National Institute for Health and Care Excellence

Medical technologies evaluation programme

Digitally enabled therapies for adults with anxiety disorders: early value assessment

Consultation comments table

There were 37 comments from 4 groups:

- 12 comments from 4 companies
- 6 comments from 2 members of the public
- 1 comment from 1 patient representative
- 18 comments from NHS England

Some of the comments have been split because they represented multiple themes. The following themes have been identified:

- Recommendations: comments 1 to 7
- Potential benefits and risks: comments 8 to 13
- Technology: comments 14 to 17
- Care pathway and clinical need: comments 18 to 21
- Clinical evidence: comments 22 to 24
- Cost and resource use: comments 25 to 26
- Implementation and patient considerations: comments 27 to 30
- Equality considerations: comment 31
- Evidence generation: comments 32 to 39
- Corrections: comments 40 to 42
- Supporting documents: comments 43 to 46

Comment no.	Consultee ID	Group	Section	Comments	NICE response (including changes made to MTCD, if applicable)
Recommendations (n=7 comments)					
1	1	NHS England		Significant concerns with inconsistency across the adult products vs CYP products, in particular when guidance could have market shaping impacts. The underlying objective of this work was to be able to more clearly articulate what evidence levels industry needs to meet and support NHS in making good commissioning decisions. This flexible and subjective approach does not support these core objectives. Different evidence levels will be required by different product types based on risk, but there needs to be a consistent approach to determining risk level of use case and what this means for evidence level required for a conditional recommendation through NICE, given the market shaping impacts EVA guidance could have. This approach also risks significant implications on markets and wider NHS programmes that have not been fully considered within NICE's methodology. Whilst we are very much supportive of a clear expectation being set for digital health technologies and acknowledge that this will likely result in negative outcomes for some products, it is also critical that the implications of the guidance on markets, NHS and impact on innovation are considered in the design of methodologies. We are further concerned by the rationale that NICE have put forward for the intentional inconsistency: Determination of greater unmet need for children and young people than adults, despite larger demand gap in adult populations and very similar mode of action across pathways. Comparison in CYP to alternative waitlist interventions is incorrect as the recommendation by NICE includes	Thank you for your comment. The Medical Technologies Advisory Committee (MTAC) is an independent committee that makes recommendations based on evidence on the clinical and cost effectiveness of medical technologies along with clinical expert and patient expert opinion and experience. Each early value assessment (EVA) topic is assessed and considered separately. The committee's considerations vary across topics and these have been outlined in the draft guidance (Section 3). While NICE has sought to explain the committee's considerations, it does not influence the committee's recommendations. Evidence and any uncertainty is considered in the context of which a technology will be used, including financial and clinical risk, as well as factors relevant and important to the user. For example, the 2 mental health topics differ in clinical pathway and service provision, different unmet need, multiple indications and different range of technologies. Guidance recommendations made by the NICE committee are therefore focussed on the use of a technology

				assessment by clinician and guidance, meaning it should not be cons Expert advice that CYP evidence generalisable, but Adult evidence not generalisable, however this advice was given by different people without an explicit comparison made across the topics Assumption that a small number of products recommended in adult space could successfully meet user need, despite clear feedback with NHS that range of products and a positive market to drive innovation needed to support adoptions	in specific scenarios to address an unmet need of the NHS or patients, and may differ across or within disease areas and conditions. Evidence generation plans are also specific to the use of technology in context and so inform industry and the NHS on the evidence needed for that specific use to demonstrate the benefits to patients and the NHS, and ensure clinical and financial risk is managed appropriately. NICE can review guidance when new evidence that could materially affect the recommendations is produced so this guidance approach should not prevent innovation but provide an approach to managing value for money while benefits are assessed during the lifecycle of a new technology.
2	6	Patient representative		These comments are submitted on behalf of a Patient and Public Voice representative who sits on the NHS England Talking Therapies Expert Advisory Group: My first thoughts were that this is long overdue for those for whom it is suitable as obviously, as we all know ‘one size doesn’t fit all’ and not everyone is IT Literate. In the very first paragraph, I was unsure as to whether the further evidence to be generated referred to the Technology, Individuals Needs or both and as this document is for Public Consultation felt this should be clarified.	Thank you for your comment. This EVA guidance is focused on the clinical and cost-effectiveness of digitally enabled therapies and their use in NHS Talking Therapies for anxiety and depression services. The committee concluded that 6 digitally enabled therapies showed enough promise to recommend them as treatment options for adults with anxiety disorders while further evidence is generated. It considered that more evidence on their clinical and cost effectiveness is needed before they can be recommended for

					routine use. We have amended Section 1.1 of the guidance to read: 'Six digitally enabled therapies can be used as treatment options for adults with anxiety disorders while further evidence is generated *on their clinical and cost effectiveness.'*
3	8	Company		About us: [redacted] is a provider of psychological therapy services to the NHS in England and Scotland. We provide primary care treatments for common mental health conditions in adults using a digital text-based interface where a therapist has a 1:1 typed conversation with a patient. Learning from our decade of experience as a digital health provider, we are currently building out digital therapeutics to treat a variety of indications. Overview We welcome the publication of the draft NICE Early Value Assessment (EVA) guidance on digitally enabled therapies (DET) for adults with anxiety. It represents a key step towards (1) making evidence-based treatment more readily available to patients, (2) reducing costs while ensuring valued-based care for more people in need, and (3) making the NHS an attractive location for innovators by enabling national commissioning of DET for anxiety and supporting an integrated marketplace instead of fragmented arrangements within individual ICSs. Based on research conducted by [redacted], there is good reason to believe that providing better access to people in need of psychological therapy will lead to (1) better mental health outcomes (Catarino et al., 2018 https://doi.org/10.1192/bjo.2018.57), (2) lower healthcare costs (Catarino et al., under review), and (3) broader economic savings resulting from keeping people in employment (Layard et al., 2007 https://doi.org/10.1177/0027950107086171).	Thank you for your comment.
4	3	Member of the public	Recommendations (Section 1)	Given that the first objective of the NICE guidance is to help people achieve complete relief (remission) from anxiety disorder and within this document it is stated that the key driver of costs is the clinical effectiveness of each intervention I	Thank you for your comment. This EVA guidance focuses on using digitally enabled therapies for treating anxiety disorders in adults accessing

				can not support any solution, whether digital or otherwise, that implies that CBT is an effective tool that delivers that objective. CBT does not seek to remove anxiety issues but its use encourages sufferers to "manage" or "cope" with their symptoms and thus prolong use of the online products, talking therapies or drugs. Use of CBT within therapy involving humans to deliver it also prolongs suffering in many cases as does the use of drugs. Irrational levels of anxiety are caused by an irrational response to life events, where the subconscious makes an instant decision to protect wellbeing by installing a behaviour (such as OCD, a Phobia, or any other anxiety symptom) which is intended to avoid further contact with the perceived threat. In order to be effective the original experience must be concealed (repressed) and this is why CBT will not be able to result in remission, because it deals with the conscious mind. Only by utilising the subconscious can the reason behind the anxiety be revealed and, provided circumstances have changed, it can be shown to no longer be rational or desirable behaviour. At this point the mind will (again instantly) change the decision and the behaviour, resulting in remission. Putting it very simply, we can cope well with worrying about things we know and understand, it is what we don't know about (consciously) that causes irrational responses. From an adult perspective the things that affected us when young can be seen to be irrational and an adjustment takes place. Caveats are that the initial event must usually have occurred in early life (say 4 to 14 years of age). Anxiety related to events later than this age period may not be suitable for regression but can often be helped with positive suggestion hypnosis but PTSD related to abuse or combat events would not normally be expected to respond well because the experience is too recent and the protective decision may well be rational. The different approach suggested in this paper is therefore probably sensible. For the other anxiety issues the most sensible approach would be Regression using Hypnosis. This should be conducted in person because this situation allows the patient to engage more fully with the process (rather than wonder how they are doing or when it should end) and be more successful. Handled	NHS Talking Therapies for anxiety and depression services. NHS Talking Therapies for anxiety and depression services offer evidence-based psychological interventions in line with NICE guidelines as outlined in Sections 2.2 and 2.3 of the guidance. Health technologies outside of the scope for this EVA can be notified to NICE using the NHS Innovation Service.

				properly the success rate can be very high and the outcome is remission, more quickly and at lower cost than the digital or talking therapy or drug routes - and without negative side-effects. Of course, not all patients will succeed and be removed from the waiting lists and treatment processes but the other options may still be tried. Placing Hypnosis at the earliest intervention point would be better than the current activity. I would like to see GPs encouraged to suggest this to patients even though it requires a relationship with different therapists. I believe that the cost would be lower and the results better when compared against the current overall costs and outcomes of anxiety treatment. I realise that this is not what you want to hear and you will probably ignore me but restricting input to 'digital therapies' is too simplistic. There is a lot more to consider than I should try to cover here but I will add a few comments elsewhere and you can contact me if you wish.	
5	1	NHS England	Recommendations (Section 1.1)	Section 1.1 (Recommendations). Page 3, Line 5 The “NHS Talking Therapies digitally enabled therapies assessment from NHS England “ is mentioned. Please add the weblink so readers of the EVA can access it. The weblink is: https://www.england.nhs.uk/mental-health/adults/nhs-talking-therapies/digital/assessment-criteria/	Thank you for your comment. The link has been added to Section 1.1.
6	1	NHS England	Recommendations (Section 1.2)	1.2 Would recommend also including rates of reliable deterioration and average number of treatment sessions at step 2, step 3 and both (with and without DET)	Thank you for your comment. Section 1.2 of the guidance has been amended to include these outcomes.
7	1	NHS England	Recommendations (Section 1.2)	Section 1.2 (Recommendations). Page 4, line 1 Please insert “and symptom severity” after “baseline data including demographics…” It is essential that any report on outcomes for DETs includes data on the severity of the sample that received the DET. Without this information, it will be impossible to benchmark outcomes against those normally obtained with non-digital therapy in NHS Talking Therapies for Anxiety and Depression services. There is a strong correlation between baseline severity and the probability of a patient	Thank you for your comment. Section 1.2 has been amended to read: ‘baseline data including the demographics *and symptom severity* of the people using the technology and their risk classification.’

				recovering and that relationship needs to be taken into account in any benchmarking.	
Potential benefits and risks (n=6 comments)					
8	6	Patient representative		Also I had concerns around Digital Technologies actually exacerbating the condition it could be used to help. This would be around the flexibility of the Technology as from past experience, you can sometimes be taken down unwanted paths just to move on and of course the level of Therapist Support and this being tailored to individuals. I noted that Perspectives (Koa Health) had included Suicide Hotline Information and would like to see this as a given for all interested/considered companies.	Thank you for your comment. The committee carefully considered the safety of using these technologies in NHS Talking Therapies for anxiety and depression services and the level of support needed. All digitally enabled therapies should be used with the support of an appropriately trained mental health professional and in line with local safety protocols. This means if the treatment is not working and symptoms worsen, it can be identified quickly (see Sections 3.2 and 3.3 of the guidance). The committee also recommended that further evidence should include outcomes related to adverse effects, escalation of care and patient experiences (Section 1.2). This will help generate more evidence on this important consideration and inform the routine adoption of these technologies across the NHS.
9	6	Patient representative		There was reference made to Digital Therapies being a good service for people experiencing problems with leaving the home! In the short term maybe, but again I had concerns of Digital Therapies exacerbating this condition. I didn't see any mention of a triage prior to Digital Therapies being seen as suitable for individuals, but assuming this is the case, I had concerns around the responsibility put on the Therapist conducting the triage and making the decision and any support or guidance for them around this?	Thank you for your comment. Digitally enabled therapies may not be suitable for everyone. All treatment options should be discussed by healthcare professionals and patients before deciding on the most appropriate care (see Section 3.6 of the guidance). Digitally enabled therapies will be used with established protocols in NHS Talking

				Depending on the format of the Digital Therapy, could there be scope for the user to be influenced in their answers by others?	Therapies for anxiety and depression services. This includes initial clinical assessment and triaging to match the right treatment to people's needs and preferences, and ongoing monitoring and management of patient safety (Section 3.3). Section 3.5 has been amended to include more information on support for therapists: 'Practitioners and therapists need training and support to effectively deliver digitally enabled therapies. *Healthcare professionals working in NHS Talking Therapies for anxiety and depression have ongoing supervision to ensure the quality of treatment and to provide support to practitioners and therapists in the delivery of assessments and treatment*.' Section 3.7 has been amended to read: 'Patient experts said that appropriate privacy and security measures should be in place to reassure people using the technology. People would also need to be told about any additional support measures in place, especially when the technology is used outside of working hours. *People should discuss any concerns with using digitally enabled therapies with their practitioner or therapist before starting treatment*.'
10	1	NHS England	Recommendations (Box on potential benefits and risks)	Box on the benefits and risks of DETs (page 5) Please change the two high level titles for this box. We suggest changing "Potential benefits of early access" to	Thank you for your comment.

				"Potential benefits of digitally enabled therapies" and changing "Managing the risk of early access" to "Managing the risk of digitally enabled therapies". The text below the titles does not need to be changed. The change of titles is required because treatment with DETs will NOT start earlier than the equivalent non-digital treatment. DETs may require less therapist time and therefore could help services see more people with a given workforce. This is likely to reduce overall wait times for the service. However, patients will still have to wait for a free therapist slot to start with a DET, just as they do with telephone, video, or in-person therapy delivery. Services are not going to tell their therapists to allocate therapy slots, so people get seen quicker if they opt for digital delivery and slower if they opt for some other modality of treatment delivery. That would be discriminatory and would deprive patients of genuine choice about the modality of their treatment. NHS England is concerned that the EVA panel have not understood this point. While observing the public section of the 17th February Panel Meeting we noted that several panel members seemed to incorrectly assume that opting for a DET would result in earlier treatment. When speaking about DETs [redacted] a panel member [redacted] incorrectly stated that patients would be given the choice between being treated quickly with a DET or having to wait longer for a non-digital therapy. It is essential that the final NICE document does contain any such suggestion.	The use of 'early access' in the guidance reflects the aim of EVA to get promising technologies into the NHS quicker than full guidance. For clarity, the headings in the Benefits and Risk box (Section 1) have been amended to read 'Potential benefits of early *value assessment*' and 'Managing the risk of early *value assessment'*.
11	1	NHS England	Recommendations (Box on potential benefits and risks)	Box with managing the risks, resources bullet "This could reduce demand on some mental health services…" implies people with DETs won't be treated by the services, which isn't the intention. Could we amend to "This could free up resources that could be allocated elsewhere in the services to increase access or reduce waiting times."	Thank you for your comment. This section has been amended to better describe the potential benefits.
12	1	NHS England	Recommendations (Box on potential benefits and risks)	Box with managing the risks, care pathway bullet	Thank you for your comment.

				‘This guidance focuses on using digitally enabled therapies for treating anxiety in adults who have been referred to NHS Talking Therapies.’ Can we say ‘This guidance focuses on using digitally enabled therapies for treating anxiety in adults accessing NHS Talking Therapies.’ This then covers self-referral.	This section has been amended to better capture all methods of referral.
13	3	Member of the public	Recommendations (Box on potential benefits and risks)	As far as I can tell there is no mention of Hypnosis and Regression other than to enable 'progressive muscular relaxation training'. Patients are not being offered this potentially significant option.	Thank you for your comment. Please see response to comment 4 on the scope of this EVA guidance. The EVA guidance recommends 6 digitally enabled therapies as treatment options for adults with anxiety disorders while further evidence is generated. People should be offered a choice of treatments in line with their individual needs and clinical assessment.
Technology (n=4 comments)					
14	1	NHS England	Technologies (Section 2.1)	Section 2.1 Also add overview per product or as an overview other use cases and functionalities for products not considered in this guidance.	Thank you for your comment. The scope for this assessment outlines the criteria for technologies to be included in this EVA. Section 2.1 provides a brief overview of all technologies that were found to be in scope for this assessment. Section 2.1 of the guidance has been amended with a link to the scope: ‘NICE has assessed 11 digitally enabled therapies as an option for treating anxiety disorders in adults while evidence is generated. *The criteria for including technologies in this early value assessment (EVA) are in the in the topic scope on the NICE website*.’
15	1	NHS England	Technologies (Section 2.1)	2.1 Technologies	Thank you for your comment.

				'They are delivered with support from a trained practitioner in NHS Talking Therapies Services who facilitates the self-help intervention, encourages completion, and reviews progress and outcomes'. Can we add 'recommends complementary material' (or similar) after 'encourages completion so it reads: They are delivered with support from a trained practitioner in NHS Talking Therapies Services who facilitates the self-help intervention, encourages completion, recommends complementary material, and reviews progress and outcomes'.	This sentence does not appear in this section of the draft guidance. No change has been made.
16	2	Company	Technologies (Section 2.1)	Please mention that iCT-SAD administers all the IAPT recommended outcome measures for SAD (SPIN, GAD-7, PHQ-9 & WSAS) and exports them into the IT system of local services.	Thank you for your comment. The technology description for iCT-SAD in Section 2.1 has been amended as follows: '*It administers all outcome measures for social anxiety disorder recommended in NHS Talking Therapies in anxiety and depression services and exports them to local services' IT systems*.'
17	2	Company	Technologies (Section 2.1)	Please add memory and meaning- focused techniques to the description of the programme as these are the heart of the intervention and are what one would expect to see from a programme that is delivering NICE recommended trauma-focused CBT for PTSD. Please also mention that iCT-PTSD administers all the IAPT recommended outcome measures for PTSD (PCL-5, GAD-7, PHQ-9 & WSAS) and exports them into the IT system of local services.	Thank you for your comment. This has been added to the technology description for iCT-PTSD in Section 2.1 as follows: 'It includes modules with *memory and meaning-focused techniques*, psychoeducation, case examples, monitoring sheets, videos, behavioural experiments and assignments. *It also administers all outcome measures for PTSD recommended in NHS Talking Therapies in anxiety and depression services and exports them to local services' IT systems*.'
Care pathway and clinical need (n=4 comments)					
18	6	Patient representative		Another concern I have and always do around Anxiety and Depression is the language used and the inference it creates	Thank you for your comment.

				and in particular when they are referred to as ‘Mild to Moderate’. I see and hear this a lot, not just in this document but in the Mental Health Environment in general and to me it has made these conditions seem less serious that others. Surely any Mental Health condition carries the severity it has on the individual?	It is important the language used in the guidance aligns with patient preferences of how their experiences are described. We have limited the use of ‘mild to moderate’ in the guidance to the technology descriptions in Section 2.1 which describe the indications for use provided by the companies.
19	3	Member of the public	Comparator (Section 2.2)	With the exception of PTSD all these approaches seek to use CBT to help patients manage their problem. The concept that reminding people that they have a problem that they can not solve is more likely to aggravate things. It is like painting over the mould on your wall rather than fixing the leak in the roof. The source of the emotional response must be exposed and resolved in order to prevent repetition. An additional worry with the mould analogy is that the paint manufacturer would love people to believe that the paint is the solution. Ref BDD I assume you are familiar with "Ugly Me". We watched a patient go through a failed process, even meeting with another who it was claimed had recovered but clearly had not. If you are able to contact her I am confident that she will still be suffering, her relationship will have ended and she will have been prescribed drugs. In recent years a long list of celebrities have publicised their anxiety problems and most of those that have had the usual therapy show it to have failed. My observation of these cases is that most would be resolved with between 1 and 6 sessions of Regression Hypnotherapy and they would be living more fully now.	Thank you for your comment. Please see response to comment 4.
20	1	NHS England	Comparator (Section 2.3)	Section 2.3 (Comparator). Pages 9 & 10, third and seventh bullet points in section 2.3. This section summarizes the standard care options that are available in NHS Talking Therapies services for different clinical conditions. The statements about the treatment of Health Anxiety (bullet point 3) and Social Anxiety Disorder (bullet point 7) are not entirely accurate and should be corrected.	Thank you for your comment. Section 2.3 has been amended to reflect the treatment of these disorders in NHS Talking Therapies for anxiety and depression. The changes are as follows: ‘Health anxiety: *high intensity CBT for health anxiety*’

				Health Anxiety: it is stated that “the NHS recommends self-help programmes”. Actually, the main treatment for health anxiety in NHS Talking Therapies services is a particular type of high intensity CBT. All high intensity CBT therapists are expected to have developed competence in delivering this treatment by the time they have completed their training (see pages 24 and 25 of the National Curriculum for High intensity Cognitive Behavioural Therapy Courses, 4th edition. Available at https://www.hee.nhs.uk/our-work/mental-health/improving-access-psychological-therapies) Social Anxiety: the standard therapies are listed as “ high intensity psychological interventions include individual CBT for social anxiety disorder, CBT-based supported self-help, or short-term psychodynamic psychotherapy”. This is also not quite correct. Please amend to reflect NICE guidance and the NHS Talking Therapies Manual more accurately. The social anxiety NICE guideline (CG159) recommends high intensity individual CBT (based in the Clark and Wells model or the Heimberg model) as the first-choice treatment with the other interventions only being offered if individual CBT is declined. In contrast with depression and many other anxiety disorders, stepped care is not recommended (see the NHS Talking Therapies Manual, Table 2).	‘Social anxiety disorder: high intensity individual CBT for social anxiety disorder *(based on the Clark and Wells model or the Heimberg model) as first-line treatment*. CBT-based supported self-help or short-term psychodynamic psychotherapy *may be offered if individual CBT is declined.*’
21	1	NHS England	Unmet need (Sections 3.1 and 3.2)	3.1 and 3.2 Unmet need This reads as if DET is a way of reducing treatment waits and system pressures rather than a way of delivering therapy via methods that may be more suited to certain patients. I don’t think this will help clinician ‘buy in’ to the effectiveness of DET. 3.2 also refers to those who need more ‘personalised’ care which suggests that application of DET isn’t personalised (which shouldn’t be the case). Again, I’m unsure this will enhance clinician buy in (many see DET as a bronze treatment offer). Please can we reframe to better reflect the impact on access and waits and position benefits around being a more appropriate therapy option for some people.	Thank you for your comment. It is important that our guidance supports the use and implementation of the recommended technologies and ‘buy in’ from patients and healthcare professionals. We have amended Section 3.1 to better describe the potential of digitally enabled therapies to address the unmet need and to remove any suggestion that digitally enabled therapies are not personalised. The changes are as follows:

					'*Some people may prefer digitally enabled therapies over other treatment options in standard care*. Digitally enabled therapies may especially benefit people who are socially anxious or are unable to leave home for treatment. They may reduce the time needed by mental health professionals to deliver treatment, which could free up clinical resources *that could be allocated elsewhere in the services to increase access or reduce waiting times*.'
Clinical evidence (n=3 comments)					
22	7	Company		With regard to the consultation question 'has all the relevant evidence been considered', we understand the position the committee took in only considering research data and RCTs occurring within the UK, as NICE is recommending products for use within the UK. As a global company with the app in use in tens of countries, we feel the evidence base we are generating across multiple different countries would add to the evidence base locally in terms of our ability to serve different communities and equality cohorts across the UK. We have submitted similar evidence to the MHRA which has been accepted. We would ask for future reviews of evidence for NICE to consider evidence generated in the USA or elsewhere in settings where the academic rigour around the studies is of a high enough standard to be acceptable for institutions such as the FDA etc.	Thank you for your comment. The assessment and committee considerations were not limited to research data and randomised controlled trials in the UK as shown in Table 5 of the external assessment report (EAR) which includes a range of study designs and locations. In order to capture relevant evidence for the assessment, the external assessment group (EAG) used the following exclusion criteria (outlined in Appendix B of the EAR): 'Where a technology had evidence available, the decision to include a study was based on criteria such as outcomes, comparators, sample size and setting. Studies were excluded if the outcomes were not relevant to the scope regardless of whether there was any alternative evidence. For technologies where the outcomes were relevant, inclusion

					was based on meeting one of the following criteria • Comparator relevant to the scope • Sample size <100 • Conducted in UK / IAPT service' Studies were therefore only excluded if they did not meet any of these criteria and there was other evidence on the technology. Only 1 study (Thew 2022 on iCT-SAD) was excluded because it was not a UK study and also lacked a relevant comparator with a sample size less than 100. Please see Appendix B and addendum of the EAR for more information on excluded studies.
23	8	Company		Comments to the committee questions This draft EVA guidance on digitally enabled therapies for adults with anxiety is informed by a robust analysis on the 11 digital health technologies under scrutiny. The relevant evidence has been considered based on the scope of the evaluation and its interpretations are reasonable. As such, the recommendations are a suitable basis for EVA guidance to the NHS. Moreover, equality issues have been adequately considered.	Thank you for your comment.
24	3	Member of the public	Clinical effectiveness (Section 3.9)	The analysis completed for this report was comprehensive and shows that there is very little reliable evidence that therapy based on CBT is effective. As I stated earlier, CBT is focused on conscious behaviour but serious anxiety problems involve subconscious activity so it is simple to see that the solution must involve the subconscious mind. Until this is accepted and changes implemented the problems of treatment availability and cost will only worsen.	Thank you for your comment. The EAR concluded that the clinical evidence suggests digitally enabled therapies can reduce anxiety symptoms and that reductions can persist up to 12 months post treatment. There was limited comparative evidence but this showed that the reduction in anxiety symptoms was larger in those using digitally enabled therapies compared

					with waitlist controls or usual care. The committee concluded that 6 digitally enabled therapies showed enough promise to be used as treatment options for adults with anxiety disorders while further evidence is generated on their clinical and cost effectiveness.
Costs and resource use (n=2 comments)					
25	1	NHS England	Costs and resource use (Section 3.13)	Section 3.11: Costs and resource use Could more be said about what cost and resource implications were considered in the analysis for the digital and for the comparator treatments? For example license costs and therapist time. Aware this is detailed further in the evidence reports but this section will often be read without reference to that and costs are important considerations for commissioners.	Thank you for your comment. We have added the following to Section 3.14 (previously Section 3.13) for ease of reference: '*The EAG's model included estimated technology licence costs in the digitally enabled therapies arm, healthcare professional costs based on staff grade and time needed to deliver the intervention, and the clinical effectiveness of the interventions*. *The assumptions used in the model are outlined in Tables 15 and 17 of the assessment report.* The EAG noted that a main driver of the model was the clinical effectiveness of the technologies.'
26	2	Company	Costs and resource use (Section 3.12)	There seems to be an error in the statement about cost effectiveness for DETs that focus on social anxiety disorder. It is stated that iCT-SAD, Minddistrict and Silvercloud could all be cost effective. However, as stated in section 3.10 there is no data on the effectiveness of either Minddistrict or Silvercloud in social anxiety, so it makes no sense to make a statement about their cost effectiveness. This principle is clearly stated on page 5 of the External Assessor Report and needs to be carried through to this document. In contrast to Minddistrict and Silvercloud, there is evidence that iCT-SAD is cost effective. In particular, the Clark et al (2022) RCT included in the evidence review found that non-	Thank you for your comment. EVA guidance assesses promising health technologies that have the potential to address national unmet need. It is expected that they technologies may have early or emerging evidence on their clinical and cost effectiveness. The EAG therefore utilised other forms of data and evidence for technologies that did not have relevant published evidence in the specified indication.

				digital therapy required 2.45 times more therapist time to achieve the same outcomes with IAPT patients as the digital therapy.	The EAG estimated the possible net monetary benefit of Minddistrict using information from the company submission. This reported a 72% recovery rate based on data from 2 IAPT providers (see Table 16, p. 94 of the external assessment report). The EAG acknowledged the limitations of this data and advised that it should be treated with additional caution. The EAG estimated the possible net monetary benefit of SilverCloud using recovery rate from Richards et al. 2020 which had a heterogenous population of people with anxiety and depression. We have included a summary of this in Section 3.13 as follows: '*There was no published evidence on Minddistrict or SilverCloud for treating social anxiety disorder. The EAG estimated the possible cost effectiveness of Minddistrict for this indication using unpublished data from 2 NHS Talking Therapies for anxiety and depression services. The cost modelling for SilverCloud used clinical effectiveness from a study by Richards et al. 2020, which included a heterogenous population of people with anxiety and depression.* There was not enough evidence on the efficacy of Cerina, Iona Mind, Resony and Wysa to model their cost effectiveness.'
Implementation and patient considerations (n=4 comments)					

27	1	NHS England		Generally, the anxiety paper reads better than the depression paper as it provides more detail/context behind its recommendations – particularly in the 'unmet need', 'implementation' and 'patient considerations' sections.	Thank you for your comment.
28	6	Patient representative		Obviously we must remain Patient Centric and Cost Effectiveness must not be the first consideration.	Thank you for your comment. The committee considered the clinical and cost effectiveness of digitally enabled therapies as well as patient experiences and concerns, and adoption considerations. The committee for this topic included 4 specialist committee members with lived experience of anxiety and depression. This sought to ensure that patient experiences and opinions were heard throughout the assessment and reflected in the EVA guidance (Sections 3.1, 3.6, 3.7).
29	8	Company		Patients and clinicians need to be at the heart of DET development and deployment As highlighted in the draft EVA guidelines, it is crucial that patients are at the heart of digital mental health provision. Patient, clinician and wider public trust is fundamental to promoting adoption of DETs, engagement with treatment, and ultimately recovery. We must ensure that patients are informed and empowered to choose the right treatment for them and that they can trust that they are safe while using DETs, with human support available at the point of need. While the adoption report highlighted the challenge of gaining clinicians' confidence in DETs (see pg. 257 of the supporting documentation), this point is not fully addressed in the draft EVA guidelines. Rather, these focused more on support and training, and the need for clinicians to be 'comfortable using the technology'. While these are very important considerations, we believe that building trust in DETs amongst clinicians is integral to ensuring their wide adoption (and therefore improved outcomes), and separable to competency	Thank you for your comment. The committee carefully considered many factors that could impact the implementation of digitally enabled therapies, including patient and clinician confidence and trust in the technologies. We have added the following to Section 3.5 of the guidance and also referenced the supporting adoption report: 'Technologies should be integrated into a service's system rather than being a standalone technology. This would help with data collection and reporting. *It is also important for healthcare professionals to have confidence in the effectiveness of digitally enabled therapies compared with other treatment options. This can be strengthened by developing*

				and skillset factors. The draft EVA guidelines should recognise this implementation challenge and innovators should proactively address it. For example, at [redacted], we involve our two key user groups, experts by lived experience and clinicians, in shaping our research and digital product development to ensure we are approaching and disseminating our work in a responsible way that understands and responds to their needs, perceptions and concerns.	*and maintaining robust quality assurance process. There is more information on implementing digitally enabled therapies in the adoption report on the NICE website*.'
30	5	Member of the public	Patient considerations (Section 3.6)	It is important that even though this is a digital technology that the patient feels they are being treated as an individual with feedback from the Therapist showing this and not just a cut and paste exercise. The requirement to say what you actually mean rather what is what you want the therapist or computer to hear is far more important than thinking that that if you answer correctly the emotion will automatically follow	Thank you for your comment. The committee considered the experiences of people with anxiety and the importance of patient choice and empowerment. It also highlighted the importance of capturing patient experiences during further evidence generation. This will be considered by the NICE data and analytics team who is developing an evidence generation plan based on the guidance.
Equality considerations (n=1 comment)					
31	4	Company	Equality considerations (Section 3.9)	Literal translation might not suffice in terms of making these interventions relevant and acceptable to culturally and linguistically diverse populations. The emotional content and cultural meaning attributed to the conditions and/or expression of the symptoms should be taken into consideration. Recently, Heim and colleagues (see Heim E, Mewes R, Abi Ramia J, Glaesmer H, Hall B, Harper Shehadeh M, Ünlü B, Kananian S, Kohrt BA, Lechner-Meichsner F, Lotzin A, Moro MR, Radjack R, Salamanca-Sanabria A, Singla DR, Starck A, Sturm G, Tol W, Weise C, Knaevelsrud C. Reporting Cultural Adaptation in Psychological Trials - The RECAPT criteria. Clin Psychol Eur. 2021 Nov 23;3(Spec Issue):e6351. doi: 10.32872/cpe.6351. PMID: 36405678; PMCID: PMC9670826.) proposed a framework (RECAPT criteria) for the cultural adaptation of psychological interventions. This is an important point in terms	Thank you for your comment. NICE is committed to reducing health inequalities and eliminating unlawful discrimination. The committee carefully considered equality issues and considerations for this topic and values the input of stakeholders in ensuring these have been adequately captured. We have added this consideration for cultural adaptation of digitally enabled therapies to Section 3.9 of the guidance as follows: '*Companies should also consider how to adapt their technologies to be*

				of inclusivity and representativeness of the digitally enabled therapies.	*inclusive of all cultures and suitable for use in diverse populations*.'
Evidence generation (n=8 comments)					
32	1	NHS England		The three year review window does not seem appropriate for pace of product development and research, especially if there is not a consistent approach and clear expectation for review. With guidance that is potentially limiting for some products in the market, it is even more important that we get this right first time, as the current approach specifies a 3 year period for evidence review. A number of the products reviewed have live RCT studies, which will not be considered until the end of the three years, creating potentially substantial barriers to being commissioned for what is a very extended period for companies of this nature. Alternatively a rolling research review could be considered to allow updates to research to be made.	Thank you for your comment. The EVA interim statement states that evidence generation should be for the shortest time necessary to collect the data needed to sufficiently resolve uncertainties in the evidence. The 3-year evidence generation period aims to provide enough time for all companies in the assessment to generate relevant evidence before the topic is considered for multiple technology guidance.
33	6	Public representative		Apart from the obvious times we are currently living in I would also like to have seen some research data around the high demand for Mental Health Services – a tackling of the cause rather than the resultant symptoms as always or so it seems.	Thank you for your comment. This EVA guidance is focused on the clinical and cost effectiveness of digitally enabled therapies and their use in NHS Talking Therapies for anxiety and depression. NICE welcomes any research which increases our understanding of mental health conditions, their causes and unmet needs but this is outside of the scope of this EVA.
34	6	Patient representative		Finally, in time it would be great to see data of Digital Technologies Outcomes for those who had not sought or accessed face to face Talking Therapies before.	Thank you for your comment. The NICE data and analytics team is developing an evidence generation plan based on the guidance and will take this into consideration when selecting appropriate outcomes.
35	7	Company		We would like to understand the offer of ongoing support from NICE following the recommendations and to ask whether NICE would consider broadening that scope. Our understanding is that only the products recommended for treatment will enjoy NICE's further support in evidence generation. However, we	Thank you for your comment. A research only recommendation is made when the committee are uncertain if the technology has the

				would argue that products that haven't already reached that threshold, but have been recommended for research might benefit the market more if they were also supported by NICE to generate the requisite evidence to become a product recommended for therapy. Could this support offer be reconsidered?	potential to solve the unmet need. In this instance a research only recommendation was made as the committee felt that there was currently not enough clinical evidence on the indicated population to determine if the technology would provide benefit. The EAR provides an overview of the evidence gaps to help with further evidence generation for all the technologies. Please see the interim process and methods for Early Value Assessment for further information.
36	7	Company		It is our understanding from the feedback EVA session that the recommendations won't be re-reviewed for a minimum period of 3 years. We would strongly urge NICE to consider a different review mechanism than temporal (every 3 years) for the EVA review and instead set the burden of evidence for a quantitatively assessed review threshold. When we entered into the EVA process, to the best of our understanding and from the documents shared with us at the time, we were not aware of a 3 year review cycle. The market will struggle to operate like this as it disincentives companies from accepting to undertake EVA, as they enter effectively an additional 3 year evidence gathering cycle which wasn't in place before. It is our expectation that in advance of 3 years, we will have generated enough evidence from research that NICE would possibly consider us a recommended therapy. We currently have multiple RCTs which are due to end in 2023/24 in the UK as an example. If companies remain labelled as a status of 'for research only for 3 years', as an SME, revenue generation will be difficult as effectively the recommendation could act as an inhibitor to trade and revenue generation. We ask that NICE reconsider this periodic review and offer an earlier review period in order that businesses are profitable enough to go the distance. As an example, the EVA recommended for therapy products have been trading in the UK for many years prior to the introduction of the NICE EVA. Their trade has not been restricted by the NICE EVA process or their status. We would	Thank you for your comment. The EVA interim statement states that evidence generation should be for the shortest time necessary to collect the data needed to sufficiently resolve uncertainties in the evidence. The 3-year evidence generation period aims to provide enough time for all companies in the assessment to generate relevant evidence before the topic is considered for multiple technology guidance.

				ask to be treated with the same opportunities as these predecessor products	
37	8	Company		Opportunity for innovation – Moving beyond improving treatment access to improving treatment effectiveness The NICE EVA process, combined with the NHS proposed Digital health Tech Pathway, is designed to address unmet needs within the NHS, accelerating access to scalable technologies that are beneficial to patients. While access to mental healthcare is a recognised issue, it does not fully solve the challenge of improving recovery rates within the NHS Talking Therapies service (formerly known as IAPT), which have remained stagnant at around 50% over the last 6 years (Psychological Therapies, Reports on the use of IAPT services, NHS Digital) Session-by-session monitoring of outcomes, combined with evidence-based treatment, has been central to the success of the NHS Talking Therapies service and has enabled improvements in treatment quality and recovery rates over the past decade (from mid-30% to around 50%). Operating within this system, with EVA-recommended DETs offer a unique opportunity to scale a data-led approach to treatment to (1) improve the accessibility of mental healthcare, and (2) drive innovations in mental health research and development that deliver more effective treatments and higher recovery rates. At [redacted], we are taking a data-led approach to improve treatment effectiveness by interrogating patient outcome data in combination with treatment variables to understand which specific elements of psychological therapy work best for particular patients, in which contexts and why. Specifically, based on our globally-unique dataset of outcomes-indexed transcripts (collected, with permission, following more than 600, 000 hours of human-to-human typed therapy), we have developed AI-based tools to automatically annotate 100% of therapy delivered (Cummins et al., 2019 https://doi.org/10.1145/3308558.3314128). By monitoring session-by-session patient outcomes, and analysing how they	Thank you for your comment. This EVA aims to improve access to effective evidence-based interventions for adults with anxiety disorders. Digitally enabled therapies show promise in not only providing more flexible access to care but supporting personalised treatment. The NICE data and analytics team is developing an evidence generation plan based on the guidance and will take this into consideration when selecting outcomes and methods related to adoption and implementation and its impact on clinical and cost effectiveness.

				relate to precise elements of psychological therapy, we have started to pinpoint the 'active ingredients' of therapy (Ewbank et al., 2020, https://doi.org/10.1001/jamapsychiatry.2019.2664 ; Bateup et al., 2020 https://doi.org/10.1017/S1754470X20000252). By applying these insights, we will be able to adopt a precision medicine approach to mental healthcare that will enable us to treat more people faster and more effectively. By scaling treatment delivery to larger and more diverse populations, DETs offer the opportunity to enhance a real-world, data-led approach to mental health research and innovation that will improve recovery rates for more people. It is paramount that such innovation is conducted responsibly by maximising patient benefit and minimising harm at all times.	
38	3	Member of the public	Implementation (Section 3.2)	Whilst I agree that efficacy data is essential to assess treatment quality the current systems give me cause for concern. Most of what I am aware of elicits subjective opinion about whether the patient is feeling better or not at various stages of interaction with therapy. This can come from the patient and could be affected by their mood on the day, their desire to stay in the programme, their desire to escape the programme, their wish to please the therapist, the way the therapist reacts to their scores, the fact that they feel they are marking their own performance, etc. The surveys are linked to the patient and run by the therapy provider so anonymity and question design can influence results. In addition there is probably a significant placebo effect due to simply getting some attention. Results are very sketchy and unreliable, as shown by the analysis contained in the report. One fundamental issue is the definition of success. I regard success to be the complete remission of the anxiety symptoms but the existing measure counts a claimed improvement as success, whilst I count this as a measure of failure because it tends to keep patients in therapy for too long. The detailed measures should not be about feelings or perceptions but on the frequency of actual events, such as panic attacks, flight from a situation, OCD experiences, phobic	Thank you for your comment. The NICE data and analytics team is developing an evidence generation plan based on the guidance and will take this into consideration when selecting appropriate outcome measures and methods of data collection.

				attacks and so on. Maintaining a simple diary of treatment and symptom activity would reliably reveal what works. Such a diary could be digital if possible. Results or progress should not be seen by the patient except at meetings with the therapist in order to ensure an impartial current measure.	
39	1	NHS England	Further evidence (Section 4)	Section 4 This section should acknowledge that some products recommended only for research may develop more within the next year, in advance of the next NICE review. Any additional evidence may want to be considered alongside the NICE guidance by NHS organisations making commissioning decisions.	Thank you for your comment. We encourage further research and new evidence on digitally enabled therapies. The research only recommendations made by NICE do not prevent the use of these technologies in the NHS but use should be within a formal research setting.
Corrections (n=3 comments)					
40	1	NHS England		Please can we refer to 'NHS Talking Therapies for anxiety and depression' rather than 'NHS Talking Therapies' throughout.	Thank you for your comment. This has been amended throughout.
41	1	NHS England	Section 1	Box on benefits and risks (page 5) Typo under clinical assessment. Should say "assess patient safety" not access.	Thank you for your comment. This has been amended.
42	1	NHS England	Recommendations (Box on potential benefits and risks)	Box with managing the risks, access bullet Can we be more specific with workforce – instead of "supported by psychological wellbeing practitioners of therapists" can we replace with "supported by appropriately trained NHS Talking Therapies Clinicians, including Psychological Wellbeing Practitioners."	Thank you for your comment. This sentence does not appear to be in this section of the draft guidance. No change has been made.
Supporting documents (n=4 comments)					
43	2	Company	NA – supporting documents	We are concerned about inconsistencies in statements about iCT-SAD and iCT-PTSD in the Assessment Report that forms part of the Supporting Documentation. For example, the Clark et al (2022) RCT of ICT-SAD versus the first line recommended non-digital treatment for IAPT (CT-SAD) is sometimes correctly described as showing that digital therapy is as effective as the best non-digital comparator and	Thank you for your comment. The EAG has clarified that Table 5 of the assessment report relates specifically to whether the comparators are relevant to the scope. The amber marking for this trial indicates they are not completely

				sometimes is marked as Amber (see Table 5 on page 36) or as RED (see Table 31, page 105) because it is incorrectly reported as not involving a comparison with IAPT non-digital treatment. Also Table 14 (Economic Studies) says that the report we provided on an RCT comparing iCT-PTSD with an equally credible control internet therapy (iStress) was blinded data. That is not correct. We did tell NICE that group A was iCT-PTSD and Group B was iStress. The cost-effectiveness analysis favoured iCT-PTSD. The QALYs associated with iCT-PTSD in table 22 are incorrect. The value for iCT-PTSD is 0.77, not 0.74	relevant because waitlist control was not in the scope. Table 31 looks specifically at the fact that while there is evidence for iCT-SAD, it has not been generated within the IAPT setting. The EAG acknowledges that this might be confusing and with NICE will be looking at the report template to improve clarity for future EVAs. While the unpublished economic report included blinded groups, these were later defined by the company. The study did show iCT-PTSD to be more cost-effective than the comparator intervention. This is stated in section 9.5 of the assessment report but was redacted as the paper was submitted as academic in confidence. The EAG have confirmed that the utilities reported in table 22 are correct and are based on the economic model. The economic model uses standard utility values based on mild/ moderate/severe/ no symptoms health states, and the utility for each technology is calculated based on clinical effectiveness and the pathways through the model structure.
44	4	Company	NA – supporting documents	On behalf of Cerina, I would like to give compliments on the comprehensive work synthesising the existing evidence for the effectiveness and cost-effectiveness of digital interventions for anxiety disorders. The guidance is also very informative in terms of the future use of these technologies within the IAPT pathway. Cerina will certainly work towards implementing the suggestions in future studies.	Thank you for your comment. The EAR included results relating to generalised anxiety which were submitted by the company. The EAG said that these were not detailed results so only limited information

				Please see below for the comments on the missing information in the final draft report: 1. Cerina`s missing reported results on their CBT-based mobile application on OCD 2. Missing reported results on Cerina`s intermediate outcomes: Acceptability and usage on table 33, page 109 3. Missing reported results on Cerina`s clinical outcome: Symptom severity on table 33, page 109	could be included in the assessment report. It noted that this made it difficult to include this information in the gap analysis section of the report.
45	4	Company	NA – supporting document	Cerina provided unpublished evidence for OCD. This evidence is not included in the final report.	Thank you for your comment. The EAG acknowledged that Cerina provided a study protocol and results for a small study for use in OCD which was not included in the EAR. This study was discussed in the EAR addendum (see supporting documents).
46	4	Company	NA – supporting document	• Cerina has an application for OCD and we have submitted the initial results for the feasibility and the likely effects of the application for the consideration of the NICE EVA report. We noticed that these studies were not mentioned in the final report. It would be helpful to learn the reasons for not including this evidence. • We have investigated the intermediate outcomes (acceptability and usage) and the symptom reduction of Cerina`s application for GAD. However, on table 33 page 109, the report says that we did not investigate those. • Lastly, we did submit the study protocol for our pilot RCT for testing the feasibility and the likely effects of Cerina in reducing generalized anxiety symptoms among University students at Ulster. We noticed that this was not included as an ongoing study. Is this because the study is seen as being conducted in a university setting rather than in a clinical context? If so, this is a misapprehension as the study focuses on students with mild to moderate generalised anxiety symptoms (measured by GAD7).	Thank you for your comment. Please see responses to comments 44 and 45. The University based study was excluded because the EAG considered the study design was not reflective of how digital technologies would be used within the IAPT setting. This is because: • recruitment was online / e-mail / social media • waitlist control as a comparator was not within the scope of the EVA • participants on waitlist were supported by Student Wellbeing services and had the capacity to contact their GP which may result in a referral to services.

					For information, the EAG has provided the following summary: The study will use IAPT approved questionnaires (GAD-7, PHQ-9) to measure anxiety and semi structured interviews with participants will explore usability. The potential gaps the study may address will include app usability / user experience; adherence to digital programme; response rates to questionnaires. The EAG acknowledges that this study will be a useful addition to the knowledge base however and look forward to the findings.