

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Medical Technologies Evaluation Programme

### Digitally enabled therapies for adults with anxiety disorders

#### Final scope

November 2022

#### **1 Introduction**

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

NICE's topic selection oversight panel ratified digitally enabled therapies for adults with anxiety disorders as potentially suitable for an EVA by the medical technologies evaluation programme (MTEP). A list of abbreviations is provided in Appendix A.

#### **2 Description of the technologies**

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

##### **2.1 Purpose of the medical technologies**

Anxiety disorders are a major contributor to mental health problems in the UK. Improving and widening services for mental health is a commitment of the NHS, given the high prevalence of these conditions and the importance of early intervention ([NHS Long Term Plan](#)). The most recent Adult psychiatric morbidity survey reports that only 1 in 3 people with a common mental health disorder accesses treatment ([McManus et al. 2016](#)). Furthermore, early research suggests that the COVID-19 pandemic and subsequent measures have had a significant impact on the mental health of adults in the UK ([UK](#)

[parliament website](#)). In the [annual report on the use of](#) Improving access to psychological therapies ([IAPT services in England](#) 2021/22, there were 1.81 million referrals to IAPT services between April 2021 to March 2022. Of these, only 37% completed a course of treatment showing a substantial gap between the number of people referred and the number of people starting treatment ([House of Commons library 2021](#), [Nuffield Trust 2022](#)). This may be for many reasons including IAPT therapies not being suitable for a person's level of risk or impairment. Waiting times for NHS psychological therapy vary from 4 days to over 80 days in different parts of England ([House of Commons library 2021](#)).

Digitally enabled therapies are a treatment option for adults with anxiety disorders. They can potentially improve access to mental health services by offering greater flexibility, more choice and self-management through remote interventions. They can be delivered online or through apps with varying levels of practitioner or therapist support. These therapies generally include modules for the person to work through in their own time. Some can also monitor a person's progress through self-report questionnaires.

## **2.2 Product properties**

This scope focuses on digitally enabled therapies for treating and managing anxiety disorders in adults 18 and over. Digitally enabled therapies are products that deliver a substantial portion of therapy through its content but are designed to be used with practitioner or therapist support. [The draft IAPT assessment criteria for digitally enabled therapies](#) defines this as technology use based on practitioner or therapist review of a patient's progress along with regular (weekly or biweekly) interactions with the patient about their progress. The assistance will also help people deepen their understanding of the intervention materials, support them in setting goals and provide advice on real world assignment.

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

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

- are available for use in the NHS.

The scope does not include virtual reality therapies as their use in the care pathway will likely differ from online or app-based therapies.

Technologies included in this EVA are also expected to complete the IAPT Digitally Enabled Therapies (DET) assessment criteria at an appropriate point. This includes validation of clinical content in line with NICE guidelines and light-touch assessment of clinical effectiveness, to ensure the product meets baseline standards for use in IAPT. The status of each product against the IAPT DET assessment criteria will be included in the EVA. In total, 11 digitally enabled therapies for adults with anxiety disorders are included in the scope. The final list of included technologies may be subject to change.

### **Beating the Blues**

Beating the Blues (365 Health Solutions) is an online computerised CBT programme for people with mild to moderate depression and anxiety, including GAD. It has 8 sessions, with each session including 3 or 4 modules that take 10 to 15 minutes to complete. The sessions contain interactive material, videos, and practical hands-on tools that help people to understand their mental health problems and learn techniques to change their thinking and behaviours. The programme lasts about 8 to 12 weeks and can be accessed using any internet enabled device. Beating the Blues can be used as low intensity unguided self-help or with one-to-one support which allows the patient and practitioner or therapist to see regular progress reports and to adjust the intensity of the course as needed.

### **Cerina**

Cerina (NoSuffering) is a mental health app that provides disorder-specific psychological support. It has CBT interventions for GAD and obsessive-compulsive disorder (OCD) with the latter also including exposure response prevention. Both interventions consist of 7 sessions and include anxiety management exercises, journals and self-care resources. Cerina also uses evidence-based screening measures to measure symptom severity.

### **iCT-PTSD for post-traumatic stress disorder**

iCT-PTSD (OxCADAT) is an internet version of cognitive therapy for post-traumatic stress disorder based on Ehlers and Clark's cognitive model of PTSD. It is delivered in a series of modules alongside therapist support. The order of modules is individualised depending on a person's individual needs and treatment plan. Modules consist of psychoeducation, videos, case

examples, monitoring sheets, behavioural experiments and assignments. People can also track progress using measures including GAD-7 and PHQ-9.

### **iCT-SAD for social anxiety disorder**

iCT-SAD for social anxiety disorder (OxCADAT) is an internet-based programme based on Clark and Wells' cognitive therapy for social anxiety disorder. It is delivered in a series of modules alongside therapist support. Modules consist of psychoeducation, videos, case examples, monitoring sheets and assignments. It also includes video feedback, attention training, behavioural experiments and memory focussed techniques. Therapists can view completed modules and provide support using built-in messaging.

### **Iona Mind**

Iona Mind (Iona Mind) is an app-based CBT programme for people with GAD or depression. It is intended to support the delivery of step 2 interventions within IAPT services and can be used with the support of a psychological wellbeing practitioner. It creates personalised support plans to help people achieve their mental health goals through guided exercises and insight into their patterns of thinking. It uses machine learning to anticipate and adapt the programme to a person's needs and has functionality to identify crisis events and provide signposting. Behavioural health can be tracked using clinical measures such as the GAD-7 and PHQ-9. Iona Mind also monitors mood and goal progression.

### **Minddistrict**

Minddistrict (Minddistrict) is an online CBT programme for treating mental health conditions. It has a catalogue of modules, diaries and questionnaires that can be used to help people change their behaviour. It has interventions for GAD, health anxiety, social anxiety, OCD, panic disorder and phobia. Interventions can be personalised by adapting and combining components in line with a person's needs. It can be used as a standalone self-help tool or with practitioner or therapist support including video sessions delivered using the Minddistrict platform. Modules for GAD, OCD and panic disorder are described by the company as IAPT compliant and following NICE guidelines. Versions of these modules are available specifically for IAPT services. The technology can be accessed via a web browser and there is also a smartphone app.

### **Perspectives**

Perspectives (Koa Health) is an online CBT programme with interventions for adults with BDD, OCD and depression. It is a 12-week programme that

delivers core components of CBT using treatment modules. Each module includes psychoeducation, interactive exercises and CBT skills. People are also asked to complete weekly questionnaires, including PHQ-2, QIDS-SR and CGI, to track their symptoms. Perspectives also provides information on local emergency services and suicide hotlines should a person need urgent support. It is designed to be used in IAPT services with a practitioner or therapist who monitors progress and provides support via calls or asynchronous messaging. The programme is delivered through a mobile app and includes a web-based administration panel for practitioners or therapists.

### **Resony**

Resony (RCube Health) is an automated digital therapeutic designed to improve worry and anxiety and to manage GAD. It is a 6-week programme based on CBT, mindfulness and gratitude journalling. It also includes physiological techniques based on non-directive resonance breathing, applied relaxation and heart rate variability training. It also provides access to a community of users to share experiences and provide social support. People can choose specific modules and can monitor progress using the GAD-7 questionnaire and progress dashboard. Resony can be used as a self-help tool for people with worry, anxiety and stress or alongside the supervision of a healthcare professional for people with GAD. It is delivered through an app available for smartphones and tablets.

### **SilverCloud**

SilverCloud offers over 30 internet-based CBT programmes for a range of mental health conditions. 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 are made up of modules whose structure and content follow principles of CBT and incorporate mindfulness tools, positive psychology and motivational interviewing techniques. Modules include informational content, videos, interactive activities, homework suggestions and summaries. SilverCloud recommends that all programmes are used with a supporter who regularly reviews progress, provides feedback and unlocks content. Practitioners or therapists can guide people through the programme using built-in messaging within the platform. Programmes can be accessed at any time using any smartphone, tablet or computer.

### **Spring**

Spring is an online guided self-help programme for people with PTSD. It is audio narrated throughout and includes 8 steps based on core components of CBT with a trauma focus. The programme includes characters with PTSD to

different traumatic events, video content and a toolkit to easily access key components and information. It is interactive and user input dictates feedback to key activities within the programme. Spring is designed to be delivered with practitioner or therapist support. Practitioners or therapists can review a person's progress via a healthcare professional dashboard to help guide the patient through the programme. Ongoing support is provided as part of the service and the support team offer technical and clinical support. Spring can be accessed through a computer, tablet or smartphone.

### **Wysa**

Wysa (Wysa) is an artificial intelligence (AI) based app for people with mild to moderate anxiety or depression. It has a collection of CBT-based self-help programmes that are designed to be used with practitioner or therapist support. This includes a web-based therapist companion portal that lets practitioners and therapists review a person's engagement and recommend programmes. Wysa also has an AI-enabled chatbot that uses natural language processing to encourage self-reflection and to help people engage with the mental health tools. It has built in mental health assessment which collects outcome data such as the GAD-7 and PHQ-9. Wysa includes a risk alert system and pathway that provides grounding exercises, a crisis care plan and crisis numbers for emergency support. In addition to the app, Wysa also has a web-based e-triage tool that collects data based on questions from the referral form for IAPT services.

## **3 Target conditions**

The target population for this assessment is adults with anxiety disorders.

Anxiety disorders involve excessive fear, worry and anxiety that is severe enough to cause significant distress or impairment in a person's functioning and daily living. Anxiety disorders are one of the most common mental health disorders. In 2010, over 8 million people in the UK had some form of anxiety disorder ([Fineberg et al. 2013](#)). Anxiety disorders can have a lifelong course of relapse and remission and commonly occur together or with other conditions such as depression or substance misuse. Anxiety disorders treated in IAPT services include:

### **Body dysmorphic disorder (BDD)**

BDD is characterised by a preoccupation with an imagined defect in one's appearance or excessive concern with a slight physical anomaly. It is characterised by time consuming behaviours such as mirror gazing, comparing features with those of others, excessive camouflaging behaviours

to hide the defect, skin picking and reassurance seeking. People with BDD may avoid social situations and intimacy and may experience significant distress and impaired occupational and social functioning. About 0.5% to 0.7% of the population have BDD ([CG31 2005](#)).

### **Generalised anxiety disorder (GAD)**

GAD is characterised by persistent and excessive worry about many different things and difficulty controlling that worry. People with GAD often have restlessness, difficulties with concentration, irritability, muscular tension and disturbed sleep. GAD is a common condition, estimated to affect up to 6% of people in England in any given week ([McManus et al. 2016](#)). It is said to be underdiagnosed and commonly occurs with depression ([NICE 2022](#)).

### **Health anxiety**

Health anxiety involves persistent preoccupation or fear about the possibility of having or getting a serious health problem. This is accompanied by repetitive and excessive health-related behaviours or avoidance behaviours such as avoiding medical appointments. Symptoms cause significant distress or impairment in daily living and functioning. It is suggested that about 1 in 20 people may have some type of health anxiety at any given time ([iCope 2022](#)).

### **Obsessive-compulsive disorder (OCD)**

OCD is characterised by the recurrence of either obsessions or compulsions, but more often both. An obsession is an unwanted intrusive thought, image or impulse that repeatedly enters the mind and is difficult to get rid of. Compulsions are repetitive behaviours or mental acts that the person feels driven to perform. It is estimated that around 1 in 100 people in England will have OCD in any given week ([McManus et al. 2016](#)).

### **Panic disorder with or without agoraphobia**

The characteristics of panic disorder include repeated and unexpected attacks of intense anxiety followed by at least 1 month of persistent worry of having future attacks. This can result in avoidance of situations that may provoke a panic attack. Panic disorder can be diagnosed with or without agoraphobia (fear of being in situations where escape might be difficult or help would not be available if needed). Up to 2 in 100 people in the UK have panic disorder, with about a third going on to develop agoraphobia ([NHS 2018](#)).

## **Post-traumatic stress disorder (PTSD)**

PTSD encompasses psychological and physical problems that develop in response to threatening or distressing events, such as abuse, severe accidents, disasters or military action. It involves repeated and intrusive distressing memories that can feel like a person is reliving or re-experiencing the trauma, emotional detachment and social withdrawal, avoidance behaviours and sleep disturbance. About 4% of people in England will have a diagnosis of PTSD in any given week ([McManus et al. 2016](#)).

## **Social anxiety disorder**

Social anxiety disorder is characterised by intense fear of social or performance situations that results in considerable distress and impacts daily functioning. There is a fear of doing or saying something that will lead to being judged negatively by others and being embarrassed or humiliated. These feared situations are then avoided or experienced with intense distress. It is estimated that up to 12% of people will have social anxiety disorder in their lifetime with 12-month prevalence rates up to 7% ([CG159 2013](#)).

## **Specific phobias**

A phobia is an overwhelming and debilitating fear of an object or situation that is disproportionate to the real threat or danger. This may cause a person to actively avoid the thing that causes anxiety and may restrict daily living. Specific or simple phobias centre around a specific object, animal, situation or activity. Common specific phobias include fear of spiders, heights, flying, visiting the dentist, or bodily fluids. About 2% of people in England have phobias in any given week ([McManus et al. 2016](#)).

## **4 Care pathway**

This assessment will focus on the use of digitally enabled therapies for adults with anxiety disorders in IAPT services. The IAPT programme organises the provision of evidence-based psychological therapies in the NHS to people with anxiety disorders and depression ([National Collaborating Centre for Mental Health 2021](#)). IAPT services follow a stepped care approach as recommended in [NICE's clinical guideline on common mental health problems](#). This means offering the least intrusive, most effective intervention first. Generally, the stepped care approach includes:

- Step 1: Identification, assessment, psychoeducation, and active monitoring of known or suspected common mental health disorders.



- Step 2: People with GAD or mild to moderate panic disorder or OCD whose symptoms have not improved after step 1 are offered low intensity interventions such as guided self-help or psychoeducational groups. This is guided by a person's preferences.
- Step 3: People with moderate to severe disorders, marked functional impairment, or whose symptoms have not improved after step 2 are offered high intensity interventions including individual CBT or drug treatment. Treatment choice is based on patient-clinician decision-making. Only step 3 intervention is recommended for social anxiety disorder or PTSD.
- Step 4: Complex drug or psychological treatments involving multiagency teams, crisis services or inpatient care are offered to those with complex treatment-refractory disease with significant functional impairment.

IAPT services deliver low intensity and high intensity psychological interventions at step 2 and step 3 of the care pathway, respectively. Digitally enabled therapies are most commonly offered as a step 2 low intensity intervention. Low intensity interventions are delivered by psychological wellbeing practitioners who facilitate treatment and review progress. There is some variation in NICE-recommended low intensity interventions across disorders:

- GAD: [CG113](#) recommends individual guided self-help, individual unguided self-help, or psychoeducational groups. Guided or unguided self-help for GAD should include written or electronic materials based on the principles of CBT. Interventions should be completed over at least 6 weeks with guided self-help including 5 to 7 sessions with a trained practitioner.
- OCD: [CG31](#) recommends low intensity interventions as a first line treatment for people with mild functional impairment and/or who prefer a low intensity approach. This includes brief individual CBT including exposure and response prevention (ERP) using structured self-help materials or by telephone, or group CBT with ERP.
- Panic disorder with or without agoraphobia: [CG113](#) recommends guided or unguided self-help for people with mild to moderate panic disorder. People with moderate to severe panic disorder with or without agoraphobia would usually be offered step 3 interventions.

There is currently no NICE guideline on health anxiety. The NHS suggests that people with health anxiety use self-help and see a GP if symptoms do not improve or worries are significantly impacting daily living ([NHS 2020](#)). One

clinical expert advised that there is little guidance on how to treat health anxiety including if it should be treated at step 2 or step 3 in the care pathway.

The NHS advises that specific phobias can be treated using desensitisation or self-exposure therapy with the help of a professional or a self-help programme ([NHS 2022](#)). [NICE's 4-year surveillance of CG159 \(2017\)](#) does not recommend computerised CBT for the routine treatment of specific phobias because of a lack of quality evidence at that time.

In IAPT services, digitally enabled therapies may also be offered as high intensity psychological interventions if they include the same therapeutic content as recommended in the NICE guideline. Clinical experts advised that this was not usually offered in practice. [The IAPT manual](#) states that high intensity psychological interventions should be supported or delivered by a high intensity therapist trained in the specific therapies. There is variation in NICE-recommended high intensity interventions across disorders:

- BDD: [CG31](#) recommends individual or group CBT with ERP that addresses key features of BDD for adults with mild functional impairment. Adults with moderate functional impairment should be offered either a selective serotonin reuptake inhibitor (SSRI) or more intensive individual CBT with ERP, while those with severe impairment should be offered both an SSRI and CBT with ERP.
- GAD: [CG113](#) recommends CBT or applied relaxation if a person chooses a high intensity psychological intervention. This would usually consist of 12 to 15 weekly sessions each lasting an hour. Drug treatment may be offered to some people who prefer it to therapy.
- OCD: [CG31](#) recommends an SSRI or more intensive CBT with ERP for adults with moderate functional impairment or who have not benefited from low intensity treatment. Adults with severe functional impairment should be offered both an SSRI and CBT with ERP.
- Panic disorder with or without agoraphobia: [CG113](#) recommends CBT or an antidepressant for people with moderate to severe panic disorder with or without agoraphobia.
- PTSD: [NG116](#) recommends individual trauma-focused CBT as first line treatment. Eye movement desensitisation and reprocessing (EMDR) or supported trauma-focused computerised CBT may be offered to some adults who present more than 3 months after a traumatic event if they prefer it to face-to-face treatment. This should be based on a validated programme delivered over 8 to 10 sessions, with guidance and support from a trained practitioner.

- Social anxiety disorder: [CG159](#) recommends individual CBT specifically developed to treat social anxiety disorder as first line treatment. CBT-based supported self-help may be offered to people who decline individual CBT. This should include up to 3 hours of support to use CBT-based self-help materials over 3 to 4 months. People who decline either treatment may be offered drug treatment or short-term psychodynamic psychotherapy where appropriate.

### ***Potential place of digitally enabled therapies in the care pathway***

In IAPT services, digitally enabled therapies would be offered after assessment and identification of the appropriate problem descriptor in line with ICD-10. Digitally enabled therapies may be offered as an alternative to existing low intensity or high intensity interventions for adults with anxiety disorders. The place in the care pathway depends on the specific disorder, healthcare professional assessment and clinical judgement, the content of the intervention, patient preferences and risk, and the level of support needed.

## **5 Patient issues and preferences**

Digitally enabled therapies are delivered via mobile phones, tablets or computers and can thus be accessed remotely. As there is an increased need for psychological interventions, digitally enabled therapies may increase capacity and support within mental health services because they tend to require less clinical time than alternatives. Digitally enabled therapies provide more treatment options, flexible access to care, greater anonymity and increased convenience. They may allow people to better self-manage their mental health and be more involved in treatment decisions. People may be more motivated to use and engage with digitally enabled therapies if they have sufficient digital skills and prefer remote or digital interventions to face-to-face therapy.

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

## **6 Comparators**

Digitally enabled therapies would be offered as an alternative to existing low intensity or high intensity psychological interventions in IAPT services. Comparators should reflect treatment options offered in IAPT services to

adults with the same anxiety disorders according to the relevant NICE guidelines.

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

## 7 Scope of the assessment

**Table 1 Scope of the assessment**

<b>Populations</b>	Adults 18 and over with anxiety disorders who have been referred to IAPT services. Specifically, adults with: <ul style="list-style-type: none"> <li>• Body dysmorphic disorder</li> <li>• Generalised anxiety disorder</li> <li>• Health anxiety</li> <li>• Obsessive compulsive disorder</li> <li>• Panic disorder with or without agoraphobia</li> <li>• Post-traumatic stress disorder</li> <li>• Social anxiety disorder</li> <li>• Specific phobias</li> </ul>
<b>Interventions (proposed technologies)</b>	Digitally enabled therapies for adults with anxiety disorders that are delivered with practitioner or therapist support. Namely: <ul style="list-style-type: none"> <li>• Beating the Blues</li> <li>• Cerina</li> <li>• iCT-PTSD for post-traumatic stress disorder</li> <li>• iCT-SAD for social anxiety disorder</li> <li>• Iona Mind</li> <li>• Minddistrict</li> <li>• Perspectives</li> <li>• Resony</li> <li>• SilverCloud</li> <li>• Spring</li> <li>• Wysa</li> </ul>
<b>Comparator</b>	Standard care low intensity and high intensity psychological interventions currently delivered in IAPT services.
<b>Healthcare setting</b>	Improving access to psychological therapies (IAPT) services
<b>Outcomes</b>	Intermediate measures for consideration may include:

	<ul style="list-style-type: none"> <li>• Patient choice and preferences</li> <li>• Treatment satisfaction and engagement</li> <li>• Intervention adherence and completion</li> <li>• Referral to treatment time</li> <li>• Assessment to treatment time</li> <li>• Intervention-related adverse events</li> <li>• Inaccessibility to intervention (digital inequalities)</li> <li>•</li> </ul>
	<p>Clinical outcomes for consideration may include:</p> <ul style="list-style-type: none"> <li>• Change in anxiety symptoms</li> <li>• Change in other psychological symptoms</li> <li>• Global functioning and work and social adjustment</li> </ul> <p>Service level clinical outcomes:</p> <ul style="list-style-type: none"> <li>• Rates of reliable recovery</li> <li>• Rates of reliable improvement</li> <li>• Rates of reliable deterioration</li> <li>• Rates of relapse including relapse rate and time from remission to relapse</li> </ul>
	<p>Patient-reported outcomes for consideration may include:</p> <ul style="list-style-type: none"> <li>• Health-related quality of life</li> <li>• Patient experience</li> </ul>
	<p>Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration may include:</p> <ul style="list-style-type: none"> <li>• Costs of the technologies</li> <li>• Cost of other resource use (e.g., associated with managing anxiety, adverse events, or complications): <ul style="list-style-type: none"> <li>○ GP or IAPT appointments</li> <li>○ Medication</li> <li>○ Healthcare professional grade and time</li> </ul> </li> </ul>
<p><b>Time horizon</b></p>	<p>The time horizon for estimating the clinical and economic value should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p>

## 8 Other issues for consideration

### Population

- This early value assessment is focused on adults with anxiety disorders. Subgroups of interest may include people with varying levels of digital literacy or access, protected characteristics and comorbidities.

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

### **Characteristics of digital technologies**

- The digitally enabled therapies included in the scope are heterogeneous in terms of delivery mode (computer, app) and target condition. One of the technologies (Wysa) uses AI in addition to therapist support.
- In IAPT services, digitally enabled therapies may be used as low intensity or high intensity interventions depending on their therapeutic content. Low intensity interventions tend to be single strand interventions that are less complex than high intensity interventions. The components of digitally enabled therapies need to be considered to determine their place in the care pathway, risk and level of support needed.
- Technologies included in this EVA will complete the IAPT DET assessment. This includes validation of clinical content in line with NICE guidelines and assessment of clinical effectiveness. Technologies must pass this assessment to proceed to the evidence generation stage of the EVA.

### **Evidence**

- This assessment will look across a range of evidence types including RCTs, real world evidence and benchmarking against NHS Digital published metrics. Evidence considered will include evidence of clinical effectiveness, comparative outcomes to alternative treatments offered in IAPT for the relevant clinical condition and absence of harm.
- The amount and level of evidence for each of the technologies varies. Some of the identified technologies have RCT data. Some research studies were conducted in an NHS setting while others were done outside of the UK. Comparators also vary but most often include waitlist control. Study populations are also heterogeneous and include people with anxiety, depression and anxiety, GAD or stress. It is likely that the different technologies will require different levels of additional evidence.

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

### **Care pathway**

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

## **9 Potential equality issues**

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

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

The rates of anxiety disorders are higher in women and show an increasing trend in comparison with the rates in men, which have been largely stable. The prevalence of anxiety is higher during pregnancy. However, among people with a common mental health disorder, women, people from a White British background, or in midlife are more likely than others to receive treatment. The comorbidity between physical and mental illnesses is well established, as well as the fact that people with pre-existing mental illness are more likely to report worse mental health and wellbeing than those without.

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

## **10 Potential implementation issues**

NICE's adoption and implementation team spoke to clinical experts with experience of digitally enabled therapies. Key challenges raised in the adoption of digitally enabled therapies include:

### **Training**

Training is needed for healthcare professionals to work through and fully understand the intervention modules and content. This requires time and could have a resource impact given the high rate of turnover of psychological wellbeing practitioners within services. Knowledge of the technologies would vary across healthcare professionals, within services, and across regions. This would impact the delivery and effectiveness of the interventions.

### **Costs**

Costs of digitally enabled therapies may vary across technologies but also across services and regions. Smaller service areas may have higher costs because they do not need as many licenses. Digitally enabled therapies may be chosen based on the balance between costs and expected outcomes.

### **Patient selection**

Digitally enabled therapies are typically offered in a guided model of care at step 2 of the care pathway. They may be used at step 3 with select patients, but this may not be widespread. Digitally enabled therapies are not suitable for everyone. The preferred option for a person would be based on several factors including confidence using and access to the technology. Lack of motivation may be a barrier to effective use of these technologies.

### **Risk of harm**

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

## **11 Authors**

**Dionne Bowie, Ivan Maslyankov**



Topic Leads

**Rebecca Owens, Lizzy Latimer**

Technical Advisers

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## **Appendix A      Abbreviations**

AI	Artificial intelligence
CBT	Cognitive behavioural therapy
DTAC	Digital health and care technology assessment criteria
EVA	Early value assessment
EQ-5D	Euro-QoL 5 Levels
GAD	Generalised anxiety disorder
IAPT	Improving access to psychological therapies
MTEP	Medical technologies evaluation programme
OCD	Obsessive-compulsive disorder