	Thank you for your comment. The committee were aware that there may be differences in how people act depending on the targeted behaviour, so what is true for physical activity may not be true for smoking. For physical activity, expert testimony stated that attrition from an intervention may mean people have formed positive habits and no longer need the help of the intervention. However, the testimony stated that this may be different in smoking and it is likely that attrition is strongly associated with failed smoking abstinence. This assumption is common practice for smoking studies, is made in all studies included in the smoking review and made by Cochrane reviews. The rationale behind it is that smoking is a very addictive habit and staying smoke-free is a massive success. If people are doing well they are much more likely to stay a part of the study to add to their sense of achievement. When someone is trying to beat a strong addiction, they are more likely to have relapsed than stayed smoke-free if they have dropped out of the study. As cessation rates for smoking tend to be low for the vast majority of interventions, it is best practice to keep estimates conservative instead of overestimating the intervention effect.

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				assumption, as limited evidence means that there is no certainty that drop out is the result of lapse/relapse.	
Breaking Free Group	Evidence review - smoking	022	046 - 047	The committee state here that they agreed that digital and mobile smoking interventions could be effective at 6-months, regardless of modality, which contradicts the conclusions stated in the draft guidance (see our comment in point 16 below).	Thank you for your comment. After revisiting the evidence, the wording for these recommendations has now been changed to reflect that these interventions should be referred as an adjunct to existing services. The committee have also amended the wording of recommendation 1.5.1 so it says that effectiveness of these interventions is variable. Though the overall effect estimate of the smoking evidence shows in favour of smoking cessation, there is considerable heterogeneity between and within the studies. Many studies have very wide confidence intervals that cross the line of no effect. In addition, most studies did not compare with current usual care. Therefore, it is reasonable to suggest that these interventions would be beneficial to some people and should be made available as an option for behaviour change alongside existing services.
Breaking Free Group	Evidence review - smoking	023	008 – 010	The committee again state here that they agreed that digital and mobile smoking interventions could be effective at 6-months, which contradicts the conclusions stated in the draft guidance (see our comment in point 32 below).	Thank you for your comment. After revisiting the evidence, the wording for these recommendations has now been changed to reflect that these interventions should be referred as an adjunct to existing services. The committee have also amended the wording of recommendation 1.5.1 so it says that effectiveness of these interventions is variable. Though the overall effect estimate of the smoking evidence shows in favour of smoking cessation, there is considerable heterogeneity

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					between and within the studies. Many studies have very wide confidence intervals that cross the line of no effect. In addition, most studies did not compare with current usual care. Therefore, it is reasonable to suggest that these interventions would be beneficial to some people and should be made available as an option for behaviour change alongside existing services.
Breaking Free Group	Evidence review - smoking	023	023 – 025	The committee again state here that they agreed that digital and mobile smoking interventions could be effective at 6-months, which contradicts the conclusions stated in the draft guidance (see our comment in point 32 below).	Thank you for your comment. After revisiting the evidence, the wording for these recommendations has now been changed to reflect that these interventions should be referred as an adjunct to existing services. The committee have also amended the wording of recommendation 1.5.1 so it says that effectiveness of these interventions is variable. Though the overall effect estimate of the smoking evidence shows in favour of smoking cessation, there is considerable heterogeneity between and within the studies. Many studies have very wide confidence intervals that cross the line of no effect. In addition, most studies did not compare with current usual care. Therefore, it is reasonable to suggest that these interventions would be beneficial to some people and should be made available as an option for behaviour change alongside existing services.
Breaking Free Group	Evidence review - smoking	023	047 – 049	The committee state here that text message interventions may be more effective at 6-months follow-up, but mixed interventions were more effective at 12-months as no 12-month data were available for text message interventions.	Thank you for your comment. After revisiting the evidence, the wording for these recommendations has now been changed to reflect that these interventions should be referred as an adjunct to existing services. The committee have also

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				However, this contradicts conclusions reached in the draft guidance that states that text message interventions were found to be most effective (see point 17 below). We are unsure as to how the committee came to the conclusion that text message interventions are the most effective when text message interventions only have evidence for effectiveness up to 6-months follow-up, whereas mixed interventions have evidence for effectiveness up to 12-months follow-up.	amended the wording of recommendation 1.5.1 so it says that effectiveness of these interventions is variable. Though the overall effect estimate of the smoking evidence shows in favour of smoking cessation, there is considerable heterogeneity between and within the studies. Many studies have very wide confidence intervals that cross the line of no effect. In addition, most studies did not compare with current usual care. Therefore, it is reasonable to suggest that these interventions would be beneficial to some people and should be made available as an option for behaviour change alongside existing services.
Breaking Free Group	Evidence review - smoking	024	001 - 004	The committee seem to favour the utility of text messages in pre-empting certain behaviours, but as acknowledged in the previous page (p. 23) app-based interventions can also provide proactive notifications. These also have the capability of tailoring notifications to remind the user of coping strategies around times when they may be inclined to smoke.	Thank you for your comment. App-based interventions could indeed provide the same timely notifications as text messages, but we did not find evidence relevant to this protocol on apps. This paragraph highlights the benefits of a platform which can be recommended. After the committee discussed this comment, the information on apps has been added to the discussion section.
Breaking Free Group	Evidence review - smoking	024	018 - 025	Here the committee are recommending that instead of focusing on BCTs, general approaches should be considered. By saying this within the guidance, there may be a justification to move away from BCT categorisation, which would be to the detriment of the quality of research on intervention design. Instead the focus should be on improving reporting of this. Furthermore, this statement also contradicts the draft guidance report and page 27 of this	Thank you for your comment. The committee agreed that reporting of BCTs was often not sufficient to make accurate assessments on which BCTs were included in each intervention and therefore did not feel comfortable making recommendations based on these for this current guideline. The NICE evidence standards framework for digital interventions, recommended for use by developers in recommendation 1.1.1, says that BCTs included in interventions need to be described

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				smoking guidance which state that BCTs need to be considered.	well when reporting on their effectiveness in studies. If future committees agree that BCTs are reported to a higher standard they could be included in later updates. To make this clearer , this part of the evidence review has been clarified.
Breaking Free Group	Evidence review - smoking	024	044 – 049	The committee state here that they agreed that digital and mobile smoking interventions could be effective which contradicts the conclusions stated in the draft guidance (see our comment in point 32 below). It is also of interest whether there was a significant difference between text messages and other modalities that would lead to text messages being highlighted as 'more effective'? If this was not the conclusion of the evidence review, it is uncertain why this is discussed, especially without references.	Thank you for your comment. After revisiting the evidence, the wording for these recommendations has now been changed to reflect that these interventions should be referred as an adjunct to existing services. The committee have also amended the wording of recommendation 1.5.1 so it says that effectiveness of these interventions is variable. Though the overall effect estimate of the smoking evidence shows in favour of smoking cessation, there is considerable heterogeneity between and within the studies. Many studies have very wide confidence intervals that cross the line of no effect. In addition, most studies did not compare with current usual care. Therefore, it is reasonable to suggest that these interventions would be beneficial to some people and should be made available as an option for behaviour change. Digital and mobile health interventions are more effective for smoking abstinence at 6 months in comparison to other interventions and no interventions. There was no significant difference between biochemically verified and self-reported abstinence. Studies that compared with control were significantly more effective then studies that

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					compared with other intervention. However, both were still more effective than the comparator groups. There is no overall difference between digital platform subgroups. The only significant difference is between internet and text interventions.
Breaking Free Group	Evidence review - smoking	025	020 - 034	Here the committee have moved away from the evidence review question (to look at the efficacy of digital support), and these comments are not in keeping with the results of the evidence review. However, continuing down this route, this discussion represents a false dichotomy where it is assumed that service users access *either* digital *or* non-digital support. The committee have not considered that in the real clinical practice, patients would likely access online and offline interventions in tandem, and that this should be r. This may also more appropriately reflect a real-world environment, as users do not often access face-to-face or online support in isolation.	Thank you for your comment. The committee noted that the evidence was variable and inconsistent. They discussed that some interventions would be effective, and some people would experience positive outcomes using digital or mobile health interventions. To ensure clarity the wording in this recommendation has bene changed noting that there is variability in effectiveness, not uncertainty. As there is variability in effectiveness between people, the committee wanted to make sure that existing services remained available to people. Digital and mobile health interventions are therefore recommended as an adjunct to existing services. Research recommendations resulting from this guideline assess whether digital and mobile health behaviour change interventions as effective as face-to-face, standard care, or combination approaches for some populations to reflect real-world uses of interventions.
Breaking Free Group	Evidence review - smoking	025	030 - 034	It is reported that the committee discussed the preferences of users accessing face-to-face support as justification for digital services not replacing face-to-face services. As discussed above, reporting on digital vs face-to-face interventions was not the aim of the evidence	Thank you for your comment. The PICOs of the evidence review contains "digital and mobile behaviour change interventions" in the intervention portion and "Other intervention for example a healthcare professional led intervention or a combination of health professional and digital

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				review and there is no justification for making this claim within the guidelines as the papers considered within the review did not look at preferences of service users.	led interventions." in the comparator portion (see evidence reviews, Appendix A for protocols). The committee used their expertise to conclude that different people have different preferences, which should be taken into consideration when offering services to people. It is unlikely that all people who are offered services will choose the same one, and so asking people this during a consultation is an important consideration that referrers should be aware of.
Breaking Free Group	Evidence review - smoking	027	003 – 004	The committee state here that the evidence review did not allow conclusions to be made as to whether digital and mobile interventions could be more effective than usual care. However, this should not influence decisions as to whether digital and mobile interventions can be effective or not in the draft guidance, as the aim of this evidence review were to determine if components and characteristics of digital and mobile smoking interventions could be effective. The reviews' aims did not state that it was intended to determine if digital and mobile interventions were more or less effective than usual care. Besides, in the real-world, patients would likely use digital and mobile interventions alongside more conventional smoking cessation support.	Thank you for your comment. The PICOs of the evidence review contains "digital and mobile health interventions" in the intervention portion and "Other intervention for example a healthcare professional led intervention or a combination of health professional and digital led interventions." in the comparator portion (see evidence reviews, Appendix A for protocols). Saying that the review did not allow for conclusions to be made regarding the interventions compared with usual care notes the very limited evidence for this comparison. The overall evidence review in this area enabled the committee to develop recommendations that these interventions could be used as an adjunct to existing services.
Breaking Free Group	Evidence review - smoking	027	045 – 053	The committee were concerned that there was not sufficient evidence of longer term (approx. 12 months) effectiveness of digital and mobile smoking interventions. However, previously the	Thank you for your comment. The committee considered 6-month follow-up but also understood than prolonged smoking cessation is the preferred outcome for stopping smoking. This

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				committee did state that some studies in the review provided evidence of effectiveness at 12-months. Also it is uncertain why the committee feel that smoking cessation interventions need to demonstrate effectiveness beyond 12 months, when 6 months were considered sufficient for the review. Furthermore, other interventions considered as part of this process are not required to gather further longer-term evidence, therefore why is smoking specifically subject to higher standards?	is why the committee decided that 6 months was the minimum follow-up that would be considered for the smoking review, with longer follow-up periods being preferable. Longer follow-up, including 12 months, was considered for outcomes of other reviews for all behaviours, not only smoking. Where longer follow-up data is provided, it is included in the evidence reviews.
Breaking Free Group	Evidence review - smoking	028	008 – 014	The committee expressed concerns that commercially developed digital and mobile smoking interventions as these may harvest data. However, not all commercially developed interventions do this - commercial organisations, especially those that create digital health products, have to be very careful in terms of data privacy and security as lack of attention to this can mean serious legal and financial consequences for such organisations as per GDPR. Furthermore, some academically developed digital interventions also use advertising and contain in-app purchase options, so these issues are not unique to the commercial sector.	Thank you for your comment. The NICE evidence standards framework for digital health interventions recommended in 1.1.1 says interventions should be designed to allow continual outcome data retrieval from consenting users. It also says that developers need to measure the economic impact and effectiveness of these interventions. Under GDPR legislation people can set and change their preferences for whether they want to their data to be stored and what data they want to share with the product. Recommendation 1.3.3 asks referrers to remind users to check and set their preferences for data consent.
Breaking Free Group	Evidence review - smoking	029	004 - 009	The committee argue that referral to stop smoking support by a healthcare professional is associated with higher quit rates. Again, this was not the aim of the evidence review. Furthermore,	Thank you for your comment. The PICOs of the evidence review contains "digital and mobile health interventions" in the intervention portion and "Other intervention for example a

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				there is no evidence looking at the opposite, for example, how effective is it if healthcare professionals recommend an app to a service user for instance? It may not be the referral to a specific service/intervention, but perhaps the important factor is the professional who is making the referral (BCT - credible source). By solely discussing referrals to face-to-face services with no consideration of similar referrals to apps, the committee inaccurately make an assumption on digital services which is unfounded.	healthcare professional led intervention or a combination of health professional and digital led interventions." in the comparator portion (see evidence reviews, Appendix A for protocols). The aim of the evidence review was to find components and characteristics of digital and mobile health interventions that are associated with higher abstinence rates. One of the characteristics associated with positive behaviour change was how the interventions would be referred. This arose from expert testimony and was discussed by the committee as a possible characteristic of digital and mobile health interventions that may improve outcomes. No recommendation was made for this but it was included in the committee discussion as it was discussed after they heard the evidence from expert testimony.
Breaking Free Group	Evidence review - alcohol	007		This relates to the first exclusion criteria stating; 'Participants who are classified as harmful drinkers where clinical intervention may be the more appropriate action'. We would challenge this assumption - is there enough evidence to suggest 'harmful' drinkers would not benefit from digital and mobile interventions? It may be that this exclusion criteria could be more appropriate by excluding 'dependent' drinkers, because even though someone might be consuming alcohol to 'harmful' levels, they still may not be a dependent drinker. Additionally, according to the PHE guidance, individuals consuming alcohol to harmful levels may benefit from being provided	Thank you for your comment. The committee excluded harmful drinkers because even though they may not be dependent, they agreed that a digital intervention would not be enough to reduce consumption in this group and said a different approach would be more suitable for this group. In addition, they did not want to risk people who would benefit from more intensive interventions being referred digital and mobile health interventions as a result of this guideline. NICE has guidance for harmful and dependent drinkers, please refer to CG115 Alcohol-use disorders: diagnosis, assessment and management of harmful drinking (high-risk drinking) and alcohol dependence and the

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				with extended brief intervention, which many digital and mobile alcohol interventions are. Therefore, we propose that there is insufficient rationale for excluding harmful drinkers from the evidence review, and that by doing so, the evidence review may have excluded some valuable studies from the meta-analyses. Furthermore, it is unclear how stringent evidence reviewers were in meeting this inclusion criteria. For example, the Boß et al. (2018) paper includes those who are at least drinking to hazardous levels, but there is no upper limit in terms of including harmful drinkers. As levels of risk are not separated out within the paper, how can reviewers be certain that harmful drinkers are also not being investigated? This is just one example found within the included papers of this evidence review.	NICE pathway Alcohol Use Disorders overview, which provides all guidance NICE has in an interactive flowchart. Unless data for individual participants is reported, it is not possible to be sure if all participants drink to a certain level. NICE's methods use means and medians of continuous data, such as age or alcohol consumption, to assess if a study is relevant for an evidence review.
Breaking Free Group	Evidence review - alcohol	007		This also relates to the exclusion criteria stating; 'Those who have previously exhibited unhealthy drinking behaviours and no longer do so, and those who want to maintain healthy behaviours'. Is this clear within all papers included in the evidence review? For instance, how would the reviewers check that this does not include people who were previously at harmful risk levels who have now dropped down to lower/increasing risk, as typically only previous dependence is reported? Furthermore, when does an intervention change from an active intervention to a maintenance	Thank you for your comment. The exclusion criteria highlighted in the comment means that studies that include people drinking at a healthy level will be excluded from the review. This includes people who used to drink at least hazardous levels but now drink to healthy levels, and people who have always drunk at heavy levels, are excluded. The committee wanted to make it clear that people who used to drink more than the healthy level, but now drink at a healthy level will not be included. People who used to drink to harmful levels but now drink to hazardous/increasing risk level are included, as they have not yet reached a

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				intervention? To clarify, if the minimum follow-up period is 6 months, it arguably does not take this long to change a habit. Any behaviour change would have occurred during the intervention, at which point it could be argued that this becomes an intervention to maintain healthy behaviour change. We would suggest that this is amended to reflect those initially engaging with the intervention as a maintenance tool.	healthy drinking level. This step was taken to make it clear that the interventions of interest for this guideline are for people who want to reduce their drinking currently. The committee wanted to assess the effectiveness of interventions from the start of someone's behaviour change to 6 months so they could evaluate if the changed was sustained. Maintenance interventions are started after the person has made a change to their behaviour and does not initiate it.
Breaking Free Group	Evidence review - alcohol	008		In relation to the comparator criteria stating; 'If longitudinal cohort and 'before-and-after' intervention studies *need* to be included (see 'study design'), then before and after (time) will be a comparator'. It is not clear what the criteria were used to determine if longitudinal and before-and-after studies needed to be included within the review.	Thank you for your comment. By following the protocol through to the 'study design' section, it says these study types will be considered if no RCTs are found. There were RCTs identified for all of the review questions in this guideline.
Breaking Free Group	Evidence review - alcohol	011		Within the summary of studies, the evidence review omits a paper which we felt should have been included: Kay-Lambkin, F. J., Baker, A. L., Lewin, T. J., & Carr, V. J. (2009). Computer-based psychological treatment for comorbid depression and problematic alcohol and/or cannabis use: A randomized controlled trial of clinical efficacy. *Addiction*, *104*(3), 378-388. doi:10.1111/j.1360-0443.2008.02444.x We wondered whether this paper was omitted from the evidence review because of the study of drug-related outcomes. This made us question	Thank you for your comment. This study appeared in the literature search for the evidence review but was excluded because a significant proportion of the intervention was delivered by healthcare professionals - motivational interviewing and cognitive behaviour therapy. Even the participants who were randomised to receive the intervention through a computer-based programme, the input was a psychologist respond live to the participant. This makes the study ineligible for the evidence review in this guideline.

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				whether the review focused on papers specifically looking at alcohol interventions, to the exclusion of interventions for 'alcohol and other drug' (AOD) users, and if so, that this be specified within exclusion criteria.	
Breaking Free Group	Evidence review - alcohol	026	018 – 020	Were these additional outcomes, that might be considered more important in practice than alcohol consumption, taken into account when the committee made their conclusions around whether interventions were effective or not?	Thank you for your comment. The committee commented on these outcomes because they were not reported in the studies, and so could not be taken into account when making recommendations. They said this was an important point to note because to be more useful in decision-making, studies could report more outcomes that have a more direct effect on people's lives. A sentence has been added to the evidence review section to make this clearer.
Breaking Free Group	Evidence review - alcohol	026	025 - 026	In considering binge drinking, there may be occasions where this is classified as 'harmful drinking'. Therefore we questioned the purpose of including this within the evidence review when it does not meet the inclusion criteria specified.	Thank you for your comment. There may be instances where binge drinking is harmful drinking and can be a part of hazardous drinking behaviour. However, the committee used a threshold of total drinks a week as a cut-off and not drinks on single occasions. This population is considered in NICE guideline CG115 Alcohol-use disorders: diagnosis, assessment and management of harmful drinking (high-risk drinking) and alcohol dependence.
Breaking Free Group	Evidence review - alcohol	027	036 – 038	Did these studies state whether they provided ongoing access to the interventions post-treatment period? In the real-world, patients would be provided with ongoing access to digital and mobile interventions which would support them to re-engage with these interventions at	Thank you for your comment. The evidence tables (found in Appendix F of the review) provides information about the duration and frequency of the interventions. Some alcohol interventions were a computer program that lasted only an hour. This may not be applicable to

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				times when they maybe facing a possible lapse/relapse. One of the strengths of digital and mobile interventions is their ability to provide this ongoing, longer-term support. If studies provided ongoing access to these interventions, they may have found favourable outcomes at both 6 and 12-months follow-up. We would further add that by RCT methodologies only providing access to digital and mobile interventions for a defined treatment period, and then removing access to the intervention after this treatment period has elapsed, this demonstrates one of the ways in which RCT methodologies may lack ecological validity in relation to evaluating digital and mobile interventions. Additionally, here the committee should state more clearly what the 'all but one outcome' was as it is difficult to determine what this outcome was. If it was the primary outcome, i.e. alcohol consumption, then it could be concluded that these interventions were in fact effective up to 12-months follow-up. Additionally, 6 months was the minimum criteria for follow-up as specified within the evidence review. Due to attrition rates commonly associated with these interventions, many researchers may not have sought data spanning beyond this time-point. This however does not mean that this data does not exist were it not collected.	interventions that have an ongoing interaction with users, but there are one-off interventions to which this would be applicable. Excluding these studies would not give a rounded picture of the types of interventions and intervention characteristics that exist for reducing alcohol consumption. RCTs are used as they allow comparison between different treatments or interventions and can control for confounding bias better than observational studies. It is not a guarantee that an RCT will only provide the intervention a short period of time at the start of a trial. The evidence review included some RCTs assessed interventions that were implemented for the whole follow-up period. The committee agreed that 6 month follow-up was needed to assess whether the behaviour change was a prolonged change and not only a short-lived change, as they understood that changes that only exist for the short-term may have limited benefit.

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Breaking Free Group	Evidence review - alcohol	027	046 – 047	Here the committee state that the 'general student population is inherently different to the general population' – what is the rationale for this assumption? Can some evidence be provided here with concrete examples of how the student population is different to the general population, and why these differences would make a difference in terms of the responses of these populations to alcohol interventions? This also seems to be a generalisation – the student population is not a homogenous group, nor is the general population.	Thank you for your comment. As there were many studies done in student populations, the committee requested that these studies be split out as a sensitivity analysis. The committee agreed that students do have a different culture regarding drinking. Even if students are not a homogenous group, students that do drink will be more similar to each other and have similar experiences and drink in more similar contexts than non-students who drink. No subgroup is homogenous, such as people with low socioeconomic status but, it is important to identify groups who in the main have differences to other populations.
Breaking Free Group	Evidence review - alcohol	027	005 - 008	Interventions designed for those drinking below 14 units are typically considered prevention interventions, to prevent any potential harm if drinking increases. In accordance with PHE guidelines also, those classed as low-risk drinkers should not receive any intervention, apart from feedback and reinforcement for their lower risk drinking and the importance of not exceeding this level of alcohol consumption in the future. Therefore, inclusion of these prevention interventions in the evidence review contradict the aims of the review, which were to examine effectiveness of digital and mobile interventions for changing drinking behaviours that may affect health or mental wellbeing.	Thank you for your comment. To make the evidence more directly applicable to a UK setting, the committee agreed that taking out studies with a mean or median consumption of fewer than 14 units a week were excluded from the evidence review.

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British Dietetic Association – Obesity Group	Guideline	005	008 - 009	We support the testing of digital interventions in a range of target groups including those specified in the EIA. In addition groups which may have lower than usual access to medical services should be prioritised. This may include members of the Travelling community, and immigrant communities.	Thank you for your comment. The committee agrees testing interventions for a wide range of people is important, particularly to reduce inequalities. The guideline includes a research recommendation that notes the importance of research that considers the effects of digital and mobile health interventions in low socioeconomic and other underserved groups.
British Dietetic Association – Obesity Group	Guideline	005	014 - 015	We fully support the development and use of appropriate, evidence-based and audience-tested digital and mobile health interventions as adjuncts to , not replacements for, personal interventions with appropriate healthcare professionals (including one-to-one and group interventions). There is currently a lack of evidence for either their superiority or long-term efficacy, and this evidence needs to be gathered and evaluated robustly and independently.	Thank you for your comment. The committee agree that there is a lack of evidence for superiority or long-term efficacy, particularly in understanding which components and characteristics drive behaviour change. Digital and mobile health interventions should be considered as an option if these are appropriate for the local populations This is why the committee made research recommendations for testing the effectiveness of these interventions beyond 12 months, and for the components and characteristics of these interventions.
British Dietetic Association – Obesity Group	Guideline	007	021 - 022	We accept that components of lifestyle management such as self-monitoring may be less appropriate for those with disordered eating and/or activity behaviours. Nonetheless the evidence base is clear that self-monitoring is an important tool in helping individuals manage their weight, raise their self-awareness of their lifestyle behaviours, and change behaviours and therefore these components should be included in digital and mobile behaviour change	Thank you for your comment. The committee were concerned that people at risk of disordered eating may be recommended self-monitoring, therefore the committee wanted to mitigate this risk. This will help people because they may not be aware that many diet and physical activity interventions contain self-monitoring and the risk it may pose to them. By recommending other components, those at risk of disordered eating who have a consultation with a referrer are pointed away

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				interventions. It is unclear how this recommendation will work in practice, given that access to apps is generally not regulated.	from interventions with self-monitoring. The risk that self-monitoring interventions pose to people at risk of disordered eating cannot be entirely abolished because apps are unregulated. However, referrers should remain aware of the person's personal history and try to help people find an alternative.
British Dietetic Association – Obesity Group	Guideline	008	005 - 007	It is unclear how this will work in practice. Access to digital and mobile interventions such as apps is not regulated so individuals with disordered eating who wish to use self-monitoring components can already access apps which offer this. Self-monitoring is recognised as an important tool in facilitating behaviour change so the development of mobile or digital interventions which do not include self-monitoring are unlikely to be evidence-based.	Thank you for your comment. The committee's aim was not to prevent everyone at risk of disordered eating or excessive exercise access to self-monitoring interventions. They wanted to mitigate the risk and make people at risk aware of other components they could use to draw attention away from self-monitoring interventions. Without strict regulation of digital and mobile health interventions it will not be possible to prevent anyone from gaining access to these interventions but referrers can at least help those who they have seen face-to-face. In addition, the committee thought it was important to make recommendations that state existing services should remain available and not replaced. These services could be used by people at risk instead of digital interventions. Self-monitoring can be useful in behaviour change, however if it will bring a person harm it is best not to recommend they use it.
British Dietetic Association – Obesity Group	Equality impact Assessment	003		**Section 3.2 Disordered eating** Those with disordered eating or at risk of developing eating disorders will be free to access digital and mobile behaviour change apps unless the proposal is to restrict these in some way. We agree that weight tracking may be detrimental to	Thank you for your comment. It would not be possible to restrict access without stringent measures being put on individuals. Therefore, the committee's aim was to mitigate the risk and draw attention away from self-monitoring interventions. Without strict regulation of digital and

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				individuals in these categories but are unclear about how this recommendation will actually work in practice. Is the intention to restrict access to the apps? If so, a cross reference to the tools which should be used to identify those at risk of disordered eating or developing eating disorders would be helpful. If not, the practicality of this recommendation is unclear.	mobile health interventions it will not be possible to prevent anyone from gaining access to these interventions but referrers can at least help those who they have seen face-to-face. To keep options available to this group and others, the committee thought it was important to make recommendations that state existing services should remain available and not replaced. These services could be used by people at risk instead of digital interventions.
British Dietetic Association – Obesity Group	Equality impact Assessment	005		**Section 3.6** We support the need to align the development or commissioning of mobile and digital interventions to the needs of the local community e.g. through the use of a Joint Strategic Needs Assessment.	Thank you for your comment.
Cancer Research UK	Guideline	General	General	Cancer Research UK is supportive of the recommendation that digital and mobile health interventions should be considered as an *option* for behaviour change. With increasing pressure on the NHS and local health and social care services, alternative or additional support for behaviour change via digital technology could mean a lot of patients or service users could feasibly access support more quickly than waiting for a face-to-face intervention provided by the NHS or local services. However, given the evidence base for digital and mobile health interventions for reducing cancer risk factors including smoking, alcohol and	Thank you for your comment and support of the recommendation that digital and mobile health interventions should be considered as an adjunct to existing services. This is why they also recommend that existing services should still be offered, as they are currently being used and are considered to work for a wide variety of people. The committee discussed making recommendations for specific populations but the evidence could not distinguish a difference in effectiveness of different components between population groups. The committee agreed that digital and mobile health interventions are not appropriate for people that are alcohol dependent or drinking to harmful levels. NICE guideline CG115 alcohol use disorders: diagnosis, assessment and management of harmful drinking (high-risk drinking) and alcohol dependence

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				overweight/obesity is limited, patients and service users must be provided with established evidence-based interventions in addition to these technologies to promote healthy behaviours. For example, the evidence base for smoking cessation interventions and services is strong and well-established; commissioners should be made aware of this and digital and mobile health interventions should supplement but not replace these reputable interventions. Cancer Research UK support further guidance on who digital and mobile health interventions for smoking, diet, exercise and alcohol consumption may be suitable for, given the varying needs of different population groups. For example, existing evidence suggests digital interventions may reduce hazardous alcohol consumption but may not be suitable for those that are alcohol dependent or in recovery from alcohol dependence.	is available for this population: Therefore, they are an excluded population in the alcohol review (Appendix A, evidence review 2: alcohol).
Cancer Research UK	Guideline	004	004 - 010	Cancer Research UK is pleased to see the draft guideline include recommendations for developers to refer to and use standardised national frameworks when developing and evaluating digital and mobile health interventions. If the development and evaluation of digital and mobile health interventions is standardised, as more people use these digital applications, more	Thank you for your comment. The committee agree with the importance of consistency in development so interventions can be more easily compared. This is why there are recommendations for developers and commissioners to use the resources mentioned in recommendations 1.1.1, 1.1.2 and 1.2.5 when developing and assessing these interventions.

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				data can be collected which means these interventions can be consistently evaluated and compared, ultimately adding to the intervention evidence base. Developing a robust and transparent evidence base for digital and mobile health interventions ensures the most effective interventions can be recommended by healthcare professionals and more frequently used by those who need them.	
Cancer Research UK	Guideline	004 – 005	18 – 009	Cancer Research UK is pleased to see these recommendations included as it means digital and mobile health interventions should be developed and tested with input from the intended audience to ensure any interventions are acceptable, usable and effective for those who need them most. This will help to address health inequalities among people with poor diet and those who do insufficient physical activity, as well as among people who smoke or are dependent on alcohol, and those practising unsafe sexual behaviours.	Thank you for your comment. Including people from the target population during intervention development is vital. By doing this, the experiences and needs of different groups can be considered.
Cancer Research UK	Guideline	005	014 – 015	Cancer Research UK welcomes this recommendation as it is crucial the commissioning of digital and mobile health interventions is a supplement to existing services, and not as a replacement. As this draft guideline outlines, evidence on the effectiveness of digital and mobile health interventions for diet and physical activity, smoking, alcohol and unsafe sexual behaviour is	Thank you for your comment. The committee thought it was important to keep existing services. Digital and mobile health interventions should be considered as an adjunct to these, if it suits the person.

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				generally low quality. Ensuring that evidence-based interventions that do exist for diet and physical activity, smoking, alcohol and unsafe sexual behaviour are commissioned and continue to be made available to people using the NHS and local services is crucial to promoting healthy behaviours. Ensuring digital and mobile health interventions supplement existing services will help to better embed evidence-based behaviour change interventions in to people's increasingly digital lives.	
Cancer Research UK	Guideline	005	022 – 025	This recommendation is important to ensure existing evidence-based digital and mobile health interventions that meet the local needs are recommended and used to reduce duplication. This, in turn, will reduce unnecessary costs in commissioning a new product, which will be cost saving to the commissioner. As local authorities, the NHS and healthcare providers are important commissioners of these digital and mobile health interventions, it is integral that their limited funding is protected where possible. Additionally, if commissioners find an existing intervention that meets local needs from expert sources, it ensures that these evidence-based interventions and more frequently recommended by healthcare professionals and used by those who need them, which in turn improves data	Thank you for your comment. The committee agrees that existing services should not be replaced. In addition, local authorities and commissioners may wish to carry out a needs assessment of their local area if they think a digital intervention may help behaviour change for groups in their local population. It is important to facilitate the development of robust and effective interventions to enhance the quality of care that already exists for behaviour change and to reduce widening health inequalities. Digital and mobile health interventions create an opportunity to develop interventions that cater to groups' specific needs. The committee wanted further research to be conducted in this area, which is why they created 5 research recommendations, 3 of which aim to reduce inequality and increase understanding of

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				collection which adds to the evidence base for the intervention. Ultimately, robust evidence on digital and mobile health interventions is needed to ensure the most appropriate and effective digital applications can be recommended for diet, physical activity, smoking, alcohol and unsafe sexual behaviours. If a standardised set of evidence-based digital and mobile health interventions for diet, physical activity, smoking, alcohol and unsafe sexual behaviour are made available, recommended and used across England, this would improve equity of access to health services, which is critical to reduce health inequalities.	how these interventions can drive positive behaviour change.
Cancer Research UK	Guideline	006	005 – 012	Cancer Research UK strongly support this recommendation, as all digital and mobile health interventions should consider the impact the intervention has on equality of access. Digital and mobile health interventions can facilitate access to behavioural interventions for individuals who have difficulty attending face-to-face appointments. This may include people who can't get time off work to attend face-to-face appointments, those who work shifts that don't align with face-to-face appointment times, or those who can't afford to travel to attend face-to-face appointments. These barriers are often associated with more deprived individuals, meaning digital and mobile health interventions	Thank you for your comment. It is one of NICE's aims to mitigate inequalities in any guidance it produces. The committee agreed that not only should interventions be accessible to as many people as possible, there will be situations where an intervention cannot serve every group. Which is one reason why they recommended using an expert source that lists many different interventions, with each one catering for a few groups instead of recommending one intervention that caters to all, which may be difficult to design. In this way, inequalities could be reduced because there will be interventions available that are tailored to different groups. The committee were aware that people have different levels of literacy and motivation, among

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				may help to improve access to interventions for smoking, diet, exercise, alcohol consumption and unsafe sexual behaviours. Where possible, commissioners should ensure digital and mobile health interventions are made readily available, at low to no cost, and can be downloaded and used without an ongoing internet connection in order to improve accessibility for all groups, and particularly the most deprived individuals. Generally, digital and mobile health interventions can promote behaviour change among those with higher literacy levels or more self-motivation which means they inherently favour populations who are less likely to be smoking or be overweight/obese, and therefore are less likely to need them. Moreover, to be able to use and access digital and mobile health interventions it assumes patients and service users can access the internet and modern digital hardware and software to use the intervention, which can involve a cost to the patient or service user, further refining which groups of the population can access these technologies. The potential for these digital applications exacerbating health inequalities must be considered when commissioning any new products.	other factors. This is why the committee made recommendation 1.3.2 that asks healthcare professionals to consider the following factors when discussing digital or mobile health interventions with a person: •their preferences and behaviour change goals, and interventions that allow tailoring towards these •their capability, opportunity and motivation for change •their digital, health and reading literacy •the digital platforms available •the aim of the intervention •how frequently and intensely they are willing to use interventions •that interventions that have not been tested do not have evidence of effectiveness •how it would fit into their current care pathway. To ensure that all groups are considered, a recommendation in section 1.1 that tells developers to involve a wide range of stakeholders, including potential users, as early as possible and throughout development. The guideline also asks commissioners to take into account equality of access as part of an equality impact assessment. To keep access to behaviour change interventions available to as many people as possible, the guideline says if commissioning digital and mobile health interventions, do this as a supplement to existing services, not as a replacement.

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Cancer Research UK	Guideline	006	018 – 025	In theory, Cancer Research UK are strongly supportive of this recommendation. It is important that healthcare professionals consider the users, the available platforms and the aim of such interventions, as well as how it fits in to the person's current care pathway before making a recommendation. However, Cancer Research UK believes in practice it may be challenging for healthcare professionals to properly fulfil this recommendation. This recommendation relies on users accurately articulating preferences, goals, capability, opportunity and motivation for behaviour change through digital and mobile interventions, as well as healthcare professionals being aware of the range of interventions available to support this behaviour change. In addition, healthcare professionals are under increasing pressure to deliver healthcare services in England, which may limit their ability to fulfil this recommendation during short consultations with patients. It is important for healthcare professionals to consider users' previous and current interactions with established face-to-face interventions before recommending digital or mobile health interventions. If patients have not tried and are willing to use an established face-to-face intervention, this should be preferentially recommended over digital options. Cancer	Thank you for your comment. These are valid considerations that healthcare professionals should think about when discussing digital interventions with possible users. However, these discussions should happen in any discussion between healthcare professional and user about behaviour change interventions, not only for digital interventions. The committee agrees that healthcare professionals should continue to use their existing services and use digital and mobile health interventions as adjuncts to these, therefore they made recommendations to reflect this. The rationale for this recommendation explains how digital only may be best for a minority of people. This guideline makes recommendations on factors to consider if a digital or mobile health intervention has been chosen. Existing evidence-based services are valuable to public health. Therefore, recommendation 1.2.2 asks commissioners to choose digital and mobile health interventions as a supplement to existing services and should not replace them.

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				Research UK would encourage NICE to consider including this point in the draft recommendations.	
Cancer Research UK	Guideline	007	001 – 010	Cancer Research UK are committed to fulfilling the obligations set out in Article 5.3 of the World Health Organisation Framework Convention on Tobacco Control which requires that "in setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law" (WHO, 2003). As a signatory, the UK has a legal obligation to meet all articles included in the Framework – therefore we recommend that this NICE behaviour change guideline explicitly condemn and actively exclude the use of digital and mobile health interventions that are funded by the tobacco industry, given the industries' enduring and irreconcilable conflict with promoting smoking cessation and delivering comprehensive tobacco control in England. The tobacco industry has, on multiple occasions, attempted to influence tobacco control activity in England; therefore, it is imperative that NICE include an explicit recommendation to prevent the industry from attempting to influencing individual health through digital interventions. Similarly, Cancer Research UK would like to see NICE discourage and exclude the use of digital and mobile health interventions funded by the	Thank you for your comment. The UK Government is a signatory and party to the WHO Framework Convention on Tobacco Control (FCTC). As an Arm's Length Body of Government, NICE has an obligation under Article 5.3 of the FCTC to protect public health policies from the commercial and other vested interests of the tobacco industry. A recommendation has been added that reads "Do not offer digital and mobile health interventions that are funded by the tobacco industry." The consultation process for this guideline is in line with developing NICE guidelines: the manual, chapter 10 and the WHO policy on tobacco. There was no evidence identified on interventions funded by the alcohol industry. There is no such corresponding national policy for alcohol.

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				alcohol industry, given their conflict of interest with reducing alcohol consumption and improving public health.	
Cancer Research UK	Guideline	007	002 – 004	The guideline recommends using digital interventions or apps from expert sources, such as the NHS apps library. However, there is limited choice in these sources at present for smoking and alcohol consumption, which would prevent healthcare professionals from fulfilling this recommendation. In line with the Institute of Alcohol Studies response, Cancer Research UK advises NICE recommend that these expert sources improve the transparency of the inclusion criteria in the respective libraries. NICE should also advise whether this aligns with the level of scrutiny NICE would typically require.	Thank you for your comment. This is outside of NICE's remit.
Cancer Research UK	Guideline	007	005 - 006, 008	Cancer Research UK is pleased to see these recommendations included as digital and mobile health interventions rely on personal data to provide tailored interventions for smoking, diet, exercise, alcohol consumption and unsafe sexual behaviours. Given this data can be considered extremely sensitive, healthcare professionals have a duty to explicitly advise potential users of how their personal data may be used, and recommend users read the terms and conditions of any interventions so they can be informed and theoretically provide informed consent should they choose to use the intervention.	Thank you for your comment. The guideline now asks developers to make practical information about personal information and data use, mobile data, and terms and conditions clear to users. Recommendation 1.3.3 says that people should read the terms and conditions of any intervention they choose to use and check and set their preferences for how their data may be used.

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Cancer Research UK	Guideline	007	009	Cancer Research UK would also like to see NICE develop this recommendation further, so that any digital or mobile health interventions recommended by healthcare professions are free from any form of advertising that promotes unhealthy commodities; namely products containing alcohol or unhealthy foods that are high in salt, sugar and fat. To this point, Cancer Research UK assumes any digital or mobile health intervention available in the UK would be free from the advertisement or promotion of tobacco products, in line with legislation.	Thank you for your comment. The committee discussed interventions that used adverts and said that many use adverts as a way of gaining revenue. In this way, many interventions can reduce their costs or remain entirely free, increasing accessibility of these interventions. The committee were aware of the possibility of adverts having opposing effects to the aims of the intervention which is why they recommended that advert-free interventions are preferred, and for developers to be mindful of the adverts their interventions include if they have to include adverts.
Cancer Research UK	Guideline	007	011 - 022	Cancer Research UK are supportive of this recommendation, as it is important that digital and mobile health interventions are appropriate for the user and consider any possible adverse side effects and displace people who would otherwise be accessing evidence-based face-to-face services and interventions. For example, local stop smoking services are the most effective means of quitting smoking in England, so the use of digital and mobile health interventions should support the existing face-to-face service offer and not replace them. However, NICE should consider that new and emerging digital and mobile health technologies develop extremely quickly, and the ability to	Thank you for your comment. The committee agree that existing evidence-based services should not be replaced. The committee understands that interventions emerge and change very rapidly. As a result they made recommendations that ask referrers to discuss components and types of intervention that would suit the person. This will allow people to choose interventions based on content and change interventions if the one they currently use stops offering a component that works for them, so they continue to use interventions that have suitable content. In order for people to be aware of harms or adverse effects the intervention may cause, people should use interventions listed on an expert source, such as those given in recommendation 1.3.3.

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				thoroughly evaluate interventions may be difficult due to these short development cycles. Therefore, it might be hard for healthcare professionals to thoroughly consider whether the content of a digital or mobile health intervention is appropriate for the user and any possible adverse effects. Where evidence of effectiveness is lacking or research ongoing, digital interventions should at least be considered unlikely to cause harm before being recommended to anyone.	
Centre for Behaviour Change, University College London	General	General	General	We find it concerning that the only industry-related disclosure required is for any links to, or funding from, the tobacco industry. We strongly suggest that disclosures are asked for involvement with any of the industries related to this consultation, i.e. alcohol, tobacco, and junk food.	Thank you for your comment. The consultation process for this guideline is in line with national government policy and the NICE statement on engagement with tobacco industry organisations, developing NICE guidelines: the manual and the WHO policy on tobacco. There is no such corresponding national policy for alcohol.
Centre for Behaviour Change, University College London	Guideline	006	001	Point 1.2.6. It may not be obvious to commissioners whether a new digital intervention is needed. It would be helpful to have guidance on when a new one is needed versus not.	Thank you for your comment. Commissioners may conclude that there is a group within their population that requires an extra intervention to promote behaviour change. They can do this via a needs assessment, which is recommended in 1.2.3.
Centre for Behaviour Change, University College London	Guideline	006	016	Although the key guideline message/recommendation (i.e. "Consider digital and mobile health interventions as an option for behaviour change. But note that it is not clear whether or not they are effective.") may follow from the specific evidence reviewed, the review was strictly limited to RCTs with a 6-month	Thank you for your comment. The aim of the guideline was to find components of digital and mobile health interventions that produce a medium- to long-term change in behaviour. The committee were keen to produce protocols that would allow them to create guidance for prolonged change in behaviour, not based on short-term

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				follow-up. It should be noted that there is a large body of evidence including Cochrane reviews with >50 RCTs for both smoking and alcohol, but that participants have been followed up for relatively short time periods. The fact that a substantial proportion of the evidence was overlooked in the current review and that new study designs other than the RCT is used to evaluate digital interventions (e.g. factorial screening trials, micro-randomised trials) should be used to contextualise the conclusion and key recommendations. There is a serious concern that such a negative statement about the current level of evidence may deter health care practitioners from recommending digital interventions.	changes that could be caused by using a novel product and would not result in sustained behaviour change. Micro-randomised trials and factorial screening trials were considered as a type of randomised controlled trial, but no relevant micro-randomised or factorial screening trials were found. Because of this, factorial RCTs were included in research recommendations. However, as micro-randomised trials were not included in the draft research recommendations, we will add these designs to the research recommendations as a result of consultation.
Centre for Behaviour Change, University College London	Guideline	006	021	"When advising on the use of a digital or mobile health intervention take into account: the user's capability, opportunity and motivation for change" – as these constructs haven't been unpacked in the guideline, this recommendation is expected to be difficult to interpret and action for HCPs/commissioners.	Thank you for your comment. A definition for capability, opportunity and motivation has been added to the NICE glossary as it is used in multiple guidelines.
Centre for Behaviour Change, University College London	Guideline	008	009	It is not clear how the recommendation for smoking "Consider digital and mobile health interventions as an option to help people stop smoking. But note that it is not clear whether or not they are effective" fits with the findings from the evidence review on P.20 that "Behavioural interventions were effective at increasing smoking abstinence both when using	Thank you for your comment. The wording for these recommendations has now been changed to reflect that digital and mobile health are recommended as an adjunct to existing services. The committee have also amended the wording of recommendation 1.5.1 so it says that effectiveness of these interventions is variable. Though the overall effect estimate of the smoking

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				biochemical verification (8 studies) and when using self-reporting (12 studies)."	evidence shows in favour of smoking cessation, there is considerable heterogeneity between and within the studies. Many studies have very wide confidence intervals that cross the line of no effect. In addition, most studies did not compare with current usual care. Therefore, it is reasonable to suggest that these interventions would be beneficial to some people and should be made available as an option for behaviour change alongside existing services.
Centre for Behaviour Change, University College London	Guideline	008	016	Point 1.6.1. It would be helpful to include some brief details of the methods behind this as there is evidence from two recent reviews (Kaner 2017 and Riper 2018) that suggest they are effective at reducing alcohol consumption, though these reviews had different methodologies. Kaner EF, Beyer FR, Garnett C, Crane D, Brown J, Muirhead C, Redmore J, O'Donnell A, Newham JJ, de Vocht F, Hickman M. Personalised digital interventions for reducing hazardous and harmful alcohol consumption in community-dwelling populations. Cochrane Database of Systematic Reviews. 2017(9). Riper H, Hoogendoorn A, Cuijpers P, Karyotaki E, Boumparis N, Mira A, Andersson G, Berman AH, Bertholet N, Bischof G, Blankers M. Effectiveness and treatment moderators of internet interventions for adult problem drinking: An individual patient data meta-analysis of 19	Thank you for your comment. The methods for the reviews can be found in the "Methods" document on the "Guideline Documents" webpage for this guideline and within Developing NICE guidelines: the manual. Methods specific to reviews can be found in the "Methods and process" and "Synthesis" sections of the reviews. Rationale behind why the committee made recommendations can be found in the "Rationale and Impact" section for these recommendations. The evidence reviews for this guideline have different protocol to the systematic reviews referenced in the comment. Evidence for 6 month follow-up or longer was included in the evidence reviews that inform this guideline. The studies in the Kaner 2017 review were included in the evidence review or excluded for the following reasons: follow-up less than 6 months, significant healthcare professional involvement in all study arms, no relevant outcomes reported, data not extractable, released before 2000, or contained an irrelevant

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				randomised controlled trials. PLoS medicine. 2018 Dec;15(12).	population. Riper 2018 was excluded as the mean units consumed suggested the population was a dependent population. This population is covered by NICE guideline CG115 Alcohol-use disorders: diagnosis, assessment and management of harmful drinking (high-risk drinking) and alcohol dependence.
Centre for Behaviour Change, University College London	Guideline	008	019	Point 1.6.2. It's not clear why this is only included for alcohol and not for other behaviours when motivation is an important part of all behaviour change. Therefore limiting the delivery of digital alcohol interventions to people who are already motivated would exclude interventions that aim to target the person's motivation.	Thank you for your comment. Though there was evidence to suggest how motivated someone is influences behaviour change, this recommendation has been removed from the guideline. This is because there was no suitable tool NICE could recommend for conducting the motivational assessment. There was also no evidence on how the outcome of the motivational assessment should be used to inform care.
Centre for Behaviour Change, University College London	Guideline	008	022	Point 1.6.2. It seems inconsistent to state that it is not clear whether or not digital alcohol interventions are effective and then recommend using normative feedback when this evidence is also mixed (see Garnett et al., 2018). Particularly as in the evidence review for alcohol it states "Therefore, the committee decided that component-specific recommendations should not be made based on the presented evidence." Leading on from the Kaner 2017 Cochrane review, included studies were assessed in terms of which behaviour change techniques were associated with intervention effectiveness.	Thank you for your comment and additional information Though there was evidence to suggest how motivated someone is influences behaviour change, recommendation 1.6.2 has been removed from the guideline. This is because there was no suitable tool NICE could recommend for conducting the motivational assessment. There was also no evidence on how the outcome of the motivational assessment should be used to inform care. The evidence review has been amended to say that no

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				Garnett CV, Crane D, Brown J, Kaner EF, Beyer FR, Muirhead CR, Hickman M, Beard E, Redmore J, de Vocht F, Michie S. Behavior change techniques used in digital behavior change interventions to reduce excessive alcohol consumption: a meta-regression. Annals of Behavioral Medicine. 2018 Jun;52(6):530-43.	more than one component-specific recommendation could be made. The Kaner review has a different protocol and focus to the reviews in this guideline, which have a follow-up period of 6 months. This has led to different conclusions.
Centre for Behaviour Change, University College London	Guideline	015	015	"…they usually contain advertising." – although this may be true for apps available on commercial app stores, this isn't true for digital interventions endorsed in the NHS Apps Library. It needs to be emphasised that this review doesn't consider "all apps available on the market" but that it is limited to digital interventions evaluated by researchers and public health bodies. Hence, any guideline recommendation only applies to a selected proportion of all available digital interventions.	Thank you for your comment. This paragraph provides the rationale for why interventions from expert sources are preferred over any other intervention. One of these reasons is because many commercially available interventions have advertising. Another is that they have been assessed with the Digital Assessment Questionnaire, soon to be updated, which means they are likely tested to a higher standard than interventions that have not been tested. More information on how interventions are assessed before appearing in the NHS Library can be found on the website. Effectiveness of individual interventions was not the aim of the reviews but of their components and characteristics, which do apply to a wider selection of digital and mobile health interventions. Although clinicians should discuss the expert sources with people, it is up to the person to choose their own interventions and so should be made aware of the potential risks.

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Centre for Behaviour Change, University College London	Guideline	021	011	"There is limited evidence on why and when people engage with and disengage from digital and mobile health interventions." – this statement isn't supported by the available evidence. Several RCTs have assessed factors at the design level that facilitate or hinder engagement with digital interventions. Again, the strict inclusion criterion of studies having at least a 6-month follow-up assessment means that informative research on user engagement was not taken into account in the current evidence review, for example: Strecher, V., McClure, J., Alexander, G., Chakraborty, B., Nair, V., Konkel, J., ... & Little, R. (2008). The role of engagement in a tailored web-based smoking cessation program: randomized controlled trial. Journal of medical Internet research, 10(5), e36. Milward, J., Drummond, C., Fincham-Campbell, S., & Deluca, P. (2018). What makes online substance-use interventions engaging? A systematic review and narrative synthesis. Digital health, 4, 2055207617743354. Alkhaldi, G., Hamilton, F. L., Lau, R., Webster, R., Michie, S., & Murray, E. (2016). The effectiveness of prompts to promote engagement with digital interventions: a systematic review. Journal of medical Internet research, 18(1), e6.	Thank you for your comment. The interventions in the suggested studies have significant involvement by healthcare professionals, for example healthcare professionals sending participants notifications through apps or text to remind them to use the interventions. This is out of scope. This guideline covers digital interventions that are automated (see Appendix A of the evidence reviews for protocols). Therefore, it cannot be included in the evidence reviews for this guideline. The 6-month follow-up period was used because the committee noted that positive effect estimates after a short follow-up period is likely to be down to people using a novel digital or mobile health intervention. The committee wanted to see sustained behaviour change over a longer period to assess if these affects are more longer lasting than a few weeks. Engagement data in the studies included in the evidence reviews was lacking. This is why the committee made research recommendations that included initial, medium- and long-term engagement as outcomes to obtain more data to allow engagement to be taken into account when assessing these interventions.

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Centre for Behaviour Change, University College London	Evidence review – smoking	General	General	Two studies were included in the low SES subgroup analysis. Both (Daly 2019 and Brown 2014) found that digital interventions were effective or cost-effective for low SES subgroups but the result of subgroup analysis appears not to differentiate subgroups. Also, this systematic review may be of interest: https://www.ncbi.nlm.nih.gov/pubmed/28034998	Thank you for your comment. While Brown 2014 did show a statistical significance for abstinence between control and StopAdvisor in the evidence review a random effects meta-analysis was chosen to account for the variation between studies. This makes confidence intervals wider to account for this variation meaning Brown 2014 is not statistically significant in this meta-analysis. The other study in this subgroup, Vidrine 2018, did not show a statistically significant difference in abstinence between NRT and NRT plus text. These two studies were the only evidence for this subgroup, but expert testimony said that outcomes for people with lower SES are likely to be different. After discussing this evidence, the committee made a research recommendation for more behaviour change in people with lower SES to obtain more research in this area.
Centre for Behaviour Change, University College London	Evidence review – smoking	026	014	"The committee noted that there are no subgroup differences in studies that assessed smoking using either biochemical or self-reporting." – it should be noted that this may be due to low power given the small number of studies and that it does not provide evidence of no subgroup differences.	Thank you for your comment. The review has been changed based on this suggestion.
Centre for Behaviour Change, University College London	Evidence review – smoking	026	016	Although no large-scale RCTs have yet been published on the effectiveness of digital interventions for people with chronic conditions such as cancer, there is a lot of ongoing work in this field and early evaluations have been published, for example:	Thank you for the additional information. We will make the surveillance team aware of these studies. They will consider these when conducting a surveillance report for this guideline.

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				Mujcic, A., Blankers, M., Boon, B., Engels, R., & van Laar, M. (2018). Internet-based self-help smoking cessation and alcohol moderation interventions for cancer survivors: a study protocol of two RCTs. BMC cancer, 18(1), 364. Kanera IM, Bolman CAWW, Willems RA, Mesters I, Lechner L, I.M. K, et al. Lifestyle-related effects of the web-based Kanker Nazorg Wijzer (Cancer Aftercare Guide) intervention for cancer survivors: a randomized controlled trial. J Cancer Surviv [Internet]. 2016 Oct;10(5):883–97.	
Centre for Behaviour Change, University College London	Evidence review – alcohol	General	General	It should be noted that 21 studies were included in comparison with the most recent Cochrane review in which 57 studies were included.	Thank you for your comment. The evidence review that informs this guideline has a follow-up threshold of 6 months, which was not a consideration for the Cochrane review. This means that many studies included in the Cochrane review would not be eligible for the evidence review in this guideline.
Centre for Behaviour Change, University College London	Evidence review – alcohol	General	General	Considering there have been two recent systematic reviews on this topic (Kaner et al., 2017; Riper et al., 2018), it would be helpful to discuss these in the evidence review and provide a potential explanation for the difference in findings and conclusions.	Thank you for your comment. During the review process, these systematic reviews were checked for references that may have been relevant to the review protocol for this question for possible inclusion in the evidence review for alcohol consumption. The protocol in the evidence review for alcohol consumption in this guideline had a follow-up threshold of 6 months, which the other reviews did not have, leading to differing studies being included.

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Centre for Behaviour Change, University College London	Evidence review – alcohol	General	General	It is also worth noting that whilst the NHS Apps Library is a good source for trusted apps, there are not any related to alcohol reduction on there currently (as of 6th March 2020), so nothing to recommend.	Thank you for your comment and additional information.
Centre for Behaviour Change, University College London	Evidence review – alcohol	General	General	Evaluations are not of apps that are widely used and available in app stores, so there does appear to be a disconnect between research and those apps used in practice.	Thank you for your comment. The committee were aware that this is the case and understood the lack of data in this area is not because interventions do not exist, it is because developers are not publishing their findings. This is why the committee wrote the recommendations in section 1.1 so reporting of effectiveness improves and ideally will inform practice.
Centre for Behaviour Change, University College London	Evidence review – alcohol	017	013	A drink is 8 (and not 10) g of pure alcohol in the UK (equivalent to 1 standard unit).	Thank you. This has been amended.
Centre for Behaviour Change, University College London	Evidence review – alcohol	026	015	"In addition, the committee noted there is no core set of outcomes concerning alcohol consumption." There is a core outcome set for alcohol trials that has been led by Gillian Shorter. The final paper has not been published yet but has been presented at a number of conferences and is shared by the authors on request. Shorter GW, Heather N, Bray JW, Giles EL, Holloway A, Barbosa C, Berman AH, O'Donnell AJ, Clarke M, Stockdale KJ, Newbury-Birch D. The 'Outcome Reporting in Brief Intervention Trials: Alcohol'(ORBITAL) framework: protocol to determine a core outcome set for efficacy and	Thank you for your comment and additional information.

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				effectiveness trials of alcohol screening and brief intervention. Trials. 2017 Dec;18(1):611. Shorter GW, Heather N, Bray JW, Berman AH, Giles EL, O'Donnell AJ, Barbosa C, Clarke M, Holloway A, Newbury-Birch D. Prioritization of outcomes in efficacy and effectiveness of alcohol brief intervention trials: international Multi-Stakeholder e-Delphi consensus study to inform a core outcome set. Journal of studies on alcohol and drugs. 2019 May;80(3):299-309.	
Centre for Behaviour Change, University College London	Evidence review – alcohol	026	036	"One such measure discussed was successful recruitment to studies. The committee agreed that the substantial dropout rates in many studies in the review may suggest problems with uptake of the intervention in the wider population." – I think this can be viewed as an issue with sustained engagement and retention rather than uptake of the intervention, as uptake and engagement are two separate behaviours.	Thank you for your comment. The committee noted that many people who were eligible were approached to participate but did not take up the offer. It is important to recognise that engagement and uptake are different behaviours so the review has been updated to make the intentions of the committee clear.
Centre for Behaviour Change, University College London	Evidence review – alcohol	037		Apps and multi-media are not necessarily delivered by the internet. Many apps need the internet to be downloaded but can then be used without any future access to the internet.	Thank you for your comment. This is correct, they are first downloaded through the internet which requires internet input in the first instance. Many apps are also updated with bug fixes, which is done through connecting with the internet.
Centre for Behaviour Change, University College London	Evidence review – alcohol	039		It would be important to note that there is the potential issue of having a self-selecting sample of people who want to use a digital intervention and reduce their drinking when using a before and after trial design.	Thank you for your comment. If before-and-after studies were to be used, this risk would have been captured in the risk of bias of those studies. Since there were RCTs available, these studies were not needed.

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Centre for Behaviour Change, University College London	Equality and Impact Assessment	002	003 - 004	The statement that "older people engage with digital interventions as well as other age groups" is questionable. Had a broader range of studies been included in the evidence review (i.e. not only RCTs with a 6-month follow-up), a different conclusion might have been drawn. It should also be noted that, while many studies have found that older subgroups of study populations engage as well as younger subgroups, few studies evaluating digital interventions for the particular behaviours of interest have successfully recruited participants aged 70+ years. This should be highlighted in the report.	Thank you for your comment. Expert testimony presented to the committee and discussed by the committee described that engagement does not differ between older and younger populations as described in the comment. 6 month follow-up was considered important for the committee as they agreed that sustained behaviour change is public health importance, whereas short-lived behaviour change provides little public health benefit. In order to obtain more evidence on how effective these interventions are in different age groups, research recommendation were written for identifying groups that do not initially engage, or do not stay engaged, with digital and mobile behaviour change interventions, components and characteristics of digital and mobile interventions are most effective, separately and combined, to achieve behaviour change, which contain people over 60 as a specific consideration.
Centre for Behaviour Change, University College London	Equality and Impact Assessment	002		It is unclear why sex and race are listed under 'Disability'. Similar to the comment above about age, several studies have found that sex and ethnicity influence users' engagement with digital interventions.	Thank you for your comment. Age, disability and race are listed separately in the Equality Impact Assessment. Evidence for engagement with digital and mobile health interventions was poor and therefore cannot deduce if sex and ethnicity affect engagement. Because of this, research recommendations included these populations as specific considerations (detail of research recommendations found in Appendix B, evidence review 1: smoking).

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Centre for Behaviour Change, University College London	Supporting documentation - Methods	General	General	It is unclear why the committee decided to only include studies with outcome data at a 6-month follow-up, as this excluded >50% of available RCTs with valuable evidence on both effectiveness and user engagement.	Thank you for your comment. An intervention that is associated with a prolonged behaviour change is important to the public health of the population. The committee agreed short-term changes in behaviour could be attributed to people using a novel intervention and realised the importance of sustained behaviour change. The unhealthy behaviours in this guideline are those that require a long term behaviour change that is sustained, therefore it was this type of change that the evidence reviews focused on. This approach was also taken by NICE guideline Behaviour change: individual approaches (PH49).
Centre for Behaviour Change, University College London	Supporting documentation - Methods	General	General	It is unclear why data were not extracted on variables relating to the equality issues highlighted in the 'Equality and Impact Assessment' (e.g. moderator/predictor analyses of effectiveness/engagement). An explanation is needed as to why the different variables were selected for the sensitivity/moderator analyses for each behaviour (e.g. pregnant vs. not pregnant smokers).	Thank you for your comment. Where evidence is available, studies are split into subgroups based on the populations of specific considerations listed in the protocol for each review (Appendix A). Specific consideration is given to populations that may respond differently to interventions, or are high risk, which is why they differ between evidence reviews. The committee specified these at the protocol stage. Evidence for groups identified in the EIA were extracted into the evidence tables of the reviews. This was only possible if the included studies gave these details, and many studies did not provide this information. Because of this lack of information, expert witnesses were asked to cover these gaps across all reviews by presenting information to the committee for discussion. Details of the expert testimony that covers all reviews for this guideline and an overall

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					discussion of the evidence can be found in evidence review 1: smoking. Research recommendations were written to cover this gap in evidence, for which there are populations of specific considerations (detail of research recommendations found in Appendix B evidence review 1: smoking).
Centre for Behaviour Change, University College London	Supporting documentation - Methods	General	General	It would be helpful to have more information on the methods: How many reviewers were involved in the evidence review? Was a proportion of studies double screened by two reviewers? Any reliability checks? Were the BCTs coded on the basis of intervention descriptions? Was any double coding conducted here?	Thank you for your comment. This information is found in the 'selection process' section of protocol, Appendix A in each review. Methods that are relevant to all reviews are found in the separate "Methods chapter". Methods specific to reviews are found in the "Methods and Process" and "Synthesis and quality assessment of effectiveness evidence included in the review" headings in each review. Further information can also be found in developing NICE guidelines: the manual.
Centre for Behaviour Change, University College London	Supporting documentation - Acknowledgements	General	General	The conflicts of interests of those who provided expert testimony are not declared.	Thank you for your comment. Conflicts of interests for expert witnesses are found in the register of interests, published on the "Documents" page of the guideline development page until publication. After publication, this will be found under the "History" tab of the guideline when published.
Chartered Society of Physiotherapy	Guideline	General	General	There needs to be recognition of the role that training of health professionals needs to be reviewed as a result of this guideline.	Thank you for your comment. The training of healthcare professionals is outside of the scope of this guideline. Professional bodies usually have a leading role in identifying training needs for their healthcare professionals unless something specific is identified during the development of the guideline.

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Chartered Society of Physiotherapy	Guideline	General	General	There needs to be recognition of the training need for some staff in the existing workforce to be upskilled in digital to allow them to explore recommendations to their patients.	Thank you for your comment. The training of healthcare professionals is outside of the scope of this guideline. Professional bodies usually have a leading role in identifying training needs for their healthcare professionals unless something specific is identified during the development of the guideline.
Chartered Society of Physiotherapy	Guideline	General	General	Repeated recognition of the fact that we don't know if the digital and mobile health interventions may or may not be effective is understandable but we should be encouraging clinicians to play a role in developing that knowledge and evidence base. The repetition of the statement feels like it is an admission that we never will have the evidence of efficiency when the reality is we don't have it yet.	Thank you for your comment. The committee wanted to make referrers and potential users aware that these interventions have variable effectiveness. This means they may be suitable for some people and not for others, but it is difficult to know for whom they would be effective with the current evidence base. The committee were keen to improve the evidence base for digital and mobile health interventions, which is why they made the recommendations in 1.1 so products that are developed are of higher quality and tested more rigorously. They also made research recommendations on which components are most effective, for whom they are most effective, how to engage people who do not currently engage with these interventions, and how these interventions can reduce inequalities.
Chartered Society of Physiotherapy	Guideline	General	General	Ensuring that escalation to emergency services where appropriate is part of the use of digital and mobile health interventions is important. Where those patients are supported by self-management or remote monitoring by a professional it is essential that the signs and	Thank you for your comment. When referrers are discussing options for people, they will take into account the risk and suitability of the person for the intervention. For the behaviours considered in this guideline and the way the interventions are used, emergency intervention

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				symptoms of need for emergency escalation are recognised and not acted on too late or not at all simply because the patient was "out of sight and out of mind".	would not normally be a concern for these interventions. Interventions that are used to diagnose a condition would be considered a medical device and regulated by the MRHA, and therefore would be out of scope for this guideline.
Chartered Society of Physiotherapy	Guideline	General	General	Clinicians need to trust a digital/mobile health intervention before they can recommend it to a patient so using trusted bodies to do that will help to improve the uptake rather than clinicians not knowing enough to make recommendations or making recommendations for unsafe applications.	Thank you for your comment. The NHS Apps Library is recommended as a resource for digital interventions in the guideline (recommendation 1.3.3).
Chartered Society of Physiotherapy	Guideline	General	General	Multiple mention of cost savings is a misnomer. Experience tells us that it is unlikely that digital and mobile health interventions will make direct cost savings and cash return. However, they if implemented correctly can make efficiency savings that will not always be felt directly by the service who is implementing the intervention. Acknowledgement of this is vital if we want to implement digital and mobile health interventions at scale.	Thank you for your comment. We agree and have amended the text accordingly. The committee's discussion of the evidence sections in the evidence reviews provide more detail and explanation of the economic evidence under subheading "Cost effectiveness and resource use".
Chartered Society of Physiotherapy	Guideline	General	General	It is not mentioned in the guidance documentation but there is also the possibility that in delivering efficiency savings for one service may have an unintended negative consequence on another service. Proper investigation, evaluation and understanding of all stakeholders is essential in the planning stage and throughout implementation.	Thank you for your comment. Commissioners can make decisions on which interventions would benefit their local area, how they would sit in the care pathway and whether it is good value for money. The guideline also states that existing services should not be replaced by digital and mobile health interventions. This can be done by conducting needs and impact assessments, as recommended

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					for commissioners to do in section 1.2 of the guideline.
Chartered Society of Physiotherapy	Guideline	General	General	Guideline focusses too much on the maintenance aspect of digital interventions and should include applications supporting behaviour change at a more pro-active, preventative or prehabilitation level. These applications may lead to better health outcomes. This pro-active upstream approach would likely result in efficiency savings in services from reduced presentation and improved self-management.	Thank you for your comment. The focus of this guideline is not prevention of unhealthy behaviours or the maintenance of healthy behaviours, but on changing people's unhealthy behaviours. Other guidance is available on prevention: PH23 smoking prevention in schools; PH24 alcohol-use disorders: prevention; PH3 STIs and under-18 contraception: prevention; PH42 obesity: working with local communities; NG7 preventing excess weight gain.
Chartered Society of Physiotherapy	Guideline	005	015	Digital and mobile health interventions might form a innovative and completely new service as well as being a supplement to existing services. In places they might be able to replace services but as long as they meet a large number of criteria and eventualities so should not be ruled out completely.	Thank you for your comment. The committee understood the value of digital and mobile health interventions. However, from the evidence that is currently available they did not recommend that digital interventions should be commissioned to replace any existing services. Recommendation 1.3.1 says that referrers can discuss digital as an option for behaviour change. The rationale for this recommendation states that digital interventions would be best used alongside other existing services people may use, but for some people a digital intervention may be the best option for them. Recommendation 1.3.2 provides referrers with factors to take into account when deciding whether a digital intervention would be suitable for a person. Before a decision can be made on whether digital and mobile health interventions can replace existing

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					services, more research is needed. This is why research recommendations were made for effective components, effects for low socioeconomic and other underserved groups, populations who will benefit most from these interventions and the sustainability of behaviour changes.
Chartered Society of Physiotherapy	Guideline	006	001 - 004	Collaboration across the UK and internationally should also be explored to share developments costs and also to prevent repeated work	Thank you for your comment. The committee agree with the potential of collaboration and therefore made recommendation 1.2.6. Please also note recommendation 1.2.4 which asks commissioners to check if existing evidence-based digital or mobile health interventions can be used before commissioning a new one.
Chartered Society of Physiotherapy	Guideline	006	018 - 025	Need to also consider how and by whom the data from a digital or mobile health interventions could be used and shared	Thank you for your comment. Based on feedback from consultation, the committee concluded that the developers had a responsibility to provide information on how users can check and set preferences for how their personal information and data may be used. Therefore, the guideline now includes this in a recommendation. The NICE evidence standards framework for digital health interventions recommended in 1.1.1 says interventions should be designed to allow continual outcome data retrieval from consenting users. It also says that developers need to measure the economic impact and effectiveness of these interventions.
Chartered Society of Physiotherapy	Guideline	007	002 - 003	ORCHA are also a globally recognised reviewer of apps so should be considered an expert source	Thank you for your comment. The committee were concerned about the lack of transparency in ORCHA's review process and did not decide to recommend it.

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Chartered Society of Physiotherapy	Guideline	013	009 - 018	Clinicians being involved in the development of digital and mobile health interventions should be encouraged as a change to existing practice. There are a number of clinicians already involved in this space that could be used as examples	Thank you for your comment. The committee agrees that having both healthcare and technology experts involved in intervention development is important to create an intervention that is theoretically sound and appealing to use.
Chartered Society of Physiotherapy	Guideline	014	022	Clinicians as well as commissioners could use the NICE guidance, evidence framework and needs assessment when choosing digital and mobile health interventions that would suit the clinical practice	Thank you for your comment. Clinicians and other referrers are asked to discuss suitable options for digital intervention components with individuals and not for clinical practice generally. The expert sources provided in recommendation 1.3.3 will allow referrers and individuals make decisions more easily than by going through the evidence standards framework.
Diabetes UK	Guideline	General	General	Digital and mobile interventions may offer some people improved access to care while for others it may act as a barrier. Digital exclusion and digital literacy will have a significant impact on the uptake of digital and mobile health interventions for some people. Healthcare professionals should not make assumptions about who may or may not benefit from digital and mobile health interventions and guidance on how to assess an individual's digital literacy could be of help. This may include, for example, questions about the use of digital technologies in other areas of a person's life.	Thank you for your comment. The committee understand that digital literacy is an important consideration to make when deciding whether to discuss digital interventions with people. This is considered under the capability, opportunity, and motivation of the person, which is included as a bullet in recommendation 1.3.2. These terms are now described under the "Terms used" section in the guideline. Digital literacy has now been added to recommendation 1.3.2, alongside health and reading literacy.
Diabetes UK	Guideline	General	General	This draft guideline raises some concerns about quality control surrounding mobile and digital health interventions. While we support recommendation 1.3.3, this could be	Thank you for your comment. The guideline recommends expert sources such as the NHS Apps Library (recommendation 1.3.3).

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				strengthened to include a clear instruction that healthcare professionals should not promote the use of digital or mobile health interventions that have not been thoroughly scrutinised and are promoted via, for example, the NHS apps library.	
Diabetes UK	Guideline	004	004 - 010	We are pleased to see NICE recommending that developers refer to national frameworks when developing and evaluating their interventions. This approach will allow evidence and data on digital and mobile health interventions to be collected in a more routine manner, contributing ultimately to people accessing the best, evidence-based interventions available.	Thank you for your comment. The committee wanted developers to follow these frameworks to generate evidence of effectiveness and to maintain consistency and high standards across interventions.
Diabetes UK	Guideline	004 - 005	018 - 009	We support this recommendation on the involvement of potential product users throughout its development. In particular, we support patient and public participation 'as early as possible'. However, we would like to see this recommendation go further by encouraging user involvement beyond development and roll-out of the product, to ensure it continues to service the purpose it is designed for.	Thank you for your comment. A recommendation has been added that reads "Use feedback from testing and after releasing the intervention to continually improve the intervention."
Diabetes UK	Guideline	006	016 - 017	Recommendation 1.3.1 should specify that digital and mobile health interventions are considered as an option **in addition to** more traditional, face-to-face options.	Thank you for your comment. The committee agreed that digital services should not replace existing services. Therefore, recommendation 1.3.1 now reads "Consider digital and mobile health interventions as an option for

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				Although digital and mobile health interventions offer some people an opportunity to access care they might otherwise not receive, it is important that such interventions do not replace care in a face-to-face setting. We suggest that having the option of interventions in a face-to-face healthcare setting **and** on digital platforms would offer patients choice in their care – something key to a person-centred approach.	behaviour change as an adjunct to existing services. Be aware that effectiveness is variable.
Diabetes UK	Guideline	006	016 - 017	Recommendation 1.3.1 should state explicitly that patients being offered digital and mobile health interventions are made aware of the limits of proven effectiveness as assessed by traditional clinical research. This will allow patients to make informed decisions about the care they receive, in discussion with their healthcare professional.	Thank you for your comment. Recommendation 1.3.1 now says that effectiveness is variable. NICE agrees that any decisions about a person's care should involve an informed discussion with the person, including evidence of effectiveness. This has been added to recommendation 1.3.2.
Drinkaware	Guideline	004	016	**Recommendation 1.1.4** This recommendation may be challenging in practice as to design interventions so they can be scaled up and also customised for local needs should involve a full local needs assessment, which will have cost implications.	Thank you for your comment. A recommendation for commissioners is included in the guideline which asks them to assess whether specific digital and mobile health interventions could meet some of the needs of the local population by using a needs assessment. A resource impact assessment has been conducted by NICE and the recommendation is not expected to add substantial additional costs as local needs assessment are

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					considered good routine practice. It is anticipated that any extra costs may be offset by the benefits.
Drinkaware	Guideline	005	016	**Recommendation 1.2.3** As above. This recommendation states a needs assessment. While this should be best practice, this may be costly and is complex, which may be difficult to implement in practice.	Thank you for your comment. A resource impact assessment has been conducted by NICE and the recommendation is not expected to add substantial additional costs as local needs assessment are considered good routine practice. It is anticipated that any extra costs may be offset by the benefits.
Drinkaware	Guideline	005	022	**General - Recommendation 1.2.5** The guidance notes checking expert sources (such as PHE; NHS Apps library); Drinkaware would support this and also recommend a central database of interventions.	Thank you for your comment. The expert sources are meant to be a resource for interventions. Whilst a central database for interventions may be useful, this is out of scope for this guideline.
Drinkaware	Guideline	010	009	**General** We would suggest including into the research, examining the types of behaviours that digital interventions can be usefully used for, and the characteristics of those behaviours. For example, simple, on off behaviours vs complex, long term habitual ones.	Thank you for your comment. The guideline was commissioned to identify which components and characteristics of digital and mobile health interventions would be associated with positive behaviour change. However, the evidence base did not allow many component-specific recommendations to be made. This is why research recommendation 2 "What components and characteristics of digital and mobile health interventions are most effective, separately and in combination, to achieve behaviour change?", which will help answer the query raised in the comment.

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Institute of Alcohol Services	Guideline	General	General	**Consultation in general** This consultation relates to multiple unhealthy commodities (tobacco, alcohol, junk food) and it is very concerning that the only conflict of interest that has to be disclosed is with the tobacco industry. There is a growing focus on the corporate determinants of health and unhealthy commodities. There is also the possibility that developers and providers of digital interventions might be responding to this specific consultation. Responses to this consultation which have conflicts of interest relating to unhealthy commodities or these interventions will be indistinguishable from those without conflicts of interest. This is at odds with other guidance from NICE, as well as the World Health Organization and Public Health England.	Thank you for your comment. The statement regarding disclosing conflicts of interest with the tobacco industry is standard for all guidance that is put out for consultation. Conflict of interest from those funding studies in the included evidence base are extracted into the evidence tables provided to the committee for their discussions. The development for this guideline is in line with developing NICE guidelines: the manual and the WHO policy on tobacco. Information on funding and funders is extracted from the papers and included in the data considered by the committee.
Institute of Alcohol Services	Guideline	005	014	Digital interventions already exist and therefore evidence-based guidance on their use is welcomed. The guidance to commissioners is that digital interventions should be a supplement to existing services, not a replacement. This is important and would potentially have a big impact on existing practice, but there is limited context regarding existing practice. This may make implementation challenging, as it is not clear how this would work in practice and who would be	Thank you for your comment. The committee made recommendations for the commissioning of digital or mobile health interventions. These will enable commissioners to assess if a digital intervention is suitable for their population. The recommendations do not mandate that digital interventions should be commissioned as the committee understood that regions will consider what is the most appropriate option for their area. As recommendation 1.2.2 states, commissioners

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				commissioning these interventions. For example, are digital interventions to be recommended in addition to alcohol screening and brief intervention? Would this be the case in all settings and population groups? The guidance should make a distinction around who digital interventions for alcohol may be suitable for. For example, there is scientific evidence that digital interventions may reduce alcohol consumption among hazardous drinkers. However existing digital interventions are unlikely to be suitable for dependent drinkers wishing to cut down, who may require medically-supervised detoxification as well as pharmacological and/or psychological support for relapse prevention. There is limited evidence around the role of digital interventions in either reductions in alcohol consumption among dependent drinkers or in recovery from alcohol dependence.	should commission these interventions as a supplement to existing services. With the evidence currently available in the literature, it is not possible to make specific recommendations for population groups beyond those wanting to change any of the 4 behaviours included in this guideline.. This is why recommendations 1.3.2 and 1.3.3 list factors to consider and discuss with potential users to assess if a digital intervention would be suitable for them.. This guideline excludes dependent drinkers as the committee agreed that they would need more intensive support and treatment (please see the protocol for the alcohol review, Appendix A, evidence review 2: alcohol). NICE guideline CG115 Alcohol-use disorders: diagnosis, assessment and management of harmful drinking (high-risk drinking) and alcohol dependence covers this group.
Institute of Alcohol Services	Guideline	007	003	The guideline recommends using digital interventions or apps from expert sources, such as the NHS apps library. However, there is limited choice in these sources at present. There are currently no apps for alcohol available in the NHS apps library (as of 6th Feb 2020) and only one in the PHE library (Drink Free Days). It is unclear whether the Drink Free Days app would be recommended based on the effective components identified in the evidence review	Thank you for your comment. The aim of the reviews was to find effective components and recommend these, instead of recommending specific interventions. The guideline recommends the use of expert sources, such as the NHS Apps library. This is a rapidly changing area, it is anticipated that the availability of apps from expert sources will increase. The committee considered it important that interventions are not accessed from non-expert

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				(e.g. normative feedback) or in other systematic reviews (e.g. Garnett et al meta-regression). Linked to this, if NICE is going to recommend digital interventions to the public, it would be beneficial as part of this piece of work to improve the transparency around the criteria for inclusion in the NHS apps library. Specifically, what sort of evidence is eligible as part of 'Available evidence on outcomes', and whether this is to the same level as would be expected of other recommendations that NICE would make.	sources where the assessment of these interventions is unknown. This is outside of NICE's remit.
Institute of Alcohol Services	Guideline	008	016	It may be helpful to include in the headline guideline for alcohol (1.6.1) that this is in addition to and not replacing any existing services. The phrasing of the first alcohol guideline (1.6.1) is confusing since it recommends digital interventions and then somewhat under-states their evidence base. The guideline recommends considering digital interventions to reduce alcohol consumption, but then states it is not clear whether or not digital interventions are effective for alcohol. It is true we do not have evidence that digital interventions work for everybody, but multiple systematic reviews have already identified that digital interventions can be effective. We would welcome more clarity on and specific research recommendations on types of intervention (in particular guided vs unguided, linked to face-to-face interventions or not),	Thank you for your comment. Recommendation 1.6.1 now says digital and mobile health interventions should be used as an adjunct to existing services. The research recommendations found in evidence review 1: smoking contain the research recommendations resulting from this guideline. They contain recommendations to assess if digital interventions work in tandem with other behaviour change interventions, in which subgroups the interventions are most effective, and which components and combinations of components are effective for behaviour change. Most other systematic reviews have assessed the effectiveness of digital interventions in the short-term but do not show sustained behaviour change.

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				behaviour change techniques and population sub-groups.	
Institute of Alcohol Services	Evidence review - alcohol	General	General	The evidence review states one UK unit of alcohol is 10g ethanol (it is 8g or 10ml ethanol). It is unclear whether this is a typographical error, or whether this would also have influenced the calculations around the results of the RCTs.	Thank you for your comment. This is a typographical error which has now been corrected.
Institute of Alcohol Services	Evidence review - alcohol	General	General	The review question was around what components are effective, but the majority of the review discusses effectiveness in general. There are several existing systematic reviews of the effectiveness of digital interventions for alcohol which have not been discussed by way of background. Some of these have not been cited in the evidence review at all (e.g. Donoghue, Riper) which could indicate relevant trials may not have been identified in the search strategy. Others which have been identified have been excluded for unclear reasons (e.g. Kaner Cochrane review – excluded due to 'ineligible outcomes' when this would be very useful background and includes information on intervention components), or information relevant to the research question of the evidence review has not been utilised (e.g. Garnett meta-regression – has detailed information on behaviour change techniques that could be relevant under components of interventions).	Thank you for your comment. The aim of the review was to find effective components of digital and mobile health interventions. We aimed to do this by finding studies that assessed components directly. If no such studies could not be found, subgroup analysis and meta-regression was planned to determine which components were most effective. However, the studies that were relevant to the review protocol were too multicomponent to analyse in this way. Kaner 2017 had a number of studies with a follow-up of less than 6 months and was not included in the review. Riper 2018 included studies that had follow-up of less than 6 months. Of the studies that had follow-ups of 6 months or longer, one was included in the evidence review for alcohol. All others were considered and excluded during the systematic review process for the following reasons: intervention contained too much healthcare practitioner involvement; population contained only people drinking more than 35 units a week; baseline outcomes combined men and women to provide mean but follow-up reported men and women means separately; no follow-up data relevant to

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				For example: • Kaner, E. F., Beyer, F. R., Garnett, C., Crane, D., Brown, J., Muirhead, C., ... & Hickman, M. (2017). Personalised digital interventions for reducing hazardous and harmful alcohol consumption in community-dwelling populations. Cochrane Database of Systematic Reviews, (9). • Garnett, C., Crane, D., Brown, J., Kaner, E., Beyer, F., Muirhead, C., ... & Michie, S. (2018). Reported theory use by digital interventions for hazardous and harmful alcohol consumption, and association with effectiveness: meta-regression. Journal of medical Internet research, 20(2), e69. • Riper, H., Hoogendoorn, A., Cuijpers, P., Karyotaki, E., Boumparis, N., Mira, A., ... & Blankers, M. (2018). Effectiveness and treatment moderators of internet interventions for adult problem drinking: An individual patient data meta-analysis of 19 randomised controlled trials. PLoS medicine, 15(12). • Riper, H., Spek, V., Boon, B., Conijn, B., Kramer, J., Martin-Abello, K., & Smit, F. (2011). Effectiveness of E-self-help interventions for curbing adult problem drinking: a meta-analysis. Journal of medical Internet research, 13(2), e42. Donoghue K, Patton R, Phillips T, Deluca P, Drummond C. The Effectiveness of Electronic	protocol However, it was citation checked and relevant references were included in the evidence review. The Donoghue and Riper 2011 systematic reviews were too old to be included. Garnett includes studies with less than 6 months follow-up and it is unclear which these are.

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				Screening and Brief Intervention for Reducing Levels of Alcohol Consumption: A Systematic Review and Meta-Analysis. Journal of Medical Internet Research. 2014 Jun 2;16(6):e142.	
Institute of Alcohol Services	Evidence review - alcohol	General	General	The decision to exclude trials with a follow-up of less than six months has not been justified. A large number of trials have been excluded on this basis, so a justification should be provided.	Thank you for your comment. Limiting protocols to 6-month follow-up or longer has now been justified in the reviews. The committee agreed that sustained behaviour change should be demonstrated by the interventions considered in the reviews. This allows them to assess if the behaviour change observed is ingrained behaviour change and not just attributed to short term behaviour change resulting from people using novel interventions. The reasoning for this is explained in the protocols and committee discussions of the evidence, found in the evidence reviews.
Institute of Alcohol Services	Evidence review - alcohol	026	014	The review mentions there is no core outcome set for alcohol consumption – one has been developed and will be published shortly. Some details here http://inebria.net/meetings-and-activities/special-interest-groups/update-for-outcome-reporting-in-brief-intervention-trials/	Thank you for your comment and additional information.
Institute of Alcohol Services	Evidence review - alcohol	026	030	The review mentions there is limited evidence on engagement with digital interventions and suggests poor retention in RCTs could indicate engagement with interventions may be difficult. Retention in RCTs may be linked to the intervention, but could also be due to various other reasons (such as inadequate resource for follow-up, intrusive trial procedures), and likewise	Thank you for your comment. The committee commented on the high attrition rates in the studies and the lack of engagement data. They were aware of other factors that may lead to attrition but suggested that attrition is a good indicator of how engaging the intervention is. As you have commented, factors associated with the trial itself might be associated with attrition. To combat this, data on how people use these interventions in the

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				poor engagement with an intervention does not necessitate drop-out from a trial. Engagement with digital alcohol interventions is certainly an issue, and there is an emerging body of work on this topic (e.g. work of Jo Milward and Olga Perski, examples below). • Milward, J., Drummond, C., Fincham-Campbell, S., & Deluca, P. (2018). What makes online substance-use interventions engaging? A systematic review and narrative synthesis. Digital health, 4, 2055207617743354. Perski, O., Baretta, D., Blandford, A., West, R., & Michie, S. (2018). Engagement features judged by excessive drinkers as most important to include in smartphone applications for alcohol reduction: A mixed-methods study. Digital health, 4, 2055207618785841.	real world would be valuable. The NICE evidence standards framework for digital technologies has been recommended by the guideline for developers to follow, which should increase the amount of real world data retrieved by new interventions. The Milward systematic review and its references were checked for applicability for the alcohol and smoking reviews. None of the studies were relevant to the protocols for the following reasons: chewing tobacco; preventing relapse; smokeless tobacco users (which is covered by the tobacco guidelines that are currently being updated and amalgamated into one guideline, Tobacco: preventing uptake, promoting quitting and treating dependence); follow-up shorter than 6 months; alcohol consumption too high. The Perski study focuses on participants' preferences for features on smartphone apps, and not behaviour change or engagement outcomes which are relevant to the evidence review protocols for this guideline.
Johnson & Johnson Ltd	Guideline	General	General	We welcome the development of guidelines for interventions that use a digital or mobile platform to help people change established unhealthy behaviours, and – given the abundance and varying quality of such interventions available to people – we recognise the need for clear evidence-based guidance for policy makers, commissioners, health care professionals and individuals.	Thank you for your comment.

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Johnson & Johnson Ltd	Guideline	008	009	(1.5.1) We fully support the guidance that digital and mobile health interventions should be considered as an option to help people stop smoking. We have some concerns about the phrasing of this recommendation, specifically "…*it is not clear whether or not they are effective"* which suggests that the evidence is equivocal on the efficacy of mobile and detail interventions, when actually, because of a recognised paucity of studies on digital interventions for behaviour change, it is the precise lack of any evidence which is the issue. The absence of evidence does not call into doubt their efficacy any more than an absence of evidence would support their efficacy.	Thank you for your comment. The wording for these recommendations has now been changed to reflect that that digital and mobile health are recommended as an adjunct to existing services. The committee have also amended the wording of recommendation 1.5.1 so it says that effectiveness of these interventions is variable. Though the overall effect estimate of the smoking evidence shows in favour of smoking cessation, there is considerable heterogeneity between and within the studies. Many studies have very wide confidence intervals that cross the line of no effect. In addition, most studies did not compare with current usual care. Therefore, it is reasonable to suggest that these interventions would be beneficial to some people and should be made available as an option for behaviour change alongside existing services.
Johnson & Johnson Ltd	Guideline	008	012	(1.5.2) We are concerned that this recommendation mixes method of delivery with effectiveness of the intervention. It highlights the efficacy of text message interventions that send tailored messages compared to other digital and mobile health interventions, but it is not clear if those "other digital and mobile health interventions" include programmes which could deliver tailored messages to their users. Rather than creating emphasis on the method of delivery (i.e. text message, app or other), the	Thank you for your comment and the additional information. Detail on other interventions are provided in the evidence reviews under 'summary of studies included in the evidence review' and evidence tables sections. None of the comparator interventions in the smoking review were tailored. This guideline gives guidance on digital and mobile health interventions, including those to aid smoking cessation. As detailed in the scope and the protocols, interventions that have significant healthcare professional input, such as phone calls or video chat, and pharmacotherapy interventions are

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				critical message here should be that personalised behavioural support alongside pharmacotherapy is known to be the most effective intervention in achieving prolonged abstinence[1]. However, the personalised support given to users is not simply limited to tailored text messages or face to face consultations with a healthcare professional, but according to several Cochrane reviews[2,3] can also include programmes where specialist counselling is given via telephone and or video chat which some apps offer as a functionality to users. Therefore, our concern is that the guidance as drafted will be susceptible to being interpreted as text message interventions being the only recommended option without consideration of the degree of personalisation other digital solutions have to offer. **Reference:** 1. *Hartmann-Boyce J, Hong B, Livingstone-Banks J, Wheat H, Fanshawe TR. Additional behavioural support as an adjunct to pharmacotherapy for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 6. Art. No.: CD009670. DOI: 10.1002/14651858.CD009670.pub4.*	excluded. Furthermore, this is why the reference Hartmann-Boyce 2019 and Stead 2016 are not included in this guideline. NICE's guidelines on tobacco are currently being amalgamated and updated, in which non-digital therapies are considered. Whittaker 2016 was considered during the systematic review process but was excluded on full text because it was published before 2017.

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				2. *Whittaker R, McRobbie H, Bullen C, Rodgers A, Gu Y. Mobile phone-based interventions for smoking cessation. Cochrane Database of Systematic Reviews 2016, Issue 4. Art. No.: CD006611. DOI: 10.1002/14651858.CD006611.pub4.* 3. *Stead LF, Koilpillai P, Fanshawe TR, Lancaster T. Combined pharmacotherapy and behavioural interventions for smoking cessation. Cochrane Database of Systematic Reviews 2016, Issue 3. Art. No.: CD008286. DOI: 10.1002/14651858.CD008286.pub3.*	
Ki Performance Lifestyle Ltd	Guideline	005	022 - 025	We agree with *Guideline 1.2.5* that expert sources should be checked for any existing evidence-based digital and mobile health interventions that can meet local needs; however, we would further emphasise the need for any expert source to be valid. For example, the Digital Assessment Questions v2.2, which developers are required to answer be published the NHS Apps Library, require evidence to support any clinical, behavioural, economic, or other outcome to be submitted. We encourage the NHS Apps Library to be transparent and	Thank you for your comment. Apps that have been listed on the NHS Apps Library would have passed the questions on the Digital Assessment Questionnaire, which is recommended by this guideline for developers to use when developing interventions. It is outside of NICE's remit to comment on the NHS Apps Library on transparency.

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				indicate which type of outcomes had been evidenced for each intervention. For example, for the digital and mobile health interventions to which these new guidelines are applicable, evidence to support positive behavioural and clinical outcomes would be most applicable when making a decision to commission or recommend an intervention to a service user.	
McKesson UK	Guideline	004	002	**Recommendations 1.1** We agree with the recommendations on developing digital and mobile health interventions, however we would like to highlight the importance of maintaining an agile approach particularly around emerging technology. Any recommendations around developing digital and mobile health interventions should not stifle innovation and enable adoption of new technologies that may not be currently apparent.	Thank you for your comment. The committee recognised that more innovation was needed to make more effective and appealing interventions. They also recognised that interventions should be developed with rigour and tested for effectiveness with people who will be using them. The committee made recommendations to enhance development of interventions and assist innovation. Testing interventions appropriately should not impede innovation and will allow good quality evidence and effective interventions to emerge.
McKesson UK	Guideline	005	010	**Recommendations 1.2** We fully support the recommendations around the use of expert resources and that digital and mobile health interventions should be evidence based and be validated by Public Health England or within the NHs apps library.	Thank you for your comment.
McKesson UK	Guideline	006	001	**Recommendations 1.2.6** The recommendation suggests that commissioners should assess whether a regional-level multidisciplinary collaboration, or partnership with other health and care	Thank you for your comment. Recommendation 1.2.4 asks commissioners to check if existing evidence-based digital and mobile health interventions can meet local needs before commissioning a new one. Recommendation 1.2.6

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				organisations would be appropriate to share development costs if a new digital and mobile health intervention is needed. The development of new, evidence-based platforms can take up to 3-5years, and therefore we suggest that commissioners should look to build on existing solutions, or work with existing providers to develop modifications or adaptations to current platforms.	asks commissioners to think about collaboration in multidisciplinary teams, which may include adapting existing interventions.
McKesson UK	Guideline	006	005	**Recommendations 1.2.7** In terms of equality of access, it is important that apps are developed to work on any platform, and not for single operating systems or specific devices.	Thank you for your comment. Bullet point 3 considers operating systems when choosing interventions.
McKesson UK	Guideline	006	013	**Recommendations 1.3** We agree with the elements that need to be taken into account at 1.3.2, and the note that, on considering digital and mobile health interventions it is important that health professionals are aware that it is not clear whether or not they are effective. We believe that there should be steps taken to increase the evidence base to compare the effectiveness of digital and mobile interventions and conventional delivery methods.	Thank you for your comment. The committee noted that some interventions work and some people experience good outcomes by using these interventions. However, it is variable across the population. Therefore, research recommendations were made to assess the effectiveness of digital and mobile health intervention components and combinations of components.
McKesson UK	Guideline	007	001	**Recommendations 1.3.3** In the main we agree with the points made, especially around using digital and mobile health interventions from expert sources such as Public Health England or the NHS apps library, we do	Thank you for your comment. The reviews informing this guideline did not find evidence on harms and adverse effects of digital and mobile health interventions. Therefore, a research recommendation was made to look into

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				have concerns however about the potential for solutions to include adverts and would strongly advise against this, as this could possibly trigger certain behaviours. It could also inadvertently enable direct to patient marketing which would also be against current regulations. Our opinion is that platforms and solutions used by the NHS for this purpose should be advert free.	these. When the guideline is updated, relevant evidence on harms and adverse events will be considered. The committee discussed interventions that used adverts and said that many use adverts as a way of gaining revenue. In this way, many interventions can reduce their costs or remain entirely free, increasing accessibility of these interventions. The committee were aware of the possibility of adverts having opposing effects to the aims of the intervention which is why they recommended that advert-free interventions are preferred, and for developers to be mindful of the adverts their interventions include.
McKesson UK	Guideline	007	011	**Recommendations 1.3.4** We agree that there should be a range of options available to healthcare professionals and people looking to access behavioural change services, so that there are multiple options available to suit individual needs. Sometime conventional methods such as face-to-face interaction are only available during working hours (9-5) which can be a barrier to people accessing behavioural change interventions and, in those cases, a digital or mobile solution is an ideal alternative, however it will not suit everyone. Choice of intervention should be discussed between the healthcare professional and the individual to understand their preferences and the likelihood of success of using one method over another.	Thank you for your comment. The committee agreed that discussing intervention options is important, and that digital interventions should be included in this. The committee identified factors that referrers should ask about and take into account when discussing behaviour change intervention options with people, found in recommendations 1.3.2 and 1.3.3. This should include how an intervention would fit into their life and current care pathway. A NICE guideline is currently being developed on shared decision making which is looking at the best ways to conduct shared decision making.

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MUTU Holdings Ltd	Guideline	017	007	Using only digital or mobile apps registered on the NHS Apps Library will help overcome challenge of using professionals' time and resources to check risk of harm - due to rigorous testing now required for registration on NHS Apps Library.	Thank you for your comment.
National Surveys of Sexual Attitudes and Lifestyles (Natsal)	General	General	General	We wish to alert NICE to the following points from the National Surveys of Sexual Attitudes and Lifestyles (Natsal). Natsal are large probability-sample bio-behavioural surveys, representative of the British population. Together, Natsal-1 (1990-1991), Natsal-2 (1999-2001) and Natsal-3 (2010-2012) have interviewed >45,000 men and women, spanning those born through much of the 20th Century. Natsal's repeat cross-sectional design enables a contemporary picture to be presented while also capturing generational changes and broad societal shifts through the measurement of both period and birth cohort effects. Natsal provides evidence of the context, influences and consequences of sexual lifestyles, and is vital for informing national and international sexual health interventions, strategies, and guidelines.	Thank you for your comment. The evidence provided is out of scope for this guideline. NICE guidelines look at comparative data to find the most effective interventions - see developing NICE guidelines: the manual.
National Surveys of Sexual Attitudes and Lifestyles (Natsal)	General	General	General	*Evidence on behavioural change at a population level:* A number of peer-reviewed outputs documenting changes over time in the reporting of key sexual behaviours, attitudes and health outcomes have	Thank you for your comment. The evidence provided is out of scope for this guideline. NICE guidelines look at comparative data to find the most effective interventions - see developing NICE guidelines: the manual.

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				been published. For Natsal-1/Natsal-2 see: http://www.natsal.ac.uk/natsals-12/publications.aspx For Natsal-3 see: http://www.natsal.ac.uk/natsal-3/publications.aspx Given this consultation's specific interest in unsafe sex it is worth noting that between Natsal-1 and Natsal-2 we recorded increases in consistent condom use (in the past 4 weeks), which were greatest for men reporting multiple partners (in the past *year*). This suggested that sexual health promotion messaging of the 1990s may have had some impact. However, the apparent increase over the same time period in the numbers of sexual partners may have served to discount some of the public health advantages of increased condom use. For example, by combining data on reported condom use and the numbers of partners - as an indicator of 'unsafe sex' – Natsal showed that overall the proportion of the population having unsafe sex according to this measure increased between the surveys.[Johnson et al., *Lancet* 2001] Between Natsal-2 and Natsal-3, no significant change was observed in the proportion of women reporting unsafe sex, while among men, this proportion had declined.[Mercer et al., *Lancet* 2013] Both of the cited Lancet papers reported estimates of unsafe sex by age-group, and show that the prevalence of unsafe sex is highest among the	

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				youngest men and women (those aged 16-24 years) in all 3 Natsal surveys, with prevalence declining with older age. Development work for the next wave of Natsal, Natsal-4, is currently underway (since May 2019) with the plan to commence an 18-month data collection phase in May 2021 involving interviews with a random sample of ~10,000 people aged 16-59 years resident in Britain. New prevalence estimates as well as results of change over time analyses among those aged 16-44 (the age-group common to all four waves) are due to be published in 2023.	
National Surveys of Sexual Attitudes and Lifestyles (Natsal)	General	General	General	*Evidence of the association between condom use/'unsafe sex' and Chlamydia in the British general population:* Chlamydia infection is an important clinical outcome indicator for interventions seeking to influence behaviour and improve sexual health. Natsal-2 and Natsal-3 used urine samples to measure Chlamydia prevalence in the general population linked to behaviour and sociodemographics. While Chlamydia risk was found to increase with increasing partner numbers, but reporting specifically two or more partners in the past year and non-use of condoms during this time continues to be more strongly associated with chlamydia than partner numbers alone, highlighting the importance of	Thank you for your comment. The evidence provided is out of scope for this guideline. NICE guidelines look at comparative data to find the most effective interventions - see developing NICE guidelines: the manual.

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				promoting condom use as a prevention strategy.[Fenton et al., *Lancet* 2001; Sonnenberg et al, 2013, *Lancet*]	
National Surveys of Sexual Attitudes and Lifestyles (Natsal)	General	General	General	*Evidence of the factors associated with having Chlamydia in the British general population:* These papers [Fenton et al., *Lancet* 2001; Sonnenberg et al., *Lancet* 2013) also show the key sociodemographic factors associated with having Chlamydia. Of note, while no association was observed with an individual's socio-economic status [Fenton et al., *Lancet* 2001], Chlamydia was more common in those living in the most deprived areas (as measured by the Index of Multiple Deprivation) in both bivariate and multivariable analyses (Sonnenberg et al., *Lancet* 2013).	Thank you for your comment. The evidence provided is out of scope for this guideline. NICE guidelines look at comparative data to find the most effective interventions - see developing NICE guidelines: the manual.
National Surveys of Sexual Attitudes and Lifestyles (Natsal)	General	General	General	*Evidence on digital and mobile health interventions from a general population perspective:* Natsal to date has not asked participants about their use of digital and/or mobile health interventions. However, Natsal-4 will include new questions that ask about use of, and reasons for accessing online STI testing services and contraception online, and purchasing of non-prescribed treatment for sexual dysfunction online. These data will be used to evaluate the impact of changes to service delivery at a population level, and to understand who in the	Thank you for your comment. This evidence provided is not relevant to the current evidence reviews in the guideline. However, qualitative evidence may be included in an update of this guideline, and may help answer research recommendation 1 "How can providers and healthcare professionals identify groups that do not initially engage, or do not stay engaged, with digital and mobile behaviour change interventions?". This reference will be passed on to surveillance to assess if it relevant for future updates of this guideline.

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				population is - and who is not - accessing sexual and reproductive services online, how this relates to risk behaviour, and why they are doing so. This follows extensive qualitative work as part of the development phase for Natsal-4 to identify not only the key questions for Natsal-4 to ask, but also *how* to ask them, and the most relevant response options to provide. These questions are available upon request.	
NHS England and NHS Improvement	Guideline	007	007	IS there any guidance for clinicians to enable understanding of how to identify how much mobile data a digital and mobile intervention uses and cost etc without this it will be difficult for clinicians to evaluate.	Thank you for your comment. Recommendation 1.3.3 tells people what they should be checking when they choose interventions. This includes checking how much data an intervention uses and its cost. We have added a recommendation into section 1.1 that asks developers to make practical information about personal information and data use, mobile data, terms and conditions and adverts clear to users. This should make it easier for people themselves to check data usage.
PAGB, the consumer healthcare association	Guideline	General	General	PAGB supports the recommendation that healthcare professionals should consider the use of digital and mobile health interventions to support behaviour change. We support the recommendation that areas where digital and mobile health interventions should be considered are diet and physical activity, smoking, alcohol and sexual health. However, PAGB also believes there is an important role for digital and mobile health interventions to support behaviour change towards self care. At the moment, too many	Thank you for your comment. More appropriate self-management is one of the aims of the guideline. This is why the committee made the recommendations in section 1.3. They facilitate what should be spoken about in a discussion between the healthcare professional and a person if a digital intervention has been decided as a good option for the person. The healthcare professional should discuss with the person what types of intervention would suit the person best and then the person goes to an expert source and

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				people are still visiting a GP or A&E for conditions for which they could self care, seeking the advice of a pharmacist if needed. PAGB has calculated that if people appropriately practiced self care, £1.5 billion of efficiencies could be released back into the NHS (https://www.pagb.co.uk/content/uploads/2019/03/PAGB_Self-Care_White-Paper_v1-0.pdf)	chooses the most appropriate from there. The committee approached it this way because digital and mobile health interventions change and emerge frequently, and therefore the most appropriate intervention for a person may change over time. It is important that people can change digital interventions if needs be and having the discussion between referrer and person will give the person the tools to do this.
PAGB, the consumer healthcare association	Guideline	General	General	PAGB believes there are opportunities for digital and mobile health interventions to support behaviour change towards self care. Our recent report 'Self Care and Technology' (https://www.pagb.co.uk/policy/self-care-technology/) makes several recommendations for the development of digital and mobile health interventions: 1. NHS England should develop a self care section in the NHS app and on the NHS website which includes fact sheets, such as those from the Self Care Forum, and easy to understand videos to improve people's understanding of self care, building on the success of initiatives already directing people to innovative resources like www.what0-18.nhs.uk 2. NHSX should explore how existing apps and wearables could support greater self care, encourage the use of pharmacies and help manage demand on local GPs	Thank you for your comment. The aim of the evidence reviews was to assess how digital and mobile health interventions can help people's behaviour relating to sex, alcohol, smoking, healthy eating and physical activity. The NHS has webpages on these behaviours that people can freely access.

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				NHSX should address barriers to the development of apps and wearables which safely promote self care.	
PAGB, the consumer healthcare association	Guideline	General	General	A survey conducted by PAGB in June 2019 found that 57% of people surveyed use at least one type of health app or wearable on a daily basis to manage their health; the focus of these is general wellbeing and lifestyle management, with the survey showing that only 16% of people use a device or app to access information about health conditions and symptoms. It is vital that information provided through digital and mobile resources is accessible, robust and consistent and people are signposted to appropriate resources (including the appropriate healthcare professional i.e. a pharmacist) to support them to self care.	Thank you for your comment. The committee agrees the importance of using expert sources for the interventions and that healthcare professionals should highlight this to people in initial consultations.
PAGB, the consumer healthcare association	Guideline	General	General	The same PAGB survey found that trust in health and wellbeing digital devices and apps is lower in older age groups, therefore it will be important for healthcare professionals to consider this when deciding whether to recommend a digital or mobile interventions. The higher levels of trust among younger people mean they are more likely to use an app consistently, where older generations may not be so willing to trust or rely on them. 68% of 18-35 year olds trust health and wellbeing digital devices and apps, compared to 28% of 46-55 year olds and 19% of 56-65 year olds.	Thank you for your comment. The committee agreed that assessing how suitable people are to use digital or mobile health interventions is important. This includes how motivated they are to use an intervention (see recommendation 1.3.2, bullet 3). The committee did not want to generalise on how populations would use interventions, especially when there is a mixture of views and product usage within the population group. Expert testimony described that if older people do express an interest in using digital technology, they are as likely to keep using it as younger people. From this evidence, the committee understood that it was important to base referrals

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					more on individual suitability than on which group they belong to. In this way, the correct interventions are available to more people. The guideline also notes the importance of considering digital exclusion, both when commissioning an intervention and when discussing the interventions with individuals the factors that may contribute to digital exclusion, such as digital and other literacy, possible costs and opportunity for change.
PAGB, the consumer healthcare association	Guideline	General	General	PAGB agrees that more research is needed to validate the effectiveness of digital and mobile health interventions for behaviour change. The use of 'real world' evidence/data will be central to this, to ensure an accurate understanding of how people use apps and other technologies and the impact this has on their behaviour.	Thank you for your comment. More evidence would be welcomed on whether or not digital and mobile health interventions are effective, particularly in how they are used in real-world settings. Therefore, a recommendation was added to section 1.1 asking developers to continually look at data feedback after releasing the intervention to improve their interventions. In addition, we made research recommendations to assess the effectiveness of digital and mobile health intervention components and combinations of components.
Public Health England	Guideline	General	General	Is there a distinction between mobile and digital or are interventions assumed to be digital and mobile? Is so what are the definitions of each?	Thank you for your comment. Digital interventions are those that can be accessed through apps, computers and other technology that stores information. Mobile interventions are those that are delivered through mobile phone, such as SMS, and wearables, such as activity watches. "Digital and mobile health interventions" is now included under the "Terms used" section, which

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					describes the differences between digital and mobile interventions.
Public Health England	Guideline	General	General	The term 'unsafe sexual behaviour' may generate confusion among service providers and the general public as, for example, sexual intercourse without condoms while using HIV pre-exposure prophylaxis can be considered to be 'safe' as the risk of HIV is markedly reduced; similarly, having sex with some with HIV who is on treatment and has a undectable viral load has no risk of onward HIV transmission. We would recommend being explicit and using the term 'condomless sex' instead.	Thank you for your comment. The committee considered using the term "condomless sex" instead of "unsafe sexual behaviour" and place emphasis on condom use in recommendation 1.7.1. This was not changed because the protocol for this evidence review includes unwanted pregnancy as an outcome and it's reasonable to allow people in monogamous relationships to use non-barrier methods of contraception to avoid pregnancy. In addition, one study in this review included using non-barrier contraception as well as condoms.
Public Health England	Guideline	General	General	The guideline mentions considerations regarding accessibility, selection of digital platforms/technologies and so on. **Including links to the GDS Service Standard** (where relevant) could better prepare the local authorities for the GDS service assessment requirements they'll face E.g. see p6 lines 7-12 GDS Service Standard: https://www.gov.uk/service-manual/service-standard	Thank you for your comment. A link to the GDS service standard to the rationale for recommendation 1.1.2 has been added.
Public Health England	Guideline	General	General	The Guidelines talk about commissioning but don't distinguish between commission to be built and procurement of a digital behaviour change intervention.	Thank you for your comment. The recommendations in 1.2 distinguish between procurement and commissioning interventions to be built. This section reflects the consideration of commissioning new interventions alongside

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				It is important to separate out as there are important nuances, particularly with local authorities etc. saying they don't know what they're supposed to check/request from technologies that already exist.	procurement of new ones, and not as separate topics, as recommendation 1.2.4 displays. Recommendation 1.2.5 says "select interventions…", which relates to procurement. Recommendation 1.2.6 is a recommendation for commissions for interventions to be built, such as looking at expert sources before commissioning the development of a new one and that these should be developed as part of a multidisciplinary team.
Public Health England	Guideline	General	General	No mention of good use of data/ data governance: while the guidelines understandably have focused on the evidence base and accessibility, there is an important point missed about using data that is of high quality and appropriately representative. Think it's important to mention this and the integration of ethics into data driven technologies, as well as ensuring data privacy and security as part of safety requirements.	Thank you for your comment. The NICE evidence standards framework for digital health interventions recommended in 1.1.1 says interventions should be designed that allow continual outcome data retrieval from consenting users. It also says that developers need to measure the economic impact and effectiveness of these interventions. After reviewing consultation comments, recommendations have been added asking developers to use feedback from testing and after releasing the intervention to continually improve the intervention.
Public Health England	Guideline	General	General	Implementation of digital interventions should be guided by the UK government's principles for digital development, but the element of collaboration should be more effectively communicated here. Behavioural scientists should work collaboratively with digital, healthcare and policy professionals - as part of truly multidisciplinary teams- to increase the likelihood of designing and developing digital	Thank you for your comment. Multidisciplinary working is paramount for producing effective interventions. Therefore, the rationale for recommendation 1.2.6 has been amended to further explain the committee's discussion: "Expert testimony suggested that interventions are often developed independently by either healthcare professionals or digital professionals, not collaboratively. Multidisciplinary teams would ensure

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				health interventions that can help people to initiate/achieve positive behaviour change	that interventions are as useful and relevant as possible." A list of people who should be included in these multidisciplinary teams has not been added as this would be too prescriptive and would change depending on the targeted behaviour and type of interventions being made.
Public Health England	Guideline	General	General	It needs to be clearer that digital health interventions are not a substitute for functioning behaviour change services, rather they should complement and enhance them. Additionally, the adoption of the recommendations in this guideline should not exclude or jeopardise the provision of quality non-digital services in places where there is no access to the digital technologies or they are not acceptable or affordable for target communities.	Thank you for your comment. Existing, evidence-based services should not be replaced with digital or mobile health interventions and should be used as adjuncts to existing services. This is why the guideline has a weak recommendation for using digital and mobile health interventions as adjuncts and a strong recommendation for them not to replace existing services. The committee understood that digital and mobile health interventions could be effective for some people and therefore should be considered as options if commissioners' local population have a need for a digital intervention. If a digital intervention is not suitable for the local population, the commissioner should not commission the use of these interventions nor the development of a new one.
Public Health England	Guideline	001		**Who is it for**: suggestion including 'national policy makers'	Thank you for your comment. It is out of NICE's remit to make guidelines for national policy makers, though these guidelines may be of interest to this group.
Public Health England	Guideline	004	004 or 007	Include a reference to PHE's guide to evaluating digital approaches : https://www.gov.uk/government/collections/evaluating-digital-health-products	Thank you for this resource. We have added the guide to recommendation 1.1.2.

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Public Health England	Guideline	004	007	Point 1.1.2 include Public Health England's "Evaluating Digital Health Products" online guidance as a resource: https://www.gov.uk/government/collections/evaluating-digital-health-products Public Health England has just launched this online guidance about evaluation with practical tools and "how to guides" for people designing and developing digital health interventions (launched January 2020 on GOV.UK). This guidance helps developers embed evaluation into product design and development. It is aimed at novice to intermediate "evaluators", which may be digital professionals, policy professionals, user researchers, designers or new academics. Public Health England developed the guidance named "Evaluating Digital Health Products" following a user-centred design, agile approach i.e., in collaboration with teams in government, industry and local authorities trying to evaluate their digital health interventions (including behaviour change products).	Thank you for your comment. We have added this resource to the recommendation 1.1.2.
Public Health England	Guideline	004	016	Design interventions so they can be scaled up and customised for local needs and use. -> word missing, assuming it's supposed to be 'so they can *be* scaled'.	Thank you for your comment. Customisation to local needs and scaling up are 2 different concepts. However, they appear in the same recommendation because they are factors that are necessary if an intervention is to be used in different regions by many people. Scaling up and customisation are both

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				It is unclear, as well, what this statement really means. Scaling and customising a product or service are pretty different concepts e.g. for customising you would want software to be open source, but that wouldn't necessarily help with scaling; and being able to update something to allow scaled growth doesn't = customised….	also important to reduce inequalities and to consider local needs by commissioners. They do not appear in the NICE evidence standards framework for digital interventions and therefore, they made a recommendation so developers consider these in addition to what is included in the evidence standards framework.
Public Health England	Guideline	004	018	When developing digital and mobile health interventions involve stakeholders, including potential users, as early as possible to: - Once developed, test how well the intervention works for a wide range of people from the target population. -> this should be its own point as 1.1.6 rather than nested under what looks like discovery/maybe alpha user research. This statement should also mention 'hard to reach' groups and digital exclusion	Thank you for your comment. The committee agreed that users and developers should work together to make interventions, which is why they recommended developers include stakeholders and potential users as early as possible to develop and review content. For clarity, the stem of the recommendation now reads "...involve a wide range of stakeholders, including potential users, as early as possible and throughout development to:" as the committee agreed that the recommendation should be clearer that having a wide range of relevant stakeholders throughout development is necessary to create an appealing and engaging intervention. They did not list different groups as this is dependent on the population and the list could be infinitely long.
Public Health England	Guideline	005	001 - 002	In addition to 'developing and reviewing content, structure, interface and flow of the intervention', **also design and develop the underlying data flow** (e.g. how to collect KPIs, how to input/output data) in order **to: a) evaluate (first baseline and then measure the impact),**	Thank you for your comment. The NICE evidence standards framework for digital health interventions recommended in 1.1.1 says interventions should be designed to allow continual outcome data retrieval from consenting users. It also says that developers need to measure the economic

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				and **b) enable ongoing monitoring, support or human/provider intervention where necessary**	impact and effectiveness of these interventions. In addition, we have added a further recommendation that reads: "Use feedback from testing and after releasing the intervention to continually improve the intervention."
Public Health England	Guideline	005	005	Amend to: Make sure users understand who the intervention is for, which behaviours or set of behaviours it's trying to change, its aims, and possible benefits any possible harms, the time needed [for what?] and frequency [of what, use?]	Thank you for your comment. The recommendation now reads "the time needed to establish behaviour change and how frequently users are likely to interact with the intervention "
Public Health England	Guideline	005	005 - 007	When "making sure users understand who the intervention is for", **do not mistake this guideline for simply telling/informing them**. Design Research / User Research best practice methodology is much more than user consultation or instructing people how to use an idea. Instead: When testing an early concept: **first see how users interpret the concept, then share the intention of the idea** When testing a usable prototype: **first "make sure users understand** who the intervention is for, which behaviour it's trying to change, its aims, any possible harms…" **then observe how end users engage with the service/experience**, **and how the "time**	"Thank you for your comment. All of the points listed in this comment are reflected in the recommendation. Users are involved as early as possible to develop and review content, which includes the points that are in the third bullet. The recommendation then tells developers to test if the intervention gets across the points made in bullet point 3, which is developed jointly by the developers and potential users. The stem of the recommendation now reads "When developing digital and mobile health interventions, involve a wide range of stakeholders, including potential users, as early as possible and throughout development to:" Bullet 3 has been changed to "Discuss and ensure users understanding for who the intervention is for, which behaviour it's trying to change, its aims, any possible harms, the time needed and frequency" for clarity."

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				needed and frequency" they commit is enough for the intervention to be effective.	
Public Health England	Guideline	005	008 - 009	**Firstly, refine ideas by iteratively prototyping and testing them with a small but representative cohort of end users. Then,** "once developed, test how well the intervention works for a wide range of people from the target population… " Potential users should be involved in all steps of development from ideation, research, prototyping, minimum viable product to continuous improvement of higher fidelity product versions. The current wording of the guidance implies developers should test with users in later stages of product development. This often leads to products that are not viable or desirable for users and are driven by business and stakeholder needs instead of user needs.	Thank you for your comment. The committee agreed that having users involved at all stages of development, hence why they made the first bullet point in this recommendation: When developing digital and mobile health interventions involve stakeholders, including potential users, as early as possible to develop and review the content, structure, interface and flow of the intervention." We have removed user acceptability testing from this bullet and changed the stem of the recommendation to read "...involve a wide range of stakeholders, including potential users, as early as possible and throughout development to:" to make it clearer that users should be involved during to development not only at the end.
Public Health England	Guideline	005	009	Suggest additional bullet point: developing ways to understand how well it works for the target users and ensure this information informs further development of the app.	Thank you for your comment. A recommendation has been added that reads: "Use feedback from testing and after releasing the intervention to continually improve the intervention."
Public Health England	Guideline	005	022	Check expert sources (such as Public Health England or the NHS apps 22 library) for any existing evidence-based digital and mobile health interventions that can meet local needs. -> this is a good general recommendation; however, Public Health England is developing its expertise	Thank you for your comment. We have removed PHE as an expert source for digital and mobile health interventions.

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				in digital and does not currently have a centralised, centre of digital excellence.	
Public Health England	Guideline	005	026	Provide a link to a NICE endorsed quality "needs assessment" template with examples.	Thank you for your comment. Different local authorities and CCGs would use different needs assessments tools to suit the population in that area. Providing a template for a needs assessment is out of remit for this guideline.
Public Health England	Guideline	006	General	Although there is good reference to considering how personal information and data will be used (1.3.3), we would like to see explicit reference to advising providers/developers of digital alcohol interventions and people who use them about the need to protect their privacy/identity. We're thinking specifically of the use of anonymous Voice over Internet Protocol (VoIP) ie Skype names (not linked to personal email accounts, using person identifiable information or, in the case of providers, with names clearly linked to alcohol consumption) when accessing some digital alcohol services. This is particularly relevant due to the stigma associated with alcohol use disorders.	Thank you for your comment. Systems to provide anonymity to users is an issue for services that specialise in dependent drinking. As the guideline focused on people with non-dependent hazardous drinking, it is out of scope. NICE has guidance for this group in CG115 Alcohol-use disorders: diagnosis, assessment and management of harmful drinking (high-risk drinking) and alcohol dependence.
Public Health England	Guideline	006	001 - 004	**Also consider technology platforms, information governance and integration considerations for the system that will underpin the proposed solution.** (i.e. do not just get overexcited by the end user experience!)	Thank you for your comment. The committee agrees that having user input while developing the intervention is key in making an intervention that works and is appealing. The recommendations say users should be involved during development and not only at the end of the development process. The stem for the recommendation says "When developing digital and

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					mobile health interventions, involve a wide range of stakeholders, including potential users, as early as possible to:" Bullet 2 of this recommendation says "identify the best digital platform for the target population". Regarding integration, customised local needs are covered by a recommendation which says "Consider designing interventions so that they can be used to create tailored goals". After reviewing consultation comments, a recommendation has been added: "Use feedback from testing and after releasing the intervention to continually improve the intervention".
Public Health England	Guideline	006	009	Other costs include wearables and enhanced services including remote coaching	Thank you for your comment. The examples in the bullet were not exhaustive, as we are aware that there are numerous factors that could have an effect on the cost of using technology. Evidence regarding remote coaching would be excluded in this review because it is likely to have too much healthcare professional involvement. This guideline focuses on interventions delivered by digital or mobile technology and not healthcare professionals.
Public Health England	Guideline	006	010	Also, availability over time of necessary up-to-date hardware that can deal with software updates i.e., some people still using iPhone4s that cannot be updated to the latest operating system and this restricts use of certain applications	Thank you for your comment. Recommendation 1.2.7 says that commissioners should be aware of equality of access, including how available the intervention is on different hardware and operating systems.
Public Health England	Guideline	006	016 - 017	It would be helpful to include within this or an additional line (such as 1.22, p.5 l.14-15) that this	Thank you for your comment. Recommendation 1.3.1 now says that digital and mobile health

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				should be supplementary to support rather than as a replacement.	interventions should be used as an adjunct to existing services.
Public Health England	Guideline	006	017	"Consider digital and mobile health interventions as an option for behaviour change. But note that it is not clear whether or not they are effective." The phrasing of the latter sentence seems too weak. There would appear to be ample high-quality evidence that some digital and mobile health interventions are effective, at least for some people in some circumstances.	Thank you for your comment. The committee were keen to produce guidance that would lead to prolonged behaviour change, which is why they restricted evidence to follow-up of 6 months or longer in the review protocols. For follow-up of 6 months or longer, effectiveness is variable. It was not possible to deduce which interventions worked and in whom. This is why the committee made several research recommendations to assess the effectiveness of digital and mobile health interventions and components and combinations of components of these interventions.
Public Health England	Guideline	006	018	When advising on the use of a digital or mobile health intervention consider: -> list of things that are user focused, all important - but no mention of impact on wider health and social care system	Thank you for your comment. Recommendations 1.3 are for healthcare professionals who are discussing options for behaviour change with people and not for commissioners, who are addressed in section 1.2. 1.3.2 lets healthcare professionals know factors to consider when talking about these options, and these factors relate directly to the person who might use these digital interventions.
Public Health England	Guideline	006	020 - 025	Establish whether the proposed solution will focus on helping someone decide on a behaviour change, and/or start a behaviour change, and/or monitor/ track behaviour. Consider that attempting to do all three is a huge undertaking and many apps already exist for the tracking part.	Thank you for your comment. If a suitable intervention is available and is appropriate for a person to use, they can use that intervention. The committee agrees that many interventions already exist and attempts to develop similar interventions should not be taken. The committee considered that the best way to promote

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					positive behaviour change for a wider population is to have a range of interventions available, catering to different needs and preferences. Expert sources are recommended for people to use when choosing interventions, such as the NHS Apps Library.
Public Health England	Guideline	006	021	This section/line should explicitly highlight for people to consider if the user has the health and **digital literacy** to use a digital behaviour change intervention	Thank you for your comment. A bullet has now been added that reads "digital, health and reading literacy" as considerations.
Public Health England	Guideline	006	025	Suggest additional bullet point: is the intervention free or will the user incur immediate cost?	Thank you for your comment. This point is addressed in recommendation 1.3.3. The committee agreed that this point fitted better under factors the person should consider themselves, rather than what the referrer thinks about when they are discussing options with people.
Public Health England	Guideline	007	General	Although there is good reference to costs of potential applications to users, we would like to see explicit reference to consideration of the potential impact of applications on widening health inequalities.	Thank you for your comment. The committee thought it was important that many interventions are made available to people and that they suit their needs and preferences. This is why they recommended using an expert source that lists many interventions, instead of specific interventions. There is now a recommendation for commissioners which provides some factors to consider when conducting an equality impact assessment. The guideline includes reference to how interventions should be developed and that developers should involve a wide range of stakeholders, including potential users, as early as possible and throughout development. Working with stakeholders will allow discussions between developers and potential users, which will highlight inequalities the

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					intervention may pose, which the developers can then address.
Public Health England	Guideline	007	001	Advise those who may use a digital and mobile health intervention to: - check how much mobile data it uses and if they can afford it -> the recommendation assumes users have the digital literacy to know how to check this and understand the implications. Also, NICE should be recommending that technology developers are transparent on data usage in terms of MB/GB burned of their product etc. read the terms and conditions -> this is putting a bit of a burden on the user, and often these are not accessible to users (due to detail etc.). Instead the focus should surely be on consent/ permissions developed in a clear, understandable and engaging way by the digital developer?	Thank you for your comment. Recommendation 1.3.2 asks referrers to check the capability of the person, this includes if they are capable of using a digital or mobile health intervention. GDPR is statute legislation which states data usage and consent to data usage needs to be made clear to the user. The committee have made a recommendation for developers to make some information clear to users, including terms and conditions, how users can check and set preferences for how their personal information and data may be used, mobile data, and any additional costs. Reading terms and conditions is a necessity for many services, but developers should make them clear to users so they are easily understandable. To support this, we have now added a recommendation in section 1.1 for developers to make information on about personal information and data use, mobile data, terms and conditions and adverts clear to users.
Public Health England	Guideline	007	001 - 010	Behaviour change apps don't just usually contain advertising but often monetise users' data. **People should be made aware that their data may be sold**	Thank you for your comment. Recommendation 1.3.3 asks referrers to remind users to check and set their preferences for these. The committee agreed that GDPR legislation does not need to be repeated in the guideline.
Public Health England	Guideline	007	004	"assessed for safety, effectiveness and data security" be clear about what standard of these three apps should meet i.e., DAQ or otherwise.	Thank you for your comment. The interventions on the NHS Apps Library used the DAQ and will use its updated version - Public Health

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				Also, this is a big assumption that all of Public Health England and other government apps have been assessed for safety, effectiveness and data security – unless there is published evidence this should not be assumed.	England's guidance on evaluating Digital Health Products guidance – when this is released. This takes into account data on safety, effectiveness and data security. Public Health England have been removed as an expert source within the guideline.
Public Health England	Guideline	007	019	Suggest changing 'be used to' to 'inadvertently'	Thank you for your comment. The bullet point highlighted is meant to alert healthcare professionals to people who may be deliberately kept from face-to-face consultations. The suggested wording would indicate that this is an accidental consequence.
Public Health England	Guideline	007	022	Do you need to define 'excessive exercise' and ' disordered eating'?	Thank you for your comment. Excessive exercise and disordered eating have now been defined in the "Terms used" section of the guideline.
Public Health England	Guideline	007	024 - 026	"But note that it is not clear whether or not they are effective." Again, there is good evidence that some are effective.	Thank you for your comment. The interventions included in these evidence reviews showed that interventions had variable effectiveness, some interventions are effective for some people, but it is not possible to deduce which or in whom they work. The evidence reviews in this guideline considered only 6 month or longer follow-up to test for sustained behaviour change.
Public Health England	Guideline	008	002	Use 'physical activity' rather than exercise as the majority of physical activity (e.g. walking and cycling) is not exercise. Also rather than using the term 'diaries' would it be better to say 'daily/weekly recording' as for many digital physical activity interventions the data will be auto-recorded rather than self-recorded diaries.	Thank you for your comment. Exercise has been changed to "physical activity. Some interventions use diaries that people write themselves as a method of self-monitoring and this was used as just one example of self-monitoring. It is correct that some interventions auto-record activities and so has been included in the recommendation.

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Public Health England	Guideline	008	005 - 006	Suggest rewording: Advise people at risk of developing or resuming an eating disorder or another unhealthy behaviour such as excessive exercise, to consider interventions that do not include self-monitoring. In evidence review, page 36 line 28, committee agreed that interventions should not include underweight as a goal and a person's health should be primary objective. Should this be included as an additional point?	Thank you for your comment. The committee were aware that the referrer would not be aware of everyone who was at risk of resuming or developing disordered eating, therefore the recommendation is worded in this way. The committee have added a recommendation saying interventions should not allow people to make an underweight goal.
Public Health England	Guideline	008	007	The evidence review document (page 35, lines 47-49) suggests that some level of individualised tailoring of dietary goals contributes to overall effectiveness - should this be included as a separate point?	Thank you for your comment. Section 1.1 now includes a recommendation that asks developers to make interventions that allow goals to be tailored to an individual.
Public Health England	Guideline	008	010 - 011	Again, there is good evidence that some are effective.	Thank you for your comment. After revisiting the evidence, the wording for these recommendations has now been changed to reflect that people should be referred to these interventions as an adjunct to existing services. The committee have also amended the wording of recommendation 1.5.1 so it says that effectiveness of these interventions is variable. Though the overall effect estimate of the smoking evidence shows in favour of smoking cessation, there is considerable heterogeneity between and within the studies. Many studies have very wide confidence intervals that cross the line of no effect. In addition, most studies did not compare with current usual care. Therefore, it is reasonable to suggest that these interventions would be

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					beneficial to some people and should be made available as an option for behaviour change alongside existing services.
Public Health England	Guideline	**008**	016	This guideline explicitly states that it **"does not cover the use of digital or mobile platforms that involve significant interaction or involvement with a healthcare or other professional."** Most alcohol users with alcohol dependence disorder will require specialist treatment involving personalised interaction with specialist professionals, without which, management of alcohol consumption could potentially be unsafe. We suggest that 1.6.1 should be amended to **read "Consider digital and mobile health interventions as an option for people who do not need specialist assessment and treatment for alcohol dependence, but who would benefit from reducing, or wish to reduce, their alcohol consumption."** Perhaps reference could be made to the NICE pathway for PH24 and CG115, which deal with assessing and intervening with non-dependent and dependent drinkers respectively. Before making a recommendation to use digital or mobile interventions therefore, there should be some assessment of the likelihood that the individual is alcohol dependent, by use of the Alcohol use disorders identification test (AUDIT). Those whose AUDIT score indicates possible	Thank you for your comment. This guideline provides guidance for people with hazardous drinking and not people with alcohol use disorders, which is covered in other NICE guidelines (CG115). The committee agreed that people with harmful and/or dependent drinking will need more support than what can be provided through a digital or mobile health intervention. Therefore, this guideline is not suitable to use for treatment of people with alcohol use disorders or dependence.

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				dependence should not be recommended to use these digital interventions	
Public Health England	Guideline	008	017 - 018	Again, there is good evidence that some are effective.	Thank you for your comment. For follow-up of 6 months or longer as specified in the review protocols, evidence of effectiveness is uncertain. The interventions included in these evidence reviews showed that interventions had variable effectiveness, some interventions are effective for some people, but it is not possible to deduce which or in whom they work.
Public Health England	Guideline	008	019	The motivational assessment should also indicate if a non-digital intervention is more suitable for an individual. This statement implies only a digital intervention can be suitable.	Thank you for your comment. Though there was evidence to suggest how motivated someone is influences behaviour change within the alcohol review, this recommendation has been removed from the guideline. This is because there was no suitable tool NICE could recommend for conducting the motivational assessment. There was also no evidence on how the outcome of the motivational assessment should be used to inform care.
Public Health England	Guideline	008	019	As part of any alcohol-related intervention, consider a motivational assessment to help decide which digital and mobile health intervention will suit the person best. -> why is this under alcohol specifically and not other addiction issues?	Thank you for your comment. Though there was evidence to suggest how motivated someone is influences behaviour change, this recommendation has been removed from the guideline. This is because there was no suitable tool NICE could recommend for conducting the motivational assessment. There was also no evidence on how the outcome of the motivational assessment should be used to inform care.
Public Health England	Guideline	009	003	Advise the person that an intervention they interact with multiple times may be better than a	Thank you for your comment. There was only evidence available that showed benefit for

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				one-off intervention, but a one-off intervention is better than no intervention at all. -> similar to above why is this comment nested under alcohol specifically?	interventions people interact with multiple times for alcohol and not the other behaviours. Without evidence, the committee were reluctant to recommend it for the other behaviours. In addition, the committee discussed review and expert testimony evidence and concluded that baseline motivation was more associated with positive behaviour change than interventions interacted with multiple times for the other behaviours. Baseline motivation, which should be considered for all behaviours as recommended in 1.3.3.
Public Health England	Guideline	010	018 - 023	**Consider that the effectiveness of components and characteristics is very dependent on the context within which they are deployed, and the quality of execution. The interaction design and resulting end user experience has a significant influence.** So, it is likely that the same component could be leveraged in two very different behaviour change digital services but be much more effective in one than the other.	Thank you for your comment. As with the current evidence reviews that inform this guideline, these considerations will be taken into account. Context and population are considered in the protocol for the question, found in evidence review 1: smoking, Appendix B. The committee were aware that context was an important factor in the effectiveness of specific interventions. The reviews were designed to allow the committee to consider this, but on the whole the evidence found was too multicomponent to isolate which components were driving behaviour change let alone decide how context affects these components.
Public Health England	Guideline	010	023	The reference to evidence review 1 implies that all the evidence in this section comes from the smoking review	Thank you for your comment. The text says that full details of the research recommendation can be found in evidence review 1: smoking but would have come from all evidence in the guideline.

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Public Health England	Guideline	010 - 011	024 – 026 / 001 - 003	It would be helpful to be more explicit on what other population groups outside of socioeconomic should be considered for research. For example there are inequalities in physical activity for people with mental health issues that drive physical health inequalities, and the evidence review specifically states that people with mental health issues were not covered by any of the studies.	Thank you for your comment. Full details of the research recommendation and the other groups included can be found in evidence review 1: smoking. The research recommendation covers • People with chronic conditions • People with physical disabilities • People with sensory impairments • People with neurodevelopmental disorders • People who live far from face-to-face services • People who distrust or fear government or health services • People who have limited ability to understand or give consent without the assistance of language services • People who have a lowered capacity to communicate effectively People with mental health conditions are specified under populations with specific consideration.
Public Health England	Guideline	011	004 - 007	This research recommendations suggests comparing digital and mobile interventions to face-to-face or standard care to understand who would most benefit. This has merits, but it won't always be a decision between digital/mobile and traditional approaches (e.g. the wider population digital interventions). Arguably the question would be better regrading when is Digital/mobile effective in combination with other support or when other support is not possible, and what are the characteristics of those who most benefit	Thank you for your comment. This is an important consideration which is considered by the "combination approach" included in the question. The research recommendation includes approaches that include a combination of both digital and mobile health interventions and face-to-face interventions. Face-to-face approaches can be compared with non-face-to-face approaches to see if there is a difference in effectiveness. The same could be done with digital and mobile health interventions. In this way, it will be possible to deduce which components of these approaches are

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					most effective at behaviour change. Different populations are also shown under 'specific considerations'. Detail of this research recommendation can be found in Appendix B, evidence review 1: smoking.
Public Health England	Guideline	013	003 - 008	**A co-production approach is certainly favourable.** However – again, **do not mistake this recommendation as simply user consultation.** Design Research / User Research best practice methodology helps stakeholders **make decisions with users' in mind, but based on what they do, think and feel, not just what they say.** **So, skill and experience is needed to develop User Research methods that unpick the latent needs that people might not express** as well as make sense of proactive comments and co-design.	Thank you for your comment. The committee agree that co-production between developers and potential users is needed to produce an appealing and engaging intervention. Therefore, the committee wrote a recommendation that says users should be involved at all stages and a multidisciplinary team, made up of healthcare experts and technology experts as specified in the rationale, should be involved when developing an intervention.
Public Health England	Guideline	013	022	Add 'quality' after 'poor'	Thank you for your comment. This has been changed to inconsistent.
Public Health England	Guideline	013	027	In section 1.2.1 it is stated that such interventions are 'options' for behaviour change , this has a different meaning to 'supplement'	Thank you for your comment. The rationale has now been changed to option.
Public Health England	Guideline	014	008	While developing Public Health England's online guidance "Evaluating Digital Health Products" it was uncovered (via user research and testing) that it is not the case that organisations or expert sources have always tested the effectiveness,	Thank you for your comment. The NHS Apps Library, which is listed in the guideline, uses Public Health England guidance to review technology that appears on their site.

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				safety and data security of digital interventions that are publicly available.	
Public Health England	Guideline	014	015	Conversely it is in the experience of Public Health England's Digital Strategy Lead that digital products are often developed by policy and healthcare professionals without adequate input from digital professionals. In the same vein, senior leaders in healthcare and public health often make decisions about digital portfolios or strategy without consulting digital professionals leading to wasted time and money investment and overpromising what a technology intervention can deliver.	Thank you for your comment. We have amended the rationale to incorporate this.
Public Health England	Guideline	015	013 - 016	Behaviour change apps don't just usually contain advertising but often monetise users' data. **People should be made aware that their data may be sold**	Thank you for your comment. Recommendation 1.3.3 asks referrers to remind users to check and set their preferences for these.
Public Health England	Guideline	015	022 - 025	"Because digital and mobile technology is a fast-moving field, the committee agreed that it was best to focus on content rather than specific interventions in any discussions because interventions may become unavailable or their content may change." While this is a fast-moving field and there are issues with interventions changing or becoming unavailable, it is not clear to what extent content can be evaluated outside of the design of specific interventions.	Thank you for your comment. The aim of the guideline was to assess which components worked in interventions, and not if they worked only in isolation. This would allow people to choose interventions that include this component. The guideline does not assume that people would use the effective component on its own. By looking at whole interventions, they would have to be evaluated every time content changed. By looking at combinations of components, this does not have to happen as often. In addition, components that are effective in isolation are more likely to be effective in combination compared with one that is not effective

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					in isolation. Research recommendation 2 will lead to research into effective components and characteristics of these interventions. Two study designs have been highlighted in the research recommendation, micro-randomised trials and factorial screening trials. Through these designs, it is possible to isolate individual components to assess effectiveness. If done across many trials, the most effective components in different context may begin to emerge.
Public Health England	Guideline	016	004	NICE should consider the unintended consequence that digital interventions are replacing traditional services when, as NICE says, there is little to no evidence for their effectiveness. What is the unintended consequence on the systems ability to support people to change their behaviour if we change the service delivery model to digital and it does not work?	Thank you for your comment. This is an important consideration hence why recommendation 1.2.2 was made to note that digital interventions should not replace existing services.
Public Health England	Guideline	016	012	NICE should provide evidence that digital saves costs i.e., does it improve health outcomes for the individual and population at a lower cost in the short and long term? This is a big statement with no evidence to back it currently.	Thank you for your comment. A resource impact assessment has been conducted by NICE and the recommendation is not expected to add substantial additional costs as local needs assessment are considered good routine practice. The rational section for the using digital and mobile health interventions section notes that there may be increased costs due to adverse consequences, e.g. increased consultations related to increased anxiety. There was insufficient evidence to support the development of a model to assess the cost

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					effectiveness of components and techniques for behaviour change. Had the RQ considered the effectiveness of digital interventions per se some modelling may have been feasible.
Public Health England	Guideline	021	027	**"harmful or binge drinking"** -The term "harmful" is one of the defined terms used to categorise risk from alcohol use. The WHO defines hazardous drinking (also referred to as increasing risk) as drinking in a way that presents a risk of long term alcohol-related ill health. Harmful drinking (also referred to as higher risk) is drinking in a way that is likely to be already causing alcohol-related ill health. Those drinkers for whom brief interventions are appropriate and those who the evidence shows are likely to benefit from digital interventions are non-dependent hazardous and harmful drinkers Most dependent drinkers are likely to be harmful drinkers. We suggest therefore that line 27 be amended to read **"hazardous, harmful or binge drinking without alcohol dependence."**	Thank you for your comment. The guideline has been amended with your suggestion. Harmful and dependent drinking is covered by NICE guideline CG115 Alcohol-use disorders: diagnosis, assessment and management of harmful drinking (high-risk drinking) and alcohol dependence.
Public Health England	Guideline	029	General	Need to make definition of meaningful clearer - statistically? Clinically? Against what criteria? Need to make any headings in the right hand columns clearer and consistent	Thank you for your comment. Meaningful differences arise from confidence intervals and whether or not they cross the minimally important difference (MID) threshold. More detail of this can be found in the methods document under "Appraising the quality of evidence > Evidence Statements"

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Public Health England	Guideline	032	014	Would help to be consistent in whether digital/mobile interventions are presented first and then compared to the alternative intervention (or vice versa). This would allow easier interpretation and comparison between each	Thank you for your comment. As the guideline scope document does not go to page 32 it is not clear where this refers to. If this is in reference to an individual review documents then when presenting comparative data, NICE review templates make it clear in GRADE tables and forest plots the direction of effect.
Public Health England	Evidence review – sexual health	General	General	This guidance is not up to date in relation to HIV risk; both PrEP and treatment as prevention need to be included as behavioural interventions.	Thank you for your comment. PrEP is not a digital or mobile behavioural intervention and therefore was not considered for the unsafe sexual behaviour review. PrEP and other non-digital interventions are considered by the NICE guideline under development on reducing sexually transmitted infections.
Public Health England	Evidence review - diet	017 - 018		The evidence reviews generally appear patchy, missing relevant RCTs and systematic reviews in the field. In particular, in Evidence review 3, the cancer review omits a number of studies: see the systematic review by Roberts et al. (2017; doi:10.1007/s11764-017-0632-1). Various digital exercise game RCTs are not included: see Ni Mhurchu et al. (2008; doi:10.1186/1479-5868-5-8); Street et al. (2017; doi:10.1089/g4h.2016.0102); Zeng et al. (2017; doi: 10.1016/j.jshs.2016.12.002). More generally, see:	Thank you for your comment. We reviewed the references and the citation within the systematic reviews provided and none were relevant to the review protocol. The reasons were: follow-up too short; interventions had too much healthcare professional involvement; non-RCTs; over half of the participants were physically active; intervention was a prevention programme; outcomes did not match the protocol; intervention was non-digital (pedometer) only.

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				Schoeppe et al. (2016; doi: 10.1186/s12966-016-0454-y) Romeo et al. (2019; doi: 10.2196/12053) Yerrakalva et al. (2019; doi: 10.2196/14343) Gal et al. (2018; doi: 10.1186/s40798-018-0157-9) Rose et al. (2017; doi:10.1016/j.jadohealth.2017.05.024) King et al. (2106; doi: 10.1371/ journal.pone.0156370)	
Public Health England	Evidence review – alcohol	007		**In PICO table** "Those (including children and young people under 16) who have never drank alcohol" should read "Those (including children and young people under 16) who have never drunk alcohol"	Thank you for highlighting this. It has now been corrected to "drunk".
Public Health England	Supporting documentation - Methods	General	General	When using evidence to shape the development of digital interventions for behaviour change, bear in mind **evidence and Randomised Control Trials can only tell us about what exists already and can be studied.** **A design-led process usually used to integrate behavioural insights into potential solutions, as design thinking methods create opportunities for new ideas to be generated and refined, in addition to improving and/or recreating interventions that have been evidenced to work.**	Thank you for your comment. The committee agreed that a robust development stage for interventions would produce high quality interventions therefore they created the recommendations in section 1.1 of the guideline.

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				Additionally, designers instinctively design behavioural components. So behavioural insights evidence is then valuable/applicable to a) enhance components as they are refined based on evidence, and b) spot gaps and check what other behavioural techniques could be tested. Anecdotally from design teams, a successful solution is not usually reached only by piecing together evidenced behavioural techniques, as the overall user flow and journey must be designed with a holistic perspective.	
Royal College of General Practitioners	Guideline	General	General	The RCGP were surprised that this guideline contained detailed recommendations on how to develop and use digital health interventions given the lack of evidence that these interventions are effective. On multiple occasions (1.3.1, 1.4.1 and 1.5.1) it is explicitly stated that it is 'not clear' whether the digital interventions that are being recommended to 'consider' are effective to use. Whilst it is essential that medicine moves forward with new interventions such as digital health it is important that these are held to the same standards as other interventions in clinical care where it is best practice is to only recommend evidence-based interventions. The RCGP suggests that NICE be cautious about publishing detailed guidance on these	Thank you for your comment. The committee discussed the evidence and agreed that the digital and mobile health interventions currently available were of variable quality. However, this is also true of much behaviour change science, whether digital or non-digital. They discussed that some interventions may be effective for some people and in some circumstances. The committee were also aware that many people will benefit from having access to these interventions, especially alongside other behaviour change services. This guideline is to help those who decide to use digital interventions with their decisions, and not to replace existing services. Recommendations 1.1.1 and 1.2.1 links to the NICE evidence standards framework for digital health interventions, which has clear instructions on how to assess if an intervention is effective or not.

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				interventions at this stage without clear evidence of effectiveness. The final recommendation, for more research, is the only part of the guideline that we would support at this current time. If NICE do decide to publish the guideline, our more details comments can be found below.	
Royal College of General Practitioners	Guideline	007	001 - 010	**Recommendation 1.3.3** This list of items to point out to patients when recommending digital interventions is long and difficult to cover in short consultation times. Does the committee really believe this is the responsibility of the clinician or could the committee consider this be the responsibility of the digital intervention platform or designer to give this information before patients read/sign up? By making this the responsibility of the clinician potentially opens them up to litigation relating to digital interventions that they have no control over and may also negatively impact on GP workload.	Thank you for your comment. The committee discussed this issue and moved some of the content from 1.3.3 into section 1. The HCP does not need to go through these points in any detail, they are there for the HCP to alert the person to them. This will free up time in consultations and puts the responsibility on the developer to make users aware of digital-specific points. The developer is also responsible for letting users know about updates to these factors, and not the person who referred them. They considered many of the points that recommendation 1.3.2 asks healthcare professionals to discuss and said that they would be discussed if a clinical treatment were offered to a patient. This discussion will also help the healthcare professional to discuss with the person and make a shared decision on which behaviour change intervention is suitable, digital or non-digital.
Royal College of General Practitioners	Guideline	007	011 - 022	**Recommendation 1.3.4** The committee does not seem to have considered the fact that some digital aids may increase anxiety and lead to an increase in	Thank you for your comment. Adverse effects data was sought but not found. This is why a research

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				consulting behaviour. Can this be added to the list of possible adverse effects and can we recommend further research into consultation behaviour relating to digital interventions?	recommendation on harms of digital and mobile health interventions has been prioritised. We have added this to the list of adverse effects that healthcare professionals should be aware of: "lead to increased anxiety around health and lead people to consult with healthcare professionals more often.
Royal College of Midwives	Guideline	006	018	We are concerned that there is no mention of evaluating the appropriateness of the use of mobile and digital interventions in comparison to an alternative non digital intervention.	Thank you for your comment. Recommendation 1.3.2 lists factors that referrers should take into account when discussing which, if any, digital or mobile health intervention would be appropriate for a person. This guideline includes interventions that are delivered by the technology and not by healthcare professionals, the possible comparators in the studies included non digital interventions. There is further detail available on the included studies in the evidence reviews for each review question which are available on the NICE website.
Royal College of Midwives	Guideline	007	007	Is this a reasonable expectation, as this information isn't necessarily readily available to the user or the professional. We are unsure that users would be able to contextualise this information if it were available.	Thank you for comment. Recommendation 1.3.2 asks referrers to check the capability of the person, this includes if they are capable of using a digital or mobile health intervention. GDPR is statute legislation which states that data usage and consent to data usage needs to be made clear to the user. Professionals are not expected to know the details of individual interventions but should be informed of the components listed in this guideline. Professionals can recommend appropriate components and the person chooses the intervention themselves.

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Royal College of Midwives	Guideline	022	002	We are concerned that there hasn't been sufficient caution raised with regards to using digital health interventions within pregnancy or while breastfeeding without sufficient supervision or evaluation of these interventions for this group.	Thank you for your comment. Pregnant women were a specific consideration for this guideline but there was little evidence for this group. Any evidence that did arise did not show there was a difference in effectiveness between pregnant women and other population groups. Therefore, specific recommendations were not made for this group.
Royal College of Nursing	General	General	General	The Royal College of Nursing (RCN) welcomes the opportunity to comment on the draft NICE Behaviour change: digital and mobile health interventions guidelines. The RCN invited member of the RCN E-Health Forum to review the draft document on its behalf. The comments below, reflect the views of our reviewers.	Thank you for your contributions.
Royal College of Nursing	Guideline	006	016 - 017	**Q2. Would implementation of any of the draft recommendations have significant cost implications?** As stated in this draft guideline, there is not enough evidence to be certain of the effectiveness of these digital and mobile interventions so in essence they are being researched 'in live use' and the cost implications relate to the clinical staff's time i.e. from the recommendation to introducing the applications to their patients and monitoring the impact on the patients' behaviour.	Thank you for your comment. A resource impact assessment has been conducted by NICE and the recommendation is not expected to add substantial additional costs as local needs assessment are considered good routine practice. It is anticipated that any extra costs mayl be offset by the benefits.

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Royal College of Nursing	Guideline	006	020 - 025	**Q3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)** Not all staff who are expected to recommend apps and mobile technologies will have skills and competence in assessing the patients' motivations and behaviour change in the use ~~the use~~ of digital and mobile technologies, therefore, there will need to be education and training in these aspects of care if these tools are to be used with any effect. Clinical staff need guidance and direction from their professional and regulatory bodies as well as from employers about how to assess these apps and make recommendations to their patients/ the public on how to use them. There are training and education need for all staff from students to frontline staff and anyone else that will be in contact with patients utilising these apps and technologies.	Thank you for your comment. The healthcare professionals are not expected to refer people to specific digital or mobile health interventions. Rather they should consider whether these interventions may be appropriate for discussion with the person aiming to change their behaviour. Recommendation 1.3.2 lists the factors healthcare professionals should take into account when discussing digital and mobile health interventions with a person, this includes the importance of accessing expert sources. The training of healthcare professionals is outside of the scope of this guideline. Professional bodies usually have a leading role in identifying training needs for their healthcare professionals unless something specific is identified during the development of the guideline.
Royal College of Nursing	Guideline	007 And 006	005 - 010 009 - 012	**Q3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)** If a healthcare professional recommends an app/ mobile technology to a patient, we suggest that an additional recommendation is required, i.e.	Thank you for your comment. The guideline now asks developers to make practical information about personal information and data use, mobile data, and terms and conditions clear to users. This will put the onus on developers to provide this information instead of taking up resource in primary and secondary care.

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				that additional expert advice is provided to the patient, for example by a non-clinical staff member with the relevant IT expertise, to find out about and discuss the type of information listed in these guidelines with the patient/ member of the public.	
Royal College of Nursing	Guideline	007	005 - 010	**Q3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)** The availability of evidence-based guidance and information/ leaflets about the features of these apps/ mobile technologies is necessary so clinicians could give these to patients when they are discussing/ recommending and these apps. There really needs to be better and up to date information about apps for clinicians to be able to discuss and recommend them. If these are going to be part of health care then there needs to be proper resources for clinical staff to access up to date resources that cover all the practical knowledge needed if they are to recommend these technologies to patients. NHS Apps Library does not cover this type of information.	Thank you for your comment. The NHS Apps Library provides information on specific apps. This is a rapidly changing area; it is anticipated that the availability of apps from expert sources will increase. The committee considered it important that interventions are not accessed from non-expert sources where the assessment of these interventions is unknown.
Royal College of Nursing	Guideline	007	005 - 010	**Q1. Which areas will have the biggest impact on practice and be challenging to**	Thank you for your comment. The training of healthcare professionals is outside of the scope of this guideline. Professional bodies usually have a leading role in identifying training needs for their healthcare professionals unless

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				implement? Please say for whom and why. Clinical staff need extra skills, expertise and time to do this as it is not part of their current role and it is more to do with being good at Information Technology (IT). It would be time consuming to learn and be proficient in this type of information technology for all the apps that could potentially be recommended to patients/ the public. Also apps/ mobile technologies develop rapidly and their features change with time – consideration needs to be given to how staff can keep up with this. It could also potentially lead staff not to recommend anything at all if they were to be accountable for imparting this type of information to patients. We would argue that it is not the role of clinical staff to do this.	something specific is identified during the development of the guideline. Much of the conversation between healthcare professionals and people will be similar to usual discussions for non-digital behaviour change interventions. The aim of the conversation is not to recommend a specific intervention but to discuss about digital and mobile health interventions overall. The person will then be better equipped to choose their own intervention based on their goals and preferences. The guideline notes that these interventions should be considered as an adjunct to existing services. This discussion includes noting the importance of the person accessing the interventions via expert sources..
Royal College of Nursing	Guideline	007	015 - 022	**Q1. Which areas will have the biggest impact on practice and be challenging to**	Thank you for your comment. The aim of the reviews was to find effective components and recommend these, instead of recommending specific interventions. Healthcare professionals are asked to assess whether a person will be suitable for a digital or mobile health intervention. The person then chooses an

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				implement? Please say for whom and why. This is the role of clinical staff but, as per previous comment, clinical staff need extra clinical and digital skills and competence to implement this recommendation which has an impact on education and training. In addition, there is currently not enough evidence for staff to make good assessments about the merits and risks of these technologies. This leaves patients at risk of being given an inappropriate intervention and staff at risk from making assessments without enough good information to inform their assessments and recommendations. This could put staff in untenable positions if they are expected, by employers and national bodies, to recommend these apps and mobile technologies but are held accountable and responsible if something goes wrong.	appropriate intervention from an expert source themselves. The training of healthcare professionals is outside of the scope of this guideline. Professional bodies usually have a leading role in identifying training needs for their healthcare professionals unless something specific is identified during the development of the guideline. The committee considered possible litigation and considered that this applies to any treatment discussed with people. In addition, healthcare professionals are not expected to provide in depth consultations on digital and mobile health interventions.
Royal College of Nursing	Guideline	007	015 - 022	**Q3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)** This recommendation will involve training and education for staff. As stated earlier, there is an urgent need for a robust evidence base about the risks and mitigations from use of these technologies and national guidance for staff	Thank you for your comment. The training of healthcare professionals is outside of the scope of this guideline. Professional bodies usually have a leading role in identifying training needs for their healthcare professionals unless something specific is identified during the development of the guideline. A research recommendation has been made for research relating to the harms and adverse effects associated with digital and mobile health behaviour change interventions. .

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				charged with recommending/ prescribing these interventions.	
Royal College of Nursing	Guideline	016	003 - 007	**Q3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)** Professional guidance, education and training for staff to be aware of and be able to assess misuse is required. This would also need to be monitored / evaluated to quantify the risk and devise mitigations and share best practices.	Thank you for your comment. The training of healthcare professionals is outside of the scope of this guideline. Professional bodies usually have a leading role in identifying training needs for their healthcare professionals unless something specific is identified during the development of the guideline.
Royal College of Nursing	Guideline	016 005	010 - 012 014 - 015	**Q2. Would implementation of any of the draft recommendations have significant cost implications?** This suggests costs savings, however, the recommendations in page 5, lines 10 – 12, state these are additional/supplement and not a replacement for existing services. This could potentially mean that it will be an extra workload on all staff, providing advice for the various apps/ mobile technologies recommended unless existing services are reduced or streamlined with the introduction of these apps.	Thank you for your comment. A resource impact assessment has been conducted by NICE and the recommendation is not expected to add substantial additional costs as local needs assessment are considered good routine practice. The rational section for the using digital and mobile health interventions section notes that there may be increased costs due to adverse consequences, e.g. increased consultations related to increased anxiety.
Royal College of Occupational Therapists	Guideline	General	General	**Q1 - Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why.**	Thank you for your comment. The NICE evidence standards framework for digital health interventions recommended in 1.1.1 says interventions should be designed that allow

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				One of the biggest challenges to implementation is evaluation of effectiveness. If someone is using a digital/mobile intervention to change behaviour and this data is not shared with health and care professionals, we are concerned that effectiveness cannot be measured? Consideration to the range of professionals involved in a persons care also needs to be considered and how this information can be shared with multiple people who may be using different systems to record data. We would suggest that there are additional considerations with regards to children and young people using digital/mobile interventions. Examples include thinking about consent as well as monitoring negative behaviours associated with technology over use.	continual outcome data retrieval from consenting users. It also says that developers need to measure the economic impact and effectiveness of these interventions. After reviewing consultation comments, a recommendation has been added asking developers to use feedback from testing and after releasing the intervention to continually improve the intervention. The committee considered consent regarding minors and referred to data protection legislation that specifies when children can provide consent.
Royal College of Occupational Therapists	Guideline	004	007	**Recommendation 1.1.2** The Digital Assessment Tool is an NHS Digital Assessment Tool and we are concerned that occupational therapists working in local authority settings may be using different tools for assessment. This guideline states that they must use this tool. We would suggest that if a universal digital assessment tool is to be recommended, an organisation such as Skills for Care should be engaged with.	Thank you for your comment. Recommendations in 1.1 are for developers. We were alerted to a new version of the Digital Assessment Questionnaire (DAQ) during consultation, the NHS Digital Health Technology Standard. The guideline recommends that developers use this so they can make interventions that are in line with NHS standards. 1.1.1 and 1.1.2 says that developers should use the framework when evaluating their work, for example to inform them of the best ways to test effectiveness.

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					Commissioners can use other tools to assess if interventions meet good standards.
Royal College of Occupational Therapists	Guideline	007	001	**Recommendation 1.3.3** We would suggest a tweak to the wording of the recommendation "Check how much mobile data it uses and if they can afford it". We feel it is more about assessing the appropriateness of a digital/mobile tool and then exploring how an individual may access the intervention. Core to this recommendation is about not making assumptions.	Thank you for your comment. This guideline does not recommend specific interventions, neither does it recommend that referrers tell users which interventions to use. Recommendation 1.3.3 is what referrers should tell users to look out for when choosing an intervention for themselves.
Royal College of Occupational Therapists	Guideline	007 / 014	001 / 008	**Recommendation 1.3.3 & 3rd paragraph on pg14** The wording "it is likely to have been assessed for safety" is ambiguous. We are concerned that individuals may not conduct an individual risk assessment if they believe that digital and mobile interventions have been assessed for safety at a national level.	Thank you for your comment. This consideration has been added to recommendation 1.3.4 on possible adverse effects of digital and mobile health interventions.
Royal College of Occupational Therapists	Guideline	016 - 017		**3rd Paragraph** We are concerned that this recommendation implies that digital/mobile tools can free up health and care practitioners time and lead to cost savings. However, our members who work across health and care settings inform us that digital/mobile technologies change the interaction rather than remove the need for interaction. We believe that any technology intervention recommended by an occupational therapist must ensure it is the right fit for the person, their health	Thank you for your comment. A resource impact assessment has been conducted by NICE and the recommendation is not expected to add substantial additional costs as local needs assessment are considered good routine practice. The committee agree that when a digital intervention is considered it should be a good fit for the person's care and lifestyle. This is why they made recommendation 1.3.2, which gives points for referrers to think about when discussing digital or mobile health interventions. For some people this may lead to them taking up a digital intervention

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				conditions, daily activities and their social and physical environment. Digital/mobile interventions should enhance the care being provided and outcomes should be collected that capture the fit of the technology to the person.	instead of a more resource-intensive service, which will free up resource for the resource-intensive service. The rationale section for the using digital and mobile health interventions section notes that there may be increased costs due to adverse consequences, e.g. increased consultations related to increased anxiety.
Royal College of Physicians (RCP)	General	General	General	The RCP is grateful for the opportunity to respond to the above consultation. We have liaised with our Clinical Director for Digital Health and would like to make the following comments.	Thank you for your contributions.
Royal College of Physicians (RCP)	General	General	General	The key issue here is whether people would use it and if they do so ensuring that it's effective. We must ensure that people who don't have access to these technologies are not disadvantaged. It should meet the needs of people with impairments (listed) such as visual or lack of literacy and that this isn't just given lip-service. These are pre-primary care as PRSB would put it but there is no doubt they have significant downstream impacts on healthcare seeking behaviour eg nearly three quarters of people receiving notifications of irregular heart betas on an Apple Watch had some form of health seeking behaviour.	Thank you for your comment. The committee agreed that making interventions accessible is important, which is why they made recommendations to ensure interventions are developed and chosen with accessibility considerations. How compliance to frameworks recommended in this guideline is assessed is out of our remit. Health seeking behaviours would exist without digital interventions and the evidence reviews did not look for any evidence on the effect of digital interventions on health seeking behaviour. The rationale and impact section notes the possibility that use of the interventions may lead to people not taking up other resource intensive services, but also that there may be increased consultations, such as those linked to increased anxiety.

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				It is important that these apps follow standards set down in the guidance such as the NICE standards framework for digital technologies but how will compliance with this be assessed? As well involving users make sure relevant patient associations and expert clinicians participate in the development. The target audience and its role needs to be clearly defined but there can be creep towards an unintended population eg Babylon chatbot is said to be advisory only but people rapidly start to use it as a definitive answer when it isn't intended to be that way. Almost inevitably despite the recommendations, organisations will use it as an alternative rather than a supplement to usual care. Any commercial considerations need to be explicit ie if it recommends vaping as smoking harm reduction strategy that this isn't affected by any commercial incentive. These apps are potentially useful and there are many of them but they can be of poor quality and not evidence based. The regulation of this area is till sub-optimal.	The committee noted that involving patients and clinicians during development was important, hence why they recommended that stakeholder and potential users should be involved. The Equality Impact Assessment for this guideline also notes where the impact on equality has been assessed during the development of this guideline. Testing in specific populations will allow referrers and commissioners know which components will work in certain populations and better or worse than others. This information is invaluable when deciding which interventions to procure or commission to be developed for their local population. The recommendations state that these interventions should not replace existing services but can be an adjunct. In addition, not everyone should be considered for digital interventions, only to whom it is suitable. An additional recommendation in the commissioning section has been added to note that interventions without adverts are preferable. The guideline recommendations also note that interventions should be accessed via expert sources where there will have been assessment of the interventions, this will help to mitigate against possible commercial influences.

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Royal College of Psychiatrists	Guideline	004	001	We are concerned that developmental needs are not mentioned alongside consent and capacity	Thank you for your comment. This box contains standard terminology for all guidelines. The document that is linked in the box "Making decisions using NICE guidelines" is meant to be used in conjunction with this guidance. It provides more information for topics that are common to all guidelines. It is not an overview of the guideline but a resource that should be used to give context to the guideline. The examples of laws considered in this linked document is not exhaustive and the document contains more information than the box provides.
Royal College of Psychiatrists	Guideline	004	009	Question 1: This recommendation will be a challenging change in practice because there is increasing awareness of the need for the personal digital information relating to children and young people to be managed differently. Thus there may need to be additional safeguards employed by application developers in addition to the UK Data protection Act.	Thank you for your comment. The committee were satisfied that the consideration around children and young people concerning GDPR were sufficient. In addition, they did not want to produce guidance that might conflict with future legislation that may arise, as this is a fast-moving area and laws may change quickly.
Royal College of Psychiatrists	Evidence review - smoking	General	General	The inclusion criteria allows a review of the evidence relating to children and young people. The review noted that there was a gap in the literature in relation people with mental health needs.	Thank you for your comment. It was noted that there was a gap in the literature for people with mental health conditions. There was some evidence for children and young people but not enough to make recommendations. This is why they are included as a population of specific consideration in the research recommendations. In addition, they are included as a population of interest in the research recommendation that will explore populations who will benefit most from digital and mobile health interventions.

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Royal College of Psychiatrists	Evidence review - sexual health	General	General	The review examined evidence to support the sexual health of children under 16 however the evidence was limited	Thank you for your comment. This was taken into account by the committee, which is why they did not make specific recommendations for children under 16. The evidence that was available did not show a difference in effectiveness between children under 16 and other populations. The committee agreed this group should be specific consideration in the research recommendations (Appendix B, evidence review 1: smoking).
Royal College of Psychiatrists	Evidence review - diet and weight loss	General	General	There is no reference to the possible impact of psychotropic medication.	Thank you for your comment. Effect of psychotropic medicine is out of scope for this guideline.
Royal College of Psychiatrists	Evidence review - Alcohol	General	General	This review did not include children under 16	Thank you for your comment. Children under 16 were relevant to this review but no studies in this age group were relevant to the rest of the protocol. This was usually because in these studies interventions were delivered in schools and had a large component delivered face-to-face, making them illegible for the review. The committee agreed this group should be given specific consideration in the research recommendations (Appendix B, evidence review1: smoking).
Royal Society for Public Health	Guideline	General	General	We increasingly live in a digital age, and opportunities presented by advances in technology to improve the health of the population should be utilised when appropriate, such as the NHS app. However, we caution using digital and mobile health interventions prior	Thank you for your comment. The committee were aware of the possibility of adverse effects of digital interventions relating to mental health and therefore made a recommendation for referrers to discuss aspects

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				to conducting a full and detailed impact assessment for local areas. Our report New Filters, highlighted that although many young people use social media as a source of health information, it can have a negative impact on mental health. We would be hesitant about using digital health interventions that have similarities with social media, and would like clarity on the digital and mobile health interventions included in the Guideline. We welcome that the Government is minded to place Ofcom as the regulator for social media platforms, and would want similar regulation for apps used for health interventions. As detailed in the Guideline, engagement with digital and mobile interventions will vary across different groups. We are concerned that these interventions have the potential to exacerbate health inequalities if not implemented correctly. For instance, individuals without the technology required to access mobile and digital interventions would be deprived of these services. There should also be consideration for groups who may not benefit from these interventions, including vulnerable groups such as people with eating disorders. The Guideline notes this as a potential consequence, and we want to see more	around the use of the intervention with the person considering using them. Research on harms was looked for but not found, which is why a research recommendation was made to assess harms of digital and mobile health interventions (see Appendix B, evidence review 1: smoking). **The training of healthcare professionals is outside of the scope of this guideline. Professional bodies usually have a leading role in identifying training needs for their healthcare professionals unless something specific is identified during the development of the guideline.** From the evidence that was identified for social media in the behaviours considered in this guideline, it was not possible to deduce whether social media was effective or ineffective at promoting positive behaviour change. Creating a regulatory body such as Ofcom for health interventions is outside of NICE's remit. The committee were aware of potential health inequalities relating to these interventions. In addition, they have recommended that commissioners think about health inequalities when deciding whether to use digital and mobile health interventions and making different options available

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				information on how the public will be protected, especially vulnerable groups. It is reassuring to see that the Guideline includes recommendations for research, particularly around engagement, under-served groups, and associated harms. We suggest doing a full audit of the health needs of local areas, including a full impact assessment, before introducing digital and mobile health interventions, and to tailor their implementation if necessary to the individual needs of specific areas. If digital and mobile health interventions are deemed appropriate for use and introduced accordingly, we advise healthcare professionals are trained on using these tools alongside and to enhance existing services.	for the needs of different groups, this includes using a needs assessment, including the need to address digital exclusion. Expert sources have been recommended, which include resources for people's differing needs. Recommendations to professional bodies on content of training is outside the remit of NICE.Healthcare staff discussing intervention options with people are not recommending specific interventions but guiding people to the type of interventions they should use based on their needs and preferences.
The Challenging Behaviour Foundation	Guideline	General	General	The Challenging Behaviour Foundation is the only charity in the UK that focusses on children, young people and adults with severe learning disabilities whose behaviour challenges and their families. The charity exists to demonstrate that individuals with severe learning disabilities who are described as having challenging behaviour can enjoy ordinary life opportunities when their behaviour is properly understood and appropriately supported. Challenging behaviour itself is often communication of an unmet need, so understanding the function of behaviour can help to improve the way a person's needs or wishes are understood. Challenging behaviour	Thank you for your comment. The committee agrees that making digital and mobile health interventions accessible for all is important. People with learning disabilities were considered in the EIA for this guideline but no evidence was found specifically for this groups. Because of this, they are included as a specific group in the research recommendations. One of the benefits of these interventions is that they can be delivered anywhere and therefore they should be accessible to as many people as possible. This is why the committee made a recommendation for interventions to be developed with a broad range of people so it is appealing and accessible for as

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				can include issues relating to diet and inappropriate sexual behaviours (both covered in this guideline). Digital behaviour change interventions might be used in the support of children, young people and adults with learning disabilities. Therefore, these interventions need to be accessible to children, young people and adults with learning disabilities and their families, and all those who support them. In order to ensure accessibility, people with learning disabilities, their families and professionals working with them must all be properly consulted in the development of the relevant interventions. Support and services for children, young people and adults with learning disabilities cross education, health and social care. If digital and mobile health interventions are deemed appropriate, they need to be used consistently and be used in conjunction with appropriate support from other services. In addition, it is important their outcome is regularly monitored to assess the impact interventions are having.	many people as possible. There is also a recommendation for commissioners to consider equality of access when choosing interventions to maximise access.
UK Society for Behavioural Medicine (UKSBM)	Guideline	005 - 006	General	Recommendation 1.2 should make reference to publicity around commissioned interventions since there is generally poor public awareness of NHS and Public Health England resources. It is likely that commissioners will need to consider	Thank you for your comment. Increasing awareness of interventions is out of scope for this guideline.

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				how they would address the challenge of raising awareness among target populations in order for any interventions to have their expected impact.	
UK Society for Behavioural Medicine (UKSBM)	Guideline	005	003	Recommendation 1.1.5 should ensure that any apps developed are compliant with NHS policies on ethics and governance, as well as being GDPR compliant.	Thank you for your comment. NHS policies on ethics are considered in the advisory and regulatory frameworks recommended in the guideline. GDPR compliance is now law and therefore the guideline does not need to restate this point.
UK Society for Behavioural Medicine (UKSBM)	Guideline	005	008	The inclusion of a clear, precise definitions of 'digital platform would be helpful in relation to Recommendation 1.1.5.	Thank you for your comment. A definition has been added to the "Terms used" section of the guideline.
UK Society for Behavioural Medicine (UKSBM)	Guideline	005	010	it is unclear whether NICE expects developers, commissioners or users of digital interventions to access/assess the evidence-base for that particular intervention themselves or whether the evidence-base will be provided. Some clarification here would be welcomed.	Thank you for your comment. This guideline will not recommend specific interventions because digital products change almost continually, meaning that the available interventions and the evidence base will also change. The guideline provides tools for developers, commissioners and referrers when thinking about which interventions to make or use and notes the importance of accessing these from expert sources.
UK Society for Behavioural Medicine (UKSBM)	Guideline	005	014 - 015	Recommendation 1.1.5 should include a requirement for rigorous, independent evaluation (of acceptability and effectiveness) alongside any development and implementation of digital platforms.	Thank you for your comment. The committee agree with the comment that rigorous testing should be carried out. Recommendation 1.1.1 links to NICE's evidence standards framework for digital health interventions, which explains how these interventions should be evaluated.

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UK Society for Behavioural Medicine (UKSBM)	Guideline	005	015 - 017	It would be useful to clarify the wording of this recommendation so that it is obvious whether the commissioning of digital interventions should be a supplement to existing services or whether it is advisable to have digital interventions even where no existing services are on offer. Perhaps the consideration of a 'stepped care model' would be helpful as away of combining both as necessary?	Thank you for your comment. The committee made clear that digital and mobile interventions should be an adjunct to existing services. This guideline did not consider whether they should be used where no existing services are on offer as for the behavioural areas included there are existing services.
UK Society for Behavioural Medicine (UKSBM)	Guideline	005	015 - 017	It would be useful to clarify the wording of this recommendation so that it is obvious whether the commissioning of digital interventions should be a supplement to existing services or whether it is advisable to have digital interventions even where no existing services are on offer. Perhaps the consideration of a 'stepped care model' would be helpful as away of combining both as necessary?	Thank you for your comment. The committee made clear that digital and mobile interventions should be an adjunct to existing services. This guideline did not consider whether they should be used where no existing services are on offer as for the behavioural areas included there are existing services.
UK Society for Behavioural Medicine (UKSBM)	Guideline	005	018	An edit of the wording of Recommendation 1.2.3 to "assess which local populations specific digital and mobile health interventions could meet the needs of, by using a needs assessment" would to be helpful.	Thank you for your comment. These needs assessments would be done by local commissioners and this would assess interventions for how appropriate they would be for their population, and not the other way around.
UK Society for Behavioural Medicine (UKSBM)	Guideline	005	022	The understanding of Recommendations 1.2.4 and 1.2.5 would be improved by reversing their order.	Thank you for your comment. The order of the recommendations has been reversed.
UK Society for Behavioural Medicine (UKSBM)	Guideline	006	001 - 002	Recommendations 1.2.6 and 1.2.7 should ensure that any apps developed are compliant with NHS policies on ethics and governance, as well as being GDPR compliant.	Thank you for your comment. The NICE evidence standards framework for digital health interventions recommended in 1.2.5 for use by commissioners to aid decision making says interventions should be designed to allow continual

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					outcome data retrieval from consenting users. General Data Protection Regulation is now a requirement by law and commissioners should assess whether interventions adhere to this legislation before choosing an intervention.
UK Society for Behavioural Medicine (UKSBM)	Guideline	006	007 - 018	Recommendation 1.2.7 should be explicit about the fact that digital interventions have the potential to increase health inequalities by attracting and engaging with more privileged individuals and groups. It should consider the issue of 'app literacy' and offer more information about the function of apps so that individuals with less technological competency have the means to properly engage with digital interventions. It should also consider the availability of producing content in a range of different formats as far as practicable. This is likely to require greater funding and effort from both commissioners and service developers.	Thank you for your comment. It is one of NICE's aims to mitigate inequalities in any guidance it produces. This is why the committee made a specific recommendation about catering to different literacy standards. The committee agreed that not only should interventions be accessible to as many people as possible, there will be situations where an intervention cannot serve every group. Which is one reason why they recommended using an expert source that lists many different interventions, with each one catering for a few groups instead of recommending one intervention that caters to all, which may be difficult to design. The training of healthcare professionals is outside of the scope of this guideline. Professional bodies usually have a leading role in identifying training needs for their healthcare professionals unless something specific is identified during the development of the guideline. In addition, the guideline is not recommending specific interventions and therefore cannot give guidance on any intervention in particular, and cannot give specific guidance on how to use all interventions as they are all so different.

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UK Society for Behavioural Medicine (UKSBM)	Guideline	006	020 - 025	Some additional information about what to do if there is no evidence for a particular intervention and yet a demand for an intervention would be welcomed as part of Recommendation 1.3.1.	Thank you for your comment. The committee agreed that the best course of action was to refer people to expert sources, such as the NHS Apps Library, as recommended in 1.3.3. The committee also said that telling the person that there was no evidence of effectiveness for this intervention may help. This has been added to recommendation 1.3.2.
University Hospitals Birmingham, NHS FT	Guideline	General	General	In general these are well written guidelines based on the very limited evidence that exists for use of these technologies. I agree that these technologies should be user designed in collaboration with clinicians and studied for evidence of benefit. I also agree with the comments that technologies can be harmful, and isolate people who would otherwise seek, and benefit from face to face help. I have nothing particular to add to this guidance.	Thank you for your comment.
Westminster Drug Project (WDP)	Guideline	General	General	We would recommend the acknowledgement that platforms or developers used by organisations may not be UK specific and that organisations should be aware of where and how data of their service users is being stored by the host (ensuring GDPR compliance)	Thank you for your comment. Recommendation 1.3.3 mentions that people should check how their personal data may be used. After consultation, a recommendation was created asking developers to make data use clear. This is also statute as it is included in GDPR legislation.
Westminster Drug Project (WDP)	Guideline	001	004	The term digital and mobile health interventions is not defined within this document. For clarity purposes it would be useful for these terms to be defined	Thank you for your comment. The term "digital and mobile health interventions" is now defined in the "Terms used" section of the guideline.
Westminster Drug Project (WDP)	Guideline	004	016	Comment 1- this should say 'so they can be scaled up'	Thank you for your comment. We have changed the recommendation to say "scaled up". This recommendation tells developers

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				Comment 2- what level should interventions be scaled up? Consider that scaling up can often depend on contract awards/providers.	to make an intervention that has the capability to be scaled up, and not necessarily used on a large scale when it is first made. This may not be possible at the start but an intervention may be successful meaning it has to be scaled up at some point. Making an intervention that can be scaled up was an important consideration for the committee regarding equality of use across the country.
Westminster Drug Project (WDP)	Guideline	005	001	We would suggest adding steps before the ones listed to include reviewing existing products that could be used/signposted to so that developers are not duplicating what already exists.	Thank you for your comment. Developers are signposted to evidence frameworks in 1.1.1 and 1.1.2 which developers can use to assess interventions and whether they would be duplicating work. Recommendation 1.2.1 links to NICE's evidence standards framework for digital interventions, which commissioners are meant to use when evaluating existing products. Recommendation 1.2.5 tells commissioners to check existing interventions before commissioning a new one.
Westminster Drug Project (WDP)	Guideline	005	014	In support of this statement, the WDP Capital Card App (http://capitalcard.org.uk/) tracks and records current treatment already being received and works alongside this treatment to integrate service users back into society.	Thank you for your comment. The WDP Capital Card App contains significant input from healthcare professionals, in the form of a dedicated care coordinator which accompanies individual and group care planning. This is outside of the review protocols for this guideline. The interventions included are those where the digital component(s) itself is delivering the active components of the intervention.

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Westminster Drug Project (WDP)	Guideline	005	017	Will NICE be providing a template of a suitable needs assessment that could be used to determine whether the intervention could be used in the wider local population or expanded nationally for a specific group	Thank you for your comment. Local authorities will consider the needs assessment templates that will be used within their areas, this is outside of NICE's remit.
Westminster Drug Project (WDP)	Guideline	005	022	Comment 1- within a structured treatment setting, it could be recommended that an assessment prior to offering the online support should take place in order to assess whether the service user is engaged in any other online digital or mobile health interventions. Comment 2- the expert sources cited or referenced within the document may exclude developers identifying many other applications within the behaviour change field as not all are acknowledged on PHE/NHS websites (this applies to **page 7, line 2**). For instance, WDP and London South Bank University are in the process of publishing a retrospective evaluation that highlights the impact of WDPs Capital Card on successful completion rates of service users using substance misuse services (https://www.wdp.org.uk/innovation-and-research-unit/current-research-and-innovation-projects/ https://www.addiction-ssa.org/author-publications/measuring-the-impact-of-the-capital-card-on-substance-use-treatment-outcomes/. This digital intervention is not on the PHE/NHS websites but has begun developing an evidence	Thank you for your comment. When referrers are discussing behaviour change options with people, their current care would be discussed. If a digital intervention is considered by the healthcare professional or person, the discussion would include information on any digital interventions the person is currently using. Expert sources are referenced in the guideline so people have a source to go to instead of using an app store that includes many that have not been adequately tested. The WDP Capital Card was not included as it does not meet the interventions in the protocols as much of the intervention is delivered by healthcare professionals. A dedicated care coordinator accompanies individual and group care planning to deliver active components of the intervention. This guideline only considers interventions where the digital component(s) itself is delivering the active components of the intervention. Evidence that commissioners may consider has been detailed in the Evidence Standards Framework, link found in recommendations 1.1.1 and 1.2.5. NICE cannot include references that have not yet been published. All studies and reviews that are included in NICE evidence reviews must go through the systematic review process to assess if it

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				base and has the potential to be used in many different fields focusing on behaviour change. Comment 3- the specification of 'evidence based' interventions requires clarification as it does not state what form of evidence is required. It may be useful to refer people to the research paper that will be published by the London School of Health and Tropical Medicine within the next few months as they are due to release a paper that reviews behaviour change/digital interventions.	is relevant to the specific protocol the committee agreed upon.
Westminster Drug Project (WDP)	Guideline	006	001	Regional multidisciplinary collaborations/partnerships could be quite difficult as within some sectors a culture of competition is perpetuated. This means there could be difficulties in co-developing interventions, particularly with the issue of rights. This issue also links to the licensing out of applications developed by other providers. This comment also applies to **page 5, section 1.2.2** as commissioners mandating the use of particular digital interventions by providers could cause issues if the interventions have been developed by a direct competitor. This may also cause problems with ensuring a fair tender process.	Thank you for your comment. The committee were aware that competition may be present between developers. In consideration of that they made a recommendation that allows developers to assess if collaboration is the right way forward. The committee noted that it would be expected that the usual fair tender process, conflicts of interest and intellectual property considerations should be settled before collaboration begins. In the main, this recommendation aims to develop collaboration between people with different skill sets. This would lead to multidisciplinary teams comprised of healthcare professionals and expert digital technology experts, and not necessarily teams with competing interests. The committee made this recommendation as they discussed that development of digital and mobile health interventions may not be developed by multidisciplinary teams, leading to non-health

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					specialist developers creating interventions with little behavioural theory informing the intervention.
Westminster Drug Project (WDP)	Guideline	007	General	It is unclear why applications of this document have only been applied to diet, physical activity, smoking, alcohol and unsafe sexual behaviour. Digital interventions and behaviour change techniques can be used in the mental health field and addiction more generally. We would also suggest unsafe sexual behaviour being changed more generally to 'sexual health'	Thank you for your comment. This guideline was developed as an addition to the behaviour change: individual approaches guideline (PH49). To keep these guidelines aligned, the 4 behaviours in PH49 were kept for this guideline. The other behaviours were considered out of scope for this guideline. Unsafe sexual behaviour has been kept as a heading as it describes the area this guideline focuses on more specifically.
Westminster Drug Project (WDP)	Guideline	007	015	As per WDP Capital Card App, face-to-face interventions should always be involved in treatment and if possible, interact with the online interventions to work collaboratively in the service user's treatment.	Thank you for your comment. This guideline assessed interventions that had minimal healthcare professional input and where the professional was not delivering the intervention themselves. The committee agrees that existing services are valuable in providing a complete care package for people, which can include face-to-face interventions.
Westminster Drug Project (WDP)	Guideline	008		**Alcohol** Comment 1- May be worth acknowledging the usefulness of apps or websites that offer the ability to screen an level of need e.g. WDPs Alcohol Test website (https://www.alcoholtest.org.uk/). Comment 2- may be worth explicitly stating that if use of alcohol is a concern, even if use is only moderate, discussions with GPs/specialists should be had. For higher risk/dependent drinkers it should be made clear that a face to	Thank you for your comment. Screening level of need was out of scope for this guideline. People should have discussions with their GPs and specialists who will decide with the person which course of action will be the best. For some people a digital intervention may be best as an adjunct, for other people other interventions may be best. Dependent drinking is out of the scope of this guidance. Existing NICE guidance covers dependent drinking, please see CG155 Alcohol-use

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				face support should always be recommended and digital interventions are thought as a complementary intervention. Comment 3- like on the alcohol test it should be explicitly states that developers should never recommend someone scoring high risk/dependent drinkers to use their intervention/stop drinking without seeing a specialist as this could pose a significant health risk. Comment 4- brief interventions, drink diaries and other harm reduction advice can be used within digital interventions for alcohol as long as safeguards are put into place to protect those who are higher risk/dependent drinkers Comment 5- alcohol is referenced however drug use is not. Behaviour change techniques and digital interventions can be used on this cohort as well.	disorders: diagnosis, assessment and management of harmful drinking (high-risk drinking) and alcohol dependence and QS 11 Alcohol-use disorders: diagnosis and management. The evidence only found an association between personalised normative feedback and a reduction in drinking. The interventions contained a mixture of many different components making it difficult to isolate any others that would be driving behaviour change. This does not mean that there aren't other components that are effective for behaviour change regarding alcohol, only that the evidence is not strong enough for current recommendations to be based on. The committee understands the importance of trying to establish which components do drive behaviour change, which is why they made a research recommendation based on this. Drug misuse is covered in CG51: Drug misuse in over 16s: psychosocial interventions, which includes sections on brief interventions and formal psychosocial interventions for people who misuse drugs.
Westminster Drug Project (WDP)	Guideline	009	003	To go further with this statement, we would suggest using the online support for a one-off intervention could signpost the user to more structured face-to-face support.	Thank you for your comment. The digital and mobile health interventions are recommended as an adjunct to existing services. A recommendation has been added to say that people should return to their healthcare professional if they have health concerns.

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Westminster Drug Project (WDP)	Guideline	009	019	An interactive scripted scenario may have a place in recovery however should not solely be relied on. Using this will not generate the thoughts and feelings that mirror real life interactions.	Thank you for your comment. The committee did not want to restrict interventions to only include components that are listed in 1.7.2. The committee discussed and agreed that if people have chosen to receive sexual health advice through a digital or mobile health intervention, then scripted scenarios are a good way to practice potential scenarios before they come into contact with them in real life.
Westminster Drug Project (WDP)	Guideline	010	013	One option for engagement with the online digital or mobile health intervention would be the use of push notifications (as per 17.22 suggesting text messages may be cost effective) to notify the user of their appointment, milestone's etc.	Thank you for your comment. The committee discussed that timely reminders and messages via digital and mobile interventions may be effective at promoting positive behaviour change. This is considered under the protocol for this research recommendation, found in Appendix B of evidence review 1: smoking.
Westminster Drug Project (WDP)	Guideline	010	025	A theory around this is that an increasing number of people with a lower socioeconomic background are owning smartphones. With this in mind, there could be an argument that using online digital or mobile health interventions could actually save money for these individuals on a lower income. The intervention could reduce travel costs to services by reducing the amount of face-to-face contact required in their treatment.	Thank you for your comment. Research recommendation 3: "What is the effectiveness and cost effectiveness of digital and mobile health interventions in low socioeconomic and other underserved groups?" will address if digital and mobile health interventions are effective and cost-effective for behaviour change.

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Westminster Drug Project (WDP)	Guideline	011	General	WDPs Innovation and Research Unit have worked on the evaluation of WDP's Digital Intervention and the following further research questions have arisen: • Impact of gamification in digital interventions • How well do digital interventions take into account the complexity of certain conditions, particular in cases where someone has a co-morbidity • What is the best methodology for developing and implementing a digital intervention in order to ensure that an evidence base can be developed that is robust enough to be acknowledged by leading bodies like PHE/NHS • Determine how the digital component of the intervention compares to the delivery of the component in other formats .	Thank you for your comment. The committee consider many areas that require further research and then prioritise the 5 most important. Gamification would be considered as a component and therefore will be assessed under research recommendation 2. The NICE Evidence Standards Framework for digital interventions outlines how to develop and test interventions. This is referred to in recommendations 1.1.1 and 1.2.5 meaning if they are followed the resulting interventions would be eligible if the studies also fit the review protocol. Digital platform will also be considered in research recommendation 2 and can be compared with usual care included face-to-face care.

**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*

[i] NICE. NG92 Stop smoking interventions and services. March 2018.
[ii] PHE. Models of delivery for stop smoking services: Options and evidences. September 2017.

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[iii] Brown J, Michie S, Geraghty AW, Yardley L, Gardner B, Shahab L, Stapleton JA, West R. Internet-based intervention for smoking cessation (StopAdvisor) in people with low and high socioeconomic status: a randomised controlled trial. Lancet Respir Med. 2014 Dec;2(12):997-1006. doi: 10.1016/S2213-2600(14)70195-X. Epub 2014 Sep 25.
[iv] Smith C, Hill S, Amos A. Stop Smoking Inequalities: A systematic review of socioeconomic inequalities in experiences of smoking cessation interventions in the UK. Cancer Research UK. July 2018.
[v] Bennett, K., Gilbert, H., and Sutton, S. Computer-tailored smoking cessation advice matched to reading ability: Perceptions of participants from the ESCAPE trial. Patient Education and Counseling. 98:1577--1584. 2015.
[vi] https://www.bestbeginnings.org.uk/evidence-impact-and-evaluation
[vii] https://www.who.int/tobacco/wntd/2012/article_5_3_fctc/en/
[viii] https://smokefreefuture.co.uk/hold-my-light/

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