NICE National Institute for Health and Care Excellence

NICE guidance

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

Health technology evaluation
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1 Recommendations

1.1 Five 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, once they have appropriate approval.

The following technologies can only be used once they have Digital Technology Assessment Criteria (DTAC) approval and an NHS Talking Therapies for anxiety and depression digitally enabled therapies assessment from NHS England:

- iCT-PTSD (OxCADAT) for post-traumatic stress disorder (PTSD)
- iCT-SAD (OxCADAT) for social anxiety disorder
- Space from Anxiety (SilverCloud) for generalised anxiety symptoms or unspecified anxiety disorder.

The following technologies can only be used once they have CE or UK Conformity Assessed (UKCA) mark approval, DTAC approval and an NHS Talking Therapies for anxiety and depression digitally enabled therapies assessment:

- Perspectives (Koa Health) for body dysmorphic disorder (BDD)
- Spring (Cardiff University) for PTSD.

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

1.2 Further evidence should be generated on:

- rates of recovery
- rates of reliable recovery
- rates of reliable improvement
- rates of reliable deterioration

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- 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 the average number of treatment sessions and level of guidance provided (defined by healthcare professional grade and time)
- baseline data including the demographics and symptom severity of the people using the technology and their risk classification.

Find out more in the evidence generation section of this guidance.

1.3 The following technologies should only be used as part of a research study that has been approved by an ethics committee, once they have appropriate regulatory approval:

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

Find out more in the research only recommendations section of this guidance.

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Potential benefits of early value assessment

- **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 over 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 their treatment choices, which could increase their autonomy and empowerment.
- **Resources:** Digitally enabled therapies may need less practitioner or therapist time for delivery than other psychological interventions in NHS Talking Therapies for anxiety and depression (formerly Improving Access to Psychological Therapies or IAPT) services. This could free up resources that could be allocated elsewhere in the services to increase access or reduce waiting times. There is preliminary evidence that suggests digitally enabled therapies may be cost effective compared with standard care.

Managing the risk of early value assessment

- **Clinical assessment**: In NHS Talking Therapies for anxiety and depression services, digitally enabled therapies would be offered after assessing and identifying the appropriate problem descriptor in line with ICD-10. Healthcare professionals would also assess the safety of patients and the suitability of these interventions.
- **Clinical support**: Digitally enabled therapies in NHS Talking Therapies for anxiety and depression services must be delivered with practitioner or therapist support including monitoring and managing the safety of patients and their 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

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their care.

- **Equality:** Digitally enabled therapies may not be accessible to everyone. Adults with limited access to equipment or an internet connection, or who are less comfortable or skilled at using digital technologies 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 using NHS Talking Therapies for anxiety and depression services. Digital therapies may be used elsewhere in the NHS care pathway, but this is outside the scope of this assessment.

The evidence generation plan gives further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources. It includes how the evidence gaps could be resolved through real-world evidence studies.

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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 criteria for including technologies in this early value assessment (EVA) are in the scope on the NICE website. The technologies are:

- Beating the Blues (365 Health Solutions) for mild to moderate depression or anxiety including generalised anxiety disorder (GAD). This technology is no longer available to the NHS.
- Cerina (NoSuffering) for GAD and obsessive compulsive disorder (OCD) 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 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.
- 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. 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.

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- 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, 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, CBT skills and symptom tracking. It also provides information on local emergency services and suicide helplines for urgent support.
- Resony (RCube Health) for GAD is a 6-week automated programme based on CBT, mindfulness and gratitude journalling. 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.

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Care pathway

2.2 NHS Talking Therapies for anxiety and depression services provide evidence-based psychological therapies for anxiety and depression using a stepped care approach. This means offering the least intrusive intervention first, in line with patient needs and preferences. NHS Talking Therapies for anxiety and depression services 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 following NICE guidelines:

- Common mental health problems: identification and pathways to care
- 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 for anxiety and depression 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

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include CBT and applied relaxation.

- Health anxiety: high intensity CBT for health anxiety.
- 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 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.

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3 Committee discussion

NICE's medical technologies advisory committee considered evidence on digitally enabled therapies for treating anxiety disorders in adults from several sources, including an early value assessment (EVA) report by the external assessment group (EAG) and an overview of that report. Full details are in the project documents for this guidance.

Unmet need

3.1 Mental health services are in high demand and access varies widely across the NHS. Because of this high demand, many people are 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. This could help some people access treatment earlier, which could improve symptoms, prevent their symptoms getting worse, and help with daily living and productivity. 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. The committee concluded that there is an unmet clinical need and that access to effective mental health treatments needs to be improved.

Implementation

3.2 Digitally enabled therapies would be used in NHS Talking Therapies for anxiety and depression with existing service protocols. Many 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.

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3.3 The committee carefully considered the safety and risks of using these technologies while further evidence is generated. The clinical experts advised that NHS Talking Therapies for anxiety and depression 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 increased when needed, in line with the stepped care approach.

3.4 The clinical experts advised that digitally enabled therapies may 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, the completed content and patient safety. This review may be done using messaging or sometimes a telephone call.

3.5 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. 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 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 maintaining robust quality assurance processes. There is more information on implementing digitally enabled therapies in the adoption report within the supporting documentation on the NICE website.

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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. 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. People should discuss any concerns with using digitally enabled therapies with their practitioner or therapist before starting treatment.

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

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inclusivity in their design. OxCADAT has translated its iCT-SAD programme 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. Companies should also consider how to adapt their technologies to be inclusive of all cultures and suitable for use in diverse populations.

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 body dysmorphic disorder (BDD)
- Beating the Blues and Space from Anxiety for generalised anxiety symptoms or unspecified anxiety disorder
- iCT-PTSD and Spring for post-traumatic stress disorder (PTSD)
- iCT-SAD for social anxiety disorder.

There was no relevant published evidence for:

- Cerina, Iona Mind, Minddistrict, Resony and Wysa for generalised anxiety disorder (GAD) or generalised anxiety symptoms
- Cerina, Minddistrict and Space from OCD for obsessive compulsive disorder (OCD)
- Minddistrict and SilverCloud for health anxiety, 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 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

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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 for anxiety and depression 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 on the NICE website 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 for anxiety and depression services. 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.

See the assessment report on the NICE website for a detailed description of the model.

3.13 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 heterogeneous population of people with anxiety and depression. There was not enough evidence on the efficacy of Cerina, Iona Mind, Resony and Wysa to model

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their cost effectiveness.

3.14 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. The limitations and uncertainties in the clinical evidence therefore created limitations and uncertainties in the economic model. Other limitations of the model also 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 for anxiety and depression 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

3.15 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 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 is 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

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effectiveness with standard care interventions. More evidence is needed in the UK, preferably in NHS Talking Therapies for anxiety and depression services, comparing digitally enabled therapies with low intensity and high intensity psychological interventions that are offered in NHS Talking Therapies for anxiety and depression services for the respective anxiety disorders.

- Outcomes: NHS Talking Therapies for anxiety and depression 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 for anxiety and depression 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.

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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 the safety of patients 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 for anxiety and depression services could increase access to treatment and support, while ensuring patient safety through continued monitoring and review.

Research only recommendations

4.3 The committee concluded that there was not enough evidence to recommend Cerina, Iona Mind, Minddistrict, SilverCloud (except Space from Anxiety), Resony and Wysa for early use in the NHS. These technologies should only be used in formal research that has been approved by an ethics committee.

4.4 Research should include well-designed and adequately powered studies with appropriate comparators in NHS Talking Therapies for anxiety and depression 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 show the benefit of using these technologies for adults with anxiety disorders.

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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.

Dionne Bowie and Lirije Hyseni
Health technology assessment analysts

Lizzy Latimer
Health technology assessment adviser

Elizabeth Islam
Project manager

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Update information

December 2023: The evidence generation plan gives further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources. It includes how the evidence gaps could be resolved through real-world evidence studies.

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