

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Early value assessment guidance consultation document

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

Early value assessment (EVA) guidance rapidly provides recommendations on promising health technologies that have the potential to address national unmet need. NICE has assessed early evidence on these technologies to determine if earlier patient and system access in the NHS is appropriate while further evidence is generated.

The medical technology advisory committee has considered the evidence and the views of clinical and patient experts. This topic is one of the pilots using the new EVA approach. EVA guidance recommendations are conditional while more evidence is generated to address uncertainty in their evidence base. Although there are uncertainties, they do not suggest a risk to patient safety. NICE has included advice in this guidance on how to minimise any clinical or system risk of early access to treatment.

Further evidence will be generated within the next 3 years to assess if the benefits of these technologies are realised in practice. NICE guidance will be reviewed to include this evidence and any new research and make a recommendation on the routine adoption of these technologies across the NHS.

**This document has been prepared for public consultation.** It summarises the evidence and views that have been considered and sets out the evidence generation recommendations made by the committee. NICE invites comments from registered stakeholders, healthcare professionals and the public. This document should be read along with the [evidence for this EVA](#) (an EVA report, cost and resource use report).

The advisory committee is interested in receiving comments on the following:

- Has all the relevant evidence been considered?

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- Are the summaries of clinical effectiveness, costs and resource use reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for EVA guidance to the NHS?

## **Equality issues**

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the recommendations may need changing to meet these aims. In particular, please tell us if the recommendations:

- could have a different effect on people protected by the equality legislation than on the wider population, for example by making it more difficult in practice for a specific group to access the technology
- could have any adverse effect on people with a particular disability or disabilities.

Please provide any relevant information or data you have about such effects and how they could be avoided or reduced.

**Note that this document is not NICE's final guidance on digitally enabled therapies for adults with anxiety disorders. The conditional recommendations in section 1 and the accompanying points on evidence generation in section 4 may change after consultation.**

After consultation, NICE will consider the comments received. The final recommendations will be the basis for NICE's EVA guidance on using the technologies with evidence generation.

## **Key dates:**

Closing date for comments: **15 March 2023**

# 1 Recommendations

1.1 Six digitally enabled therapies can be used as treatment options for adults with anxiety disorders while further evidence is generated. These technologies can be used once they have Digital Technology Assessment Criteria (DTAC) approval and NHS Talking Therapies digitally enabled therapies assessment from NHS England. The technologies are:

- Perspectives (Koa Health) for body dysmorphic disorder (BDD)
- Beating the Blues (365 Health Solutions) for generalised anxiety symptoms or unspecified anxiety disorder
- Space from Anxiety (SilverCloud) for generalised anxiety symptoms or unspecified anxiety disorder
- iCT-PTSD (OxCADAT) for post-traumatic stress disorder (PTSD)
- Spring for PTSD
- iCT-SAD (OxCADAT) for social anxiety disorder.

Low intensity interventions should be supported by a psychological wellbeing practitioner and high intensity interventions by a high intensity therapist in NHS Talking Therapies services.

1.2 Further evidence should be generated on:

- rates of recovery
- rates of reliable recovery
- rates of reliable improvement
- rates and reasons for stopping treatment
- rates of relapse
- adverse effects and stepping up of care
- patient experience
- health-related quality of life
- resource use during and after treatment, including level of guidance provided (defined by healthcare professional grade and time)

- baseline data including the demographics of the people using the technology and their risk classification.

Find out more in the [evidence generation section](#) in this guidance.

1.3 The following technologies should only be used in research for treating anxiety disorders in adults:

- Cerina (NoSuffering), Iona Mind (Iona Mind), Minddistrict (Minddistrict), Resony (RCube Health) and Wysa (Wysa) for generalised anxiety disorder (GAD) or generalised anxiety symptoms
- Minddistrict and SilverCloud programmes for health anxiety, obsessive compulsive disorder (OCD), panic disorder with or without agoraphobia, social anxiety disorder, and phobias.

## Potential benefits of early access

- **Access:** Digitally enabled therapies offer another treatment option for adults with anxiety disorders. They will particularly benefit anyone who needs more flexible access to treatment or who prefers digitally enabled therapy to face-to-face therapy.
- **Clinical benefit:** The clinical evidence suggests that digitally enabled therapies may reduce symptoms of anxiety in the anxiety disorders they were designed to treat. They may help people to better manage their anxiety and treatment choices, which could increase autonomy and empowerment.
- **Resources:** Digitally enabled therapies may need less practitioner or therapist time for delivery than other psychological interventions in NHS Talking Therapies services. This could reduce demand on some mental health services by freeing up resources that could be allocated elsewhere in the service. There is preliminary evidence that digitally enabled therapies may be cost effective compared with standard care.

## Managing the risk of early access

- **Clinical assessment:** In NHS Talking Therapies services, digitally enabled therapies would be offered after assessing and identifying the appropriate problem descriptor in line with ICD-10. Mental health professionals would also assess patient safety and suitability to use these interventions.
- **Clinical support:** Digitally enabled therapies in NHS Talking Therapies services must be delivered with practitioner or therapist support including monitoring and managing patient safety and progress. This means that if the treatment is not working and symptoms worsen, it can be identified quickly.
- **Individual choice:** Digitally enabled therapies can be offered as a treatment option for adults with anxiety disorders. Some people may choose not to use digitally enabled therapies and may prefer another treatment option such as face-to-face therapy. Everyone has the right to make informed decisions about their care. People should be offered another treatment option if they do not want to or cannot use digitally enabled therapies.

- **Equality:** Digitally enabled therapies may not be accessible to everyone. Adults with limited access to equipment, internet connection or low digital literacy skills are less likely to benefit and may prefer another treatment option.
- **Costs:** Results from the early economic analysis suggest that the technologies could be cost effective based on current prices and evidence. This guidance will be reviewed within 4 years and the recommendations may change. Take this into account when negotiating the length of contracts and licence costs.
- **Care pathway:** This guidance focuses on using digitally enabled therapies for treating anxiety disorders in adults who have been referred to NHS Talking Therapies. Digital therapies may be used elsewhere in the NHS care pathway, but this is outside the scope of this assessment.

## 2 The technology

### Technologies

2.1 Digitally enabled therapies deliver psychological interventions in a digital format with regular support from a practitioner or therapist. NICE has assessed 11 digitally enabled therapies as an option for treating anxiety disorders in adults while evidence is generated. The technologies are:

- Beating the Blues (365 Health Solutions) for mild to moderate depression or anxiety including generalised anxiety disorder (GAD). It delivers computerised cognitive behavioural therapy (CBT) through 8 sessions with interactive material, videos and tools.
- Cerina (NoSuffering) for GAD consists of 7 sessions with anxiety management exercises, journals and self-care resources. It also uses evidence-based tools to measure symptom severity.
- iCT-PTSD (OxCADAT) for post-traumatic stress disorder (PTSD) based on Ehlers and Clark's cognitive model of PTSD. It includes modules with psychoeducation, case examples, monitoring sheets, videos, behavioural experiments and assignments.
- iCT-SAD (OxCADAT) for social anxiety disorder based on Clark and Wells' cognitive therapy for social anxiety disorder. Modules include psychoeducation, case examples, monitoring, video feedback, attention training, behavioural experiments and memory focused techniques.
- Iona Mind (Iona Mind) for GAD or depression creates personalised support plans with guided exercises and uses machine learning to adapt the programme to a person's needs. It also has functionality to identify crisis events and provide signposting.
- Minddistrict (Minddistrict) for GAD, health anxiety, social anxiety, obsessive compulsive disorder (OCD), panic disorder and phobias. Interventions can be personalised by adapting and combining components in line with a person's needs.
- Perspectives (Koa Health) for body dysmorphic disorder (BDD) is a 12-week CBT programme with psychoeducation, interactive exercises,

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CBT skills and symptom tracking. It also provides information on local emergency services and suicide hotlines for urgent support.

- Resony (RCube Health) for GAD is a 6-week automated programme based on CBT, mindfulness and gratitude journaling. It also has physiological techniques based on non-directive resonance breathing, applied relaxation and heart rate variability training.
- SilverCloud programmes for anxiety disorders include Space from Anxiety, Space from GAD, Space from Health Anxiety, Space from OCD, Space from Panic, Space from Phobia and Space from Social Anxiety. Programmes incorporate CBT with mindfulness, positive psychology and motivational interviewing. Modules include informational content, videos, interactive activities and homework.
- Spring (Cardiff University) for PTSD from a single event is a guided self-help programme with 8 steps based on core components of CBT with a trauma focus. It is interactive and user input determines feedback to activities within the programme.
- Wysa (Wysa) for mild to moderate anxiety or depression is an artificial intelligence-based app with CBT programmes and a chatbot that encourages self-reflection and engagement. It also has a risk alert system with grounding exercises, a crisis care plan and crisis numbers.

## Care pathway

2.2 NHS Talking Therapies (formerly Improving Access to Psychological Therapies or IAPT) provides evidence-based psychological therapies for anxiety and depression using a stepped care approach. This means offering the least intrusive, most effective intervention first, in line with patient needs and preferences. NHS Talking Therapies deliver low intensity psychological interventions at step 2 of the care pathway and high intensity psychological interventions at step 3. Digitally enabled therapies are most commonly offered as a step 2 low intensity intervention with the support of a psychological wellbeing practitioner who facilitates treatment and reviews progress. Digitally enabled therapies may also be

offered as high intensity psychological interventions if they include the same therapeutic content as recommended in the NICE guidelines:

- [Generalised anxiety disorder and panic disorder in adults: management](#)
- [Obsessive-compulsive disorder and body dysmorphic disorder: treatment](#)
- [Post-traumatic stress disorder](#)
- [Social anxiety disorder: recognition, assessment and treatment.](#)

This should be supported by a high intensity therapist trained in the specific therapies.

## Comparator

2.3 The comparator is standard care low intensity and high intensity psychological interventions delivered in NHS Talking Therapies services. This varies depending on the condition:

- BDD: high intensity psychological interventions include individual or group CBT with exposure and response prevention (ERP).
- GAD: low intensity interventions include individual guided or unguided self-help or psychoeducation groups. High intensity psychological interventions include CBT and applied relaxation.
- Health anxiety: the NHS recommends self-help programmes.
- OCD: low intensity interventions include brief individual or group CBT with ERP. High intensity psychological interventions include more intensive CBT with ERP.
- Panic disorder with or without agoraphobia: low intensity interventions include guided or unguided self-help. High intensity psychological interventions include individual CBT.
- PTSD: high intensity psychological interventions include individual trauma-focused CBT, eye movement desensitisation and reprocessing (EMDR) or supported trauma-focused computerised CBT.

- Social anxiety disorder: high intensity psychological interventions include individual CBT for social anxiety disorder, CBT-based supported self-help, or short-term psychodynamic psychotherapy.
- Specific phobias: the NHS recommends desensitisation or self-exposure therapy with support or a self-help programme.

### **3 Committee discussion**

#### **Unmet need**

- 3.1 Mental health services are in high demand and access varies widely across the country, with many not getting the treatment and support they need. The patient experts reported many barriers to face-to-face treatment, including transport costs, travel issues and difficulty taking time off work to attend sessions. Digitally enabled therapies allow more flexible access to therapy and could fulfil a need for support. Early access to treatment could alleviate mild symptoms and prevent escalation, which could help with daily living and productivity. 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 to support those who need more personalised face-to-face care. The committee concluded that there is an unmet clinical need and access to effective mental health treatments needs to be improved.

#### **Implementation**

- 3.2 Digitally enabled therapies would be used in NHS Talking Therapies with existing service protocols. All technologies included in this assessment are being used in the NHS or have planned pilots for use. The committee acknowledged that a recommendation for use with further evidence generation would support increased adoption of these technologies and provide a mechanism for collecting real-world clinical efficacy data.
- 3.3 The committee carefully considered the safety and risks of using these technologies while further evidence is generated. The clinical experts

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advised that NHS Talking Therapies services have established protocols, which include initial clinical assessment, matching the right treatment to people's needs and preferences, and ongoing monitoring and management of patient safety. Some digitally enabled therapies also have inbuilt functionalities to promote safety, for example technologies may alert the practitioner or therapist of potential concerns so that they can contact the patient when needed. The practitioner or therapist may also contact the patient if they see worsening in patient reported outcomes or if the patient has stopped using the programme. Decline in mental health or functioning while using digitally enabled therapies should be identified by the practitioner or therapist and treatment should be escalated when needed, in line with the stepped care approach.

- 3.4 The clinical experts advised that digitally enabled therapies would need less practitioner or therapist time than other interventions, such as face-to-face therapy. Practitioner or therapist support would usually involve a review of patient progress, content completed and patient safety. This review may be done using messaging or sometimes a telephone call. The level of support may vary by services, with some practitioners or therapists also delivering parts of the intervention content. Reviews may be weekly or fortnightly depending on the service.
- 3.5 Practitioners and therapists need training and support to effectively deliver digitally enabled therapies. The clinical experts advised that practitioners and therapists also need to be comfortable using digital technologies and need to have access to the necessary systems. Technologies should be integrated into a service's system rather than being a standalone technology. This would assist with data collection and reporting.

## **Patient considerations**

- 3.6 Digitally enabled therapies can increase treatment options and offer people more choice in their mental healthcare. The patient experts shared that this could help people feel they are taking responsibility for their treatment and may create a sense of achievement. But clinical and patient

experts stressed that it must be a genuine patient choice and not a default treatment or stopgap to reduce waiting lists. People who want to use digitally enabled therapies are more likely to engage with the content and to see benefits. Digitally enabled therapies may not be suitable for everyone. People who need more support or who have more severe functional impairment may need more intensive interventions. Treatment options should be discussed by healthcare professionals, patients and (when appropriate) carers and should consider clinical assessment, patient preferences and needs, and the level of support needed.

- 3.7 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.

## **Equality considerations**

- 3.8 Digitally enabled therapy may not be suitable for everyone. It is delivered through a smart device or computer with internet connectivity. Adults with limited access to these technologies or who are less comfortable or skilled at using digital technologies may be less likely to benefit from digitally enabled therapies. They may need considerable adaptations to access the therapy, which may not be available in all services. The committee concluded that other treatment options such as face-to-face therapy may be more appropriate for some adults with anxiety disorders.
- 3.9 Additional support and resources may also be needed for people with visual or hearing impairments, problems with manual dexterity or who are unable to read or understand English. The companies said that they are taking steps to improve the accessibility and inclusivity of the technologies, including having a low reading age for the content, audio playback and consideration of diversity and inclusivity in their design. OxCADAT has translated its programme iCT-SAD into other languages and other companies are also exploring this for theirs. One company said that its programme has also been used with in-person translators.

## Clinical-effectiveness overview

3.10 There was relevant published evidence, showing a potential benefit for adults with anxiety disorders, for 6 of the 11 digitally enabled therapies:

- Perspectives for BDD
- Beating the Blues and Space from Anxiety (SilverCloud) for generalised anxiety symptoms or unspecified anxiety disorder
- iCT-PTSD and Spring for PTSD
- iCT-SAD for social anxiety disorder.

There was no relevant published evidence for:

- Cerina, Iona Mind, Minddistrict, Resony and Wysa for GAD or generalised anxiety symptoms
- Minddistrict and SilverCloud for health anxiety, OCD, panic disorder with or without agoraphobia, social anxiety disorder, and phobias.

3.11 The evidence consisted of 19 published studies, specifically 4 randomised controlled trials, 1 comparative observational cohort study, 12 single-arm studies with no direct comparator, and 2 secondary analyses of randomised controlled trials. The external assessment group (EAG) reported that the digitally enabled therapies were found to reduce anxiety symptoms in the anxiety disorders they were designed to treat. The limited comparative evidence showed larger reductions in anxiety symptoms with digitally enabled therapies than waitlist controls or usual care. The EAG noted that waitlist controls were not in scope as a standard care comparator. This should be considered when interpreting these outcomes. Spring had outcomes comparable to standard care interventions for PTSD, as did iCT-SAD for social anxiety disorder. The EAG advised that it was not appropriate to generalise evidence from specific technologies to other digitally enabled therapies or conditions. The committee also considered unpublished and real-world evidence from the technologies' use in NHS Talking Therapies services. It concluded that the evidence base was limited for all of them, but the available

evidence suggested potential benefits that could address the unmet needs. See the [assessment report](#) for further details.

## Costs and resource use

3.12 The simple decision tree model showed that digitally enabled therapies could be a cost effective option for adults with anxiety disorders when compared with standard care in NHS Talking Therapies. Specifically:

- Perspectives for BDD
- Beating the Blues, Minddistrict and SilverCloud for generalised anxiety symptoms or unspecified anxiety disorder
- iCT-PTSD and Spring for PTSD
- iCT-SAD, Minddistrict and SilverCloud for social anxiety disorder.

There was not enough evidence on the efficacy of Cerina, Iona Mind, Resony and Wysa to model their cost effectiveness.

3.13 The EAG noted that a main driver of the model was the clinical effectiveness of the technologies. The limitations and uncertainties in the clinical evidence therefore created limitations and uncertainties in the economic model. Other limitations of the model increased the uncertainty of the results (see sections 9.3 to 9.5 of the [assessment report](#)). The committee considered that, despite these limitations, digitally enabled therapies were likely to cost less than standard care because they needed less therapist time than other NHS Talking Therapies interventions. But if they are less effective, they may be more costly in the long term. Further evidence on clinical effectiveness and resource use is needed to reduce uncertainty in the cost modelling.

## Evidence gap overview

3.14 For technologies with published evidence, important evidence gaps relate to the population, comparators and main outcomes. The committee concluded that there was enough evidence of a potential benefit of these technologies for them to be used in the NHS while further evidence is

generated to address these gaps. Important evidence gaps for these technologies are:

- Population: there was no relevant published or unpublished evidence on using the technologies for health anxiety, OCD, panic disorder or phobias. Several technologies were indicated for GAD but the studies included people with generalised anxiety symptoms, depression or anxiety, or mixed depression and anxiety. The clinical experts advised that adults with anxiety disorders often have comorbidities and treatment would be offered based on their presenting problem. The committee considered this in their recommendations for use while further evidence is generated in more clearly defined populations.
- Comparators: only 2 technologies had evidence comparing their clinical effectiveness with standard care interventions. More evidence is needed in the UK, preferably in NHS Talking Therapies settings, comparing digitally enabled therapies with low intensity and high intensity psychological interventions that are offered in NHS Talking Therapies for the respective anxiety disorders.
- Outcomes: NHS Talking Therapies services use specific tools and outcome measures to report outcomes for specific anxiety disorders. Some studies used measures that are not routinely collected in these services. Further evidence generation should use measures from NHS Talking Therapies to collect outcomes on the effectiveness of the treatments, the rates and reasons for disengagement and stopping treatment, further treatment and patient experiences.
- Adverse effects: the evidence did not report any adverse events related to the use of the technologies. The committee considered that few studies reported adverse events and more evidence was needed. The clinical experts said that they did not expect to see more adverse effects for digitally enabled therapies than for standard care once these were used with local service protocols. This included offering digitally enabled therapies as one of a range of treatment options for people who do not need regular in-depth safety reviews or face-to-face care.

- Technologies: there was no relevant published evidence on Cerina, Iona Mind, Minddistrict, Resony and Wysa. The committee considered unpublished evidence on Cerina and Resony but this was very limited. The committee concluded that further research was needed on these technologies before they could be recommended for use in the NHS.
- Economic modelling: the EAG noted that the economic modelling was limited by the amount and type of data available and the uncertainty of the assumptions. The uncertainties would be reduced with further evidence generation addressing the outlined evidence gaps and providing longer-term data on continued recovery and relapse.

## 4 Further evidence

### Evidence generation

- 4.1 Further evidence will be generated while the 6 recommended technologies are used in the NHS to address the immediate unmet need, with appropriate safety processes in place. The main outcomes prioritised by the committee for evidence generation are outlined in section 1.2.
- 4.2 The clinical experts stressed the importance of monitoring and managing patient safety during evidence generation. The companies advised that they have risk management systems in place, but that risk should be managed according to local care protocols. The committee concluded that using digitally enabled therapies in NHS Talking Therapies services could increase access to treatment and support, while ensuring patient safety through continued monitoring and review.

### Research only

- 4.3 The committee concluded that there was not enough evidence to recommend the following technologies for early access in the NHS. They should only be used in research:
- Cerina, Iona Mind, Minddistrict, Resony and Wysa for GAD or generalised anxiety symptoms

- Minddistrict and SilverCloud programmes for health anxiety, OCD, panic disorder with or without agoraphobia, social anxiety disorder, and phobias.

4.4 Research should include well-designed and adequately powered studies with appropriate comparators in NHS Talking Therapies services. The main outcomes prioritised by the committee are outlined in section 1.2. Studies should address the evidence gaps outlined in this guidance and demonstrate the benefit of using these technologies for adults with anxiety disorders.

## 5 Committee members and NICE project team

### Committee members

This topic was considered by [NICE's medical technologies advisory committee](#), which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The [minutes of the medical technologies advisory committee](#), which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

### NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

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