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Early Value Assessment consultation:

Supporting documentation – Committee papers

The enclosed documents were considered by the NICE medical technologies advisory committee (MTAC) when making their draft recommendations:

1. **Front sheet**
2. **Assessment report** – an independent report produced by an external assessment group (EAG) who have reviewed and critiqued the available evidence.
3. **Assessment report overview** – an overview produced by the NICE technical lead which highlights the key issues and uncertainties in the company's submission and assessment report.
4. **Scope of evaluation** – the framework for assessing the technology, taking into account how it works, its comparator(s), the relevant patient population(s), and its effect on clinical and system outcomes. The scope is based on the sponsor's case for adoption.
5. **Adoption scoping report** – produced by the adoption team at NICE to provide a summary of levers and barriers to adoption of the technology within the NHS in England.

Please use the above links and bookmarks included in this PDF file to navigate to each of the above documents.

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Early Value Assessment

MT589 Digitally Enabled Therapies for Adults with Anxiety Disorder

External Assessment Group report

Produced by: Cedar

Authors: Dr Huey Yi Chong (Senior Researcher)

Dr Laura Knight (Senior Researcher)

Megan Dale (Principal Researcher)

Dr Rhys Morris (Cedar Director)

Simone Willis (Systematic Reviewer)

Dr Susan O'Connell (Principal Researcher)

Correspondence to: Cedar, Cardiff Medicentre, Heath Park, Cardiff CF14 4UJ

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Contains confidential information: Yes

Number of attached appendices: 2

Purpose of the early value assessment report

The purpose of this External Assessment Group (EAG) report is to review the evidence currently available for included technologies and advise what further evidence should be collected to help inform decisions on whether the technologies should be widely adopted in the NHS. The report may also include additional analysis of the submitted evidence or new clinical and/or economic evidence. NICE has commissioned this work and provided the template for the report. The report forms part of the papers considered by the Medical Technologies Advisory Committee when it is making decisions about the early value assessment.

Declared interests of the authors

Description of any declared interests with related companies, and the matter under consideration. See NICE's Policy on managing interests for board members and employees.

Megan Dale and Susan O'Connell hold honorary contracts with Cardiff University, Simone Willis is an employee of Cardiff University and the EAG team as a whole has close working links with Cardiff University. None of the team has worked in any capacity on Spring.

Acknowledgements

The EAG wish to thank all specialist committee members for their valuable input.

Responsibility for report

The views expressed in this report are those of the authors and not those of NICE. Any errors are the responsibility of the authors.

Any 'commercial in confidence' information in the submission document is underlined and highlighted in turquoise.

Any 'academic in confidence' information in the submission document is underlined and highlighted in yellow.

Contents

Abbreviations

Term	Definition
BDD	Body Dysmorphic Disorder
CBT	Cognitive Behavioural Therapy
CBT-TF	Trauma focused CBT
CI	Confidence interval
CT	Cognitive Therapy
dCBT	Digitally enabled CBT
DHSC	Department of Health and Social Care
EAG	External assessment group
EVA	Early Value Assessment
EVPI	Expected Value of Perfect Information
GAD	Generalised Anxiety Disorder
GP	General Practitioner
HIT	High Intensity Therapist
HTA	Health Technology Assessment
IAPT	Improving Access to Psychological Therapies
iCBT	Internet delivered Cognitive Behavioural Therapy
IQR	Interquartile range
ITT	Intention to Treat
MAUDE	Manufacturer and User Facility Device Experience
MHRA	Medicines & Healthcare products Regulatory Agency
MTEP	Medical Technologies Evaluation Programme
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NICE CG	NICE clinical guideline
NICE MTG	NICE medical technology guidance
NICE QS	NICE quality standard
NMB	Net Monetary Benefit
OCD	Obsessive Compulsive Disorder
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSSRU	Personal Social Services Research Unit
PTSD	Post Traumatic Stress Disorder
PWP	Psychological Wellbeing Practicioner
QALY	Quality Adjusted Life Years
QUORUM	Quality of Reporting of Meta-analyses
RCT	Randomised controlled trial
SAD	Social Anxiety Disorder
SD	Standard deviation
SSRI	Selective serotonin reuptake inhibitor
VAS	Visual analogue scale
Vs	Versus
WTP	Willingness to Pay

Executive summary

Digitally-enabled guided therapies can be used within the Improving Access to Psychological Therapies (IAPT) pathway as an intervention for symptoms of anxiety disorders. The clinical evidence (n=19 studies) suggests that guided digital therapies can reduce anxiety symptoms across a range of conditions and that reductions can persist up to 12 months post treatment. Limited comparative evidence indicates the reduction in anxiety symptoms was larger in those using the guided therapies, compared to waiting list or usual care. However, there are some major limitations with the included evidence. Firstly, there are no studies that reported for patients with a diagnosis of Generalised Anxiety Disorder. Further, the majority of this evidence groups participants with those also experiencing depression symptoms. There was a lack of relevant comparators and therapist or 'guided' element which limits applicability of evidence to the scope. Few of the included studies were conducted in a UK/NHS setting, reducing the generalisability of the results.

Wysa, Cerina, Mind District, Iona Mind and Resony technologies and the following conditions; health anxiety, obsessive compulsive disorder, panic disorder and specific phobias had no relevant published evidence.

Economic evidence was available for 4 technologies, reporting cost-effectiveness compared to non-IAPT comparators (n=3), and cost-saving compared to an IAPT comparator (n=1). The EAG created a decision tree model, with a 15 month time horizon, using the IAPT database as a comparator. This indicated the plausibility of digitally enabled therapies being less costly and equally or more effective than other IAPT interventions, but the level of uncertainty means no clear conclusions can be drawn. Where there was no clinical evidence it was not possible to include these technologies in the model, as their cost effectiveness is highly dependent on their clinical effectiveness.

There are significant gaps where technologies and conditions included in the scope had no appropriate evidence to report. To address these gaps and those identified within the included evidence, high-quality randomised controlled trials with appropriate diagnoses and comparators should be conducted within a UK/NHS setting.

1 Decision problem

The target population for this assessment is adults with anxiety disorders including 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 treated in IAPT services include body dysmorphic disorder, generalised anxiety disorder, health anxiety, obsessive compulsive disorder, panic disorder with/without agoraphobia, post-traumatic stress disorder, social anxiety disorder and specific phobias.

Full details of the decision problem can be found in the topic Scope Document and key elements are outlined in Table 1.

Table 1: Decision Problem

Decision problem	Scope	EAG comment
Population	Adults (aged 18 years and older) with anxiety disorders • Body dysmorphic disorder • Generalised Anxiety Disorder • Health Anxiety • Obsessive Compulsive Disorder • Panic disorder with/without agoraphobia • Post traumatic stress disorder • Social anxiety disorder • Specific phobias	In some cases, technologies may be described in the evidence as being used to treat symptoms of anxiety with no diagnosis of a specific anxiety disorder. The EAG will consider such evidence on a technology by technology basis and include it only where there is no evidence for use to treat specific anxiety disorders. Some of the included technologies are suitable for use by people under 18 years. If no other evidence is available, the EAG will report the evidence in young people while noting the lack of evidence in adult populations as an evidence gap.
Intervention	Digitally enabled therapies delivered with the support of a practitioner or therapist • Beating the Blues (365 Health Solutions) • Cerina • iCT-PTSD for post-traumatic stress disorder • iCT-SAD for social anxiety disorder • Iona Mind • Minddistrict (Minddistrict) • Perspectives • Resony • SilverCloud • Spring • Wysa (Wysa)	For any studies which include people with depression and anxiety, the EAG will consider the evidence where the technologies are being used for a diagnosed anxiety disorder. Where a study reports on the use of a technology for anxiety without defining or separating specific anxiety related diagnosis, the EAG will consider this on a case by case basis and include a summary of these as a separate subgroup, highlighting the potential limitations. Studies which report results for anxiety and depression combined will be considered for inclusion on case by case basis.

Decision problem	Scope	EAG comment
Comparator(s)	Standard Care within the IAPT care pathway • Low intensity (step 2) • High intensity (step 3)	It is likely that technologies are being used outside of IAPT, particularly in the case of non-UK based studies. The EAG will include any relevant evidence, noting the lack of IAPT specific evidence as a gap. Although excluded from the scope, if evidence comparing with standard interventions is limited, the EAG will consider studies comparing technologies with waitlist controls and other non-standard comparators. This will be done on a technology by technology basis.
Healthcare setting	Improving access to psychological therapies (IAPT) services	
Outcomes	Intermediate measures for consideration may include: • Patient choice and preferences • Treatment satisfaction and engagement • Intervention adherence and completion • Referral to treatment time • Assessment to treatment time • Intervention-related adverse events • Inaccessibility to intervention (digital inequalities) Clinical outcomes for consideration may include: • Change in anxiety symptoms • Change in other psychological symptoms • Global functioning and work and social adjustment Service level clinical outcomes: • Rates of reliable recovery • Rates of reliable improvement • Rates of reliable deterioration • Rates of relapse including relapse rate and time from remission to relapse Patient-reported outcomes for consideration may include: • Health-related quality of life • Patient experience	
Cost analysis	Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration may include:	

Decision problem	Scope	EAG comment

	• Costs of the technologies
	• Cost of other resource use (e.g., associated with managing anxiety, adverse events, or complications):
	  ○ GP or IAPT appointments
	  ○ Medication
	  ○ Healthcare professional grade and time	

Study Design		All study designs will be considered and the decision to include or exclude a study based on design will be made on a technology by technology basis.

2 Overview of the technology

Included in this early value assessment (EVA) are digitally enabled therapies that are intended for use by adults and deliver a therapeutic intervention in line with NICE guidelines. They can be used in IAPT services with practitioner or therapist support. The technology must deliver a substantial portion of the therapy through the technology rather than being platforms to support teletherapy. Any technologies included must have regulatory approval or be actively working towards regulatory approval, specifically DTAC and CE or UKCA mark where required, and be available for use in the NHS. It should be noted that the IAPT manual states that IAPT only supports the delivery of therapies (digital or non-digital) whose content is the same as the content of the treatments recommended in the main NICE guideline for the relevant clinical condition. The purpose of the EVA is to assess the clinical and economic evidence for the included technologies however and will not assess the content of the technologies for compliance. The included technologies are being assessed separately through the IAPT digitally enabled therapies (DET) assessment process, the findings of which will need to be considered alongside the EVA.

Virtual reality therapies are excluded as their use in the care pathway will likely differ from online or app-based therapies.

2.1 *Included Technologies*

In total, 11 digitally-enabled therapies for adults with anxiety disorders were identified as relevant to the assessment (Table 2).

Table 2: Included Technologies

Technology (Company)	Regulatory Status	Delivery	Condition(s) Treated	Key Features	EAG Comments
Beating the Blues	Class 1 under UKCA DTAC: [redacted]	Laptop, computer and/or smart device	Mild to moderate • Anxiety • Depression • Mixed anxiety and depression	• Approved for use as part of the stepped care approach • No real-time interface with therapist or helper • Collects GAD7 and PHQ9 and can be configured to send results to therapist/clinical helper	Generalised anxiety disorder mentioned on company website, however not clear whether formal GAD diagnosis required – likely used for GAD or symptom of anxiety.
Cerina (NoSuffering Ltd.)	Class 1 under UKCA DTAC: Not currently, but DTAC requirements have been considered while building the product	Smart Phone (iOS and Android)	Generalised anxiety disorder (GAD)	• Self-guided • Adults only • 7 Sessions of CBT • Not currently used in the NHS	• Low intensity therapy only based on information in company submission • Not currently supported by a therapist
iCT-PTSD for post-traumatic stress disorder	Currently uncertified however company state they will shortly be applying for CE/UKCA certificate DTAC: Not yet, but company believe product meets criteria	Can be used on mobile phones but company recommend computer, laptop or tablet	Mild to severe post-traumatic stress disorder (PTSD)	• Therapist assisted • Designed to be a 1st line treatment for PTSD within IAPT • Collects PCL-5, GAD-7, PHQ-9, WSAS • Used in 11 IAPT services • Content of treatment is in line with NICE recommendations • Reporting to PC-MIS & IAPTus	Currently used within the NHS and collects all relevant IAPT measures for PTSD as outlined in the IAPT manual.

Technology (Company)	Regulatory Status	Delivery	Condition(s) Treated	Key Features	EAG Comments
iCT-SAD for social anxiety disorder	Currently uncertified however company state they will shortly be applying for CE/UKCA certificate DTAC: Not yet, but believe product meets criteria	Can be used on mobile phones but company recommend computer, laptop or tablet	Social anxiety disorder (SAD)	• Therapist assisted • Designed to be a 1st line treatment for SAD within IAPT • Used in 6 IAPT services • Content of treatment is in line with NICE recommendations • Suitable for use by PWPs and by Hi intensity CBT therapists • Collects all relevant IAPT measures (SPIN, GAD-7, PHQ-9, WSAS) • Reporting to PC-MIS and IAPTus	Currently used within the NHS and collects all relevant IAPT measures for SAD as outlined in the IAPT manual.
Iona Mind	Unregulated Class 1 certification pending DTAC: Assessment booked for Q1 2023	Mobile App delivered via smart phone or tablet	Generalised anxiety or low mood	• Fits step 2 of IAPT pathway • Intervention within the app is recommended by PWP, clinical psychologist or assistant psychologist • Adjunct to usual step 2 treatment • Patient reported outcomes GAD7, PHQ9 can be recorded • Reporting to PCMIS and IAPTUS	
Minddistrict	Class 1		Generalised Anxiety Disorder	• Collects PHQ-9 and GAD-7 • Self-help, guided self-help and	

Technology (Company)	Regulatory Status	Delivery	Condition(s) Treated	Key Features	EAG Comments
	DTAC: Submitted, awaiting feedback		Obsessive Compulsive Disorder Panic Disorder Phobia Social Anxiety Health Anxiety	blended	
Perspectives (Koa Health)	Unregulated DTAC: Preparing for submission to DTAC	Mobile app for patients Web access for healthcare professionals	Body dysmorphic disorder (BDD)	• Replacement for step 3 interventions or as an adjunct to step 4/5 interventions • Supported by a healthcare professional • Adults only • Accessed by referral from a licensed healthcare professional or by self-referral • Cognitive behavioural therapy programme • Training required for healthcare professionals	• Developed by Koa Health/Massachusetts General hospital with a backend data storage element – may present issues for GDPR however company information states data could be held on an NHS server if required • Information provided suggests that the therapist can be a clinician equivalent to high intensity therapist or a coach (equivalent to a PWP). Specialist committee input raised concerns around the impact of therapists delivering interventions they were not trained

Technology (Company)	Regulatory Status	Delivery	Condition(s) Treated	Key Features	EAG Comments
					for • States the technology is for people with symptoms of BDD – unclear whether a diagnosis of BDD is required
Resony	Class 1 DTAC: Currently in progress	Mobile app (iOS or android) for use on smart phones or tablets	Generalised anxiety disorder (GAD) (IFU use state that it is intended for the improvement of worry and anxiety and management of GAD)	• Adjunct to usual care, to be used while people on IAPT waitlist • Healthcare professional supervision if using for GAD • Adults Only • 6 week programme, used 3 times per day • GAD-7 • Psychological and physiological techniques such as cognitive behavioural therapy (CBT) exercises, mindfulness exercises, progressive muscle relaxation exercises (PMR) and resonance frequency breathing exercises	• Cannot be used for treatment of severe GAD • NHS input to the programme content
SilverCloud	Unregulated as not classed as medical device	Cloud hosted Software-as-a-service (SAAS). Available on	• Depression • Anxiety	• Used as an alternative or adjunct to current treatment option	• Currently being used within the NHS

Technology (Company)	Regulatory Status	Delivery	Condition(s) Treated	Key Features	EAG Comments
	DTAC: accredited	all devices (smartphones, PC, tablets). Uses push notifications and text alerts	• Generalised Anxiety Disorder • Health Anxiety • OCD • Panic • Phobia • Social Anxiety • Depression & Anxiety	• Used with supervision of a trained professional provided by the patient's clinical organisation • It is intended that support monitoring would last for 1-2 months • Techniques used focus around a CBT framework with additional aspects of mindfulness, positive psychology and motivational interviewing techniques • SilverCloud has embedded a screening tools depending on the patient group, program type or risk profile etc. These include M3, BDI, PHQ9 (Patient Health Questionnaire 9), GAD7 and WHOQual.	
Spring	Unregulated as not classed as medical device DTAC: No, but are planning to apply	Internet based	Mild to moderate post-traumatic stress disorder (PTSD) from a single event	• Low intensity CBT treatment delivered with the support of a healthcare professional • Adults only • Delivered over 4 30-minute sessions in 8 weeks • Used as first line treatment for those presenting with PTSD (following standard processes after referral from GP etc)	• Used within NHS Wales • Not to be used for those with complex PTSD or any co-morbidities

Technology (Company)	Regulatory Status	Delivery	Condition(s) Treated	Key Features	EAG Comments
				• Seen as an alternative/replacement to current first line treatments	
Wysa	Class 1 CE marked device DTAC: accredited	Mainly provided via app on a mobile device Wysa's e-triage and therapist companion app are web based and can be used on any computer or tablet.	Mild to moderate anxiety and/or depression	• AI enabled chat bot that uses Natural language Processing (NLP) to support a user to reflect on their current experiences and to complete clinician written tools and activities designed to improve mental health outcomes and increase resilience • Uses a collection of IAPT mapped CCBT assisted self-help programmes designed for use alongside PWP support in self-help • Outcome measures can trigger an SOS if words associated with self-harm, abuse or suicidal thoughts are identified. This can also be triggered by the person if needed. • Integrated with patients electronic records • Aimed at stage 2 of the IAPT pathway • Intended for teenagers as well as adults	• Currently used within some NHS England trusts • Is not recommended for individuals who are currently self-harming, are actively suicidal or who have experienced psychosis within the past 6 months

Abbreviations: BDD, body dysmorphic disorder; CBT, cognitive behavioural therapy; DTAC, digital technology assessment criteria; GAD, generalised anxiety disorder; IAPT, Improving Access to Psychological Interventions; IFU, instructions for use; NLP, natural language processing; PTSD, post-traumatic stress disorder; PWP, psychological wellbeing practitioner;

3 Clinical context

This early value assessment will focus on the use of digitally enabled therapies for adults with anxiety disorders within 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. If the patient does not respond to treatment at the first level, then they would progress through the IAPT stages.

IAPT services deliver low and high intensity psychological interventions at step 2 and 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 are a number of relevant NICE guidelines covering body dysmorphic disorder, generalised anxiety disorder, obsessive compulsive disorder, panic disorder, post-traumatic stress disorder and social anxiety disorder (Table 3). The EAG note that although the NICE guideline currently has PTSD included at step 2, the IAPT manual states that PTSD and SAD should not use a stepped care approach, instead recommending that high intensity treatment is the first intervention. The EAG has therefore considered PTSD and SAD at step 3 for this assessment. There is currently no NICE guidance 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).

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. The IAPT manual states that this should be supported or delivered by a high intensity therapist trained in the specific therapies.

No other relevant guidelines were identified.

Table 3: Relevant NICE Guidelines

Guideline	Condition	Recommendation
NICE CG31	Body Dysmorphic Disorder	• 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
NICE CG113	Generalised anxiety disorder	Low intensity • 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. High Intensity • 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
NICE CG31	Obsessive Compulsive Disorder	Low Intensity • 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. High Intensity • SSRI or more intensive CBT with ERP for adults with moderate functional impairment or who have

Guideline	Condition	Recommendation
		not benefited from low intensity treatment • Adults with severe functional impairment should be offered both an SSRI and CBT with ERP
NICE CG113	Panic Disorder with or without agoraphobia	Low Intensity • 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 High Intensity • CBT or an antidepressant for people with moderate to severe panic disorder with or without agoraphobia
NICE NG116	Post-traumatic stress disorder	• 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
NICE CG159	Social Anxiety Disorder	• 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

IAPT terminology and database

All appointments and courses of therapy delivered within the IAPT framework are recorded in the IAPT database, with much of the information publicly available via NHS Digital in the form of a dashboard and regular reports Table 4 shows the total numbers of completed therapy courses recorded in the IAPT database for Depression and Anxiety descriptors. There are slightly more people with anxiety than depression, and within the anxiety group, over half are classified as have GAD.

Table 4: Extract from IAPT database 2021-22

Problem descriptor	Total Courses delivered	Selected therapy types used for economic modelling						
		Stage 2					Stage 3	
		Guided Self Help (Book)	Non-guided Self Help (Book)	Guided Self Help (Computer)	Non-Guided Self Help (Computer)	Psychoeducational peer support	Eye Movement Desensitisation Reprocessing	Cognitive Behaviour Therapy (CBT)
Depression	152,850	27.9%	1%	4.6%	0.2%	5.7%	0.4%	37.2%
Anxiety (all)	210,105	28.1%	0.6%	5.2%	0.3%	5.1%	2.4%	52.5%
Agoraphobia	2,812	37.1%	1%	4.1%	0.1%	4.3%	0.4%	51.7%
Body Dysmorphic disorder	272	1.5%	0%	0.7%	0.0%	1.5%	0.7%	95.2%
Social phobias	13,047	10.0%	0%	2.5%	0.1%	1.0%	0.2%	84.4%
Specific (isolated) phobias	3,845	19.6%	0%	3.0%	0.2%	1.3%	1.7%	72.7%
Panic disorder	9,767	36.8%	1%	6.4%	0.2%	5.9%	0.2%	47.8%
Generalised Anxiety Disorder	107,597	38.5%	1%	7.4%	0.4%	6.6%	0.4%	41.1%
Mixed anxiety and depressive disorder	7,661	21.8%	1%	4.7%	0.1%	4.0%	0.8%	46.6%
Obsessive-compulsive disorder	12,989	8.5%	0%	2.2%	0.1%	0.7%	0.4%	87.0%
Post-traumatic	25,895	2.4%	0%	0.2%	0.0%	1.0%	15.9%	77.4%

stress disorder								
Hypochondriacal disorders	7,778	12.5%	0%	3.8%	0.2%	1.8%	0.4%	80.3%
Other anxiety or stress related disorder	18,442	34.8%	2%	4.5%	0.1%	10.0%	1.1%	25.8%

Reporting of the proportion of people who access each type of therapy is restricted in table 4 to those therapies used within the economic modelling, however the full information is available via NHS digital on the IAPT dashboard. Overall, for people treated for anxiety of any kind, 28% are given guided self-help, in the form of books, 5% receive guided self-help via a computer, and 52.5% receive some form of CBT. A clinical expert did state however that patients will rarely be given books for guided self-help, but will often be offered information sheets, short booklets, videos and website links.

IAPT definitions

Courses are described as completed if the patient has finished a course of treatment and there are 2 or more attended treatment appointments. Patients are described as "*at caseness*" if at least one indicator meets the clinical threshold. For generalised anxiety these are normally PHQ-9 and GAD-7. For other anxiety disorders there are condition specific tools listed in the IAPT manual which should be used in addition to PHQ-9 and GAD-7.

IAPT manual definitions consider a person *recovered* if their scores on PHQ-9 and / or the relevant anxiety measure are above the clinical cut-off on either at the start of treatment, and their scores on both are below the clinical cut-off at the end of treatment. *Reliable improvement* is when scores on the depression and/or the relevant anxiety/MUS measure have reduced by a reliable amount and neither measure has shown a reliable increase. *Reliable recovery* is when a person meets the criteria for both recovery and reliable improvement (IAPT Manual).

Anxiety assessment tools and measurement within IAPT

Generalised Anxiety Disorder Assessment (GAD-7) is the IAPT-recommended tool for assessing anxiety, unless an additional measure is required for specific anxiety disorders such as PTSD or OCD. This tool gives a score between 0 and 21, where 21 represents the maximum level of anxiety. The IAPT definition of “caseness” requires a level of GAD-7 higher than 7. Patients may be described as recovered if they move from caseness to non-caseness, with a reliable recovery also indicating that there was an improvement of at least 4 points on the GAD-7 score. A reliable clinical improvement or deterioration is a movement of at least 4 points on the GAD-7 score without a change from caseness to non-caseness. For condition specific measures, the reliable change values are included in the IAPT manual.

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.

Special considerations, including issues related to equality

Scoping workshop participants noted that health inequalities need to be considered as a priority. Specific considerations may include (but are not limited to):

- Anxiety in specific groups (e.g. traveller community, anxiety associated with menopause)
- Some users struggle to focus on digital therapies (e.g. people with ADHD)
- Digital literacy
- Safe space for access
- General accessibility issues (e.g. language / internet / devices)

4 Clinical evidence selection

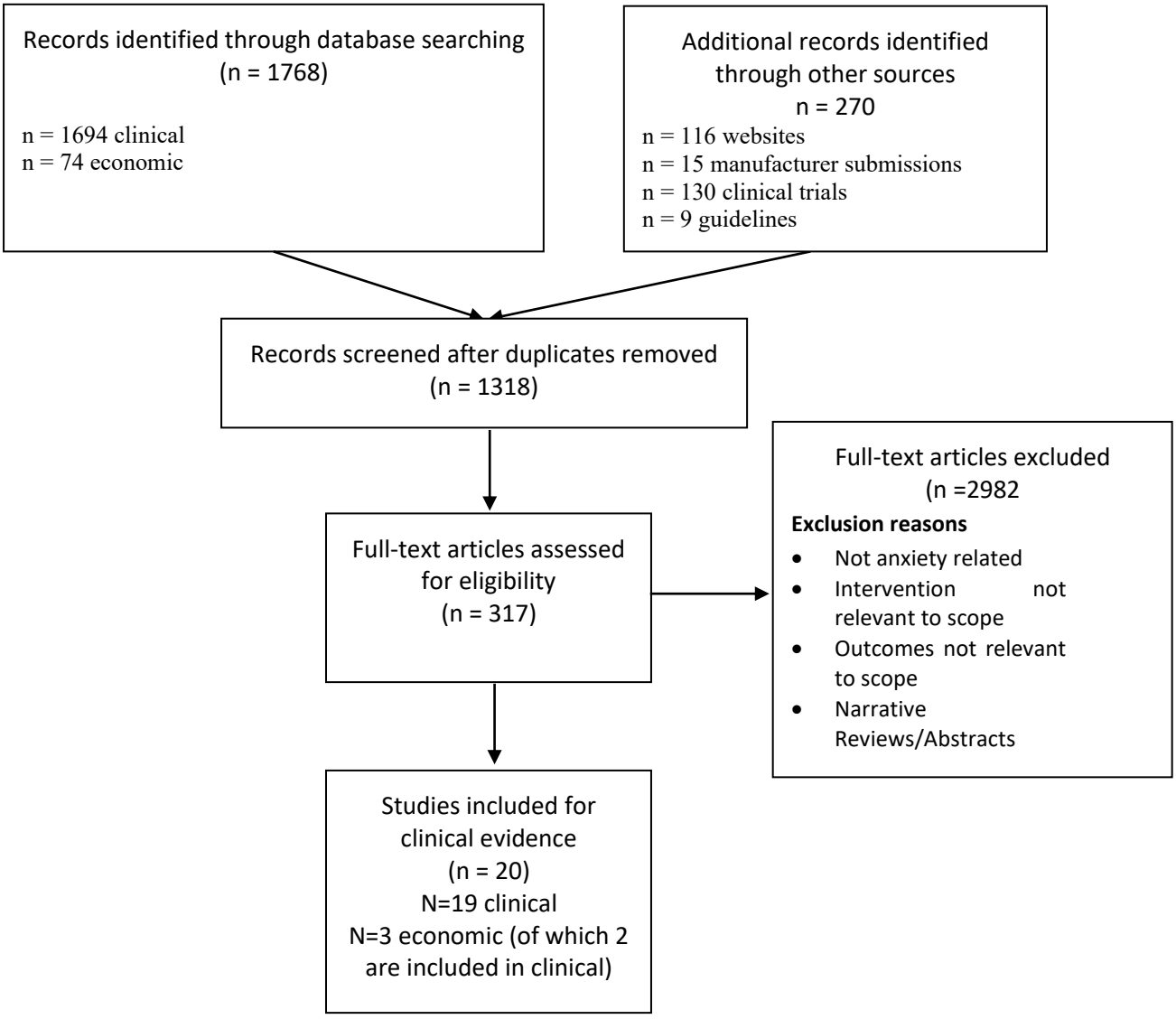
4.1 *Evidence search strategy and study selection*

The EAG conducted literature searches to ensure that all relevant evidence had been identified. The EAG literature searches identified a total of 1250 records. Fifteen studies included in the company submission were not picked up through EAG searches and were added to the database. Details of the EAG searches are provided in Appendix A.

4.2 *Included and excluded studies*

A total of 19 published studies are included in the clinical review and are summarised in Table 5. A rating of Green indicates an element that meets the scope fully, amber meets the scope partially and red indicates does not meet the scope.

Figure 1: Study Selection Flow Chart



Companies also provided some additional, unpublished evidence for their technologies and this has been included and discussed where appropriate.

Due to the volume of studies available, the EAG made some pragmatic decisions around inclusion of studies that did not meet the scope and small number of studies which included technologies named in the scope have been excluded from this review (appendix B).

Table 5: Studies selected by the EAG as the evidence base

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Spring (1 study)				
Study: Bisson 2022 **Location**: UK	**Design:** Multicentre, pragmatic, randomised controlled non-inferiority trial **Aim:** To determine if guided internet based cognitive behavioural therapy with a trauma focus (CBT-TF) is non-inferior to individual face-to-face CBT-TF for mild to moderate post-traumatic stress disorder (PTSD) to one traumatic event **Comparator:** Face to face CBT therapy **Therapist Involvement:** experienced psychological therapists who received training **Green**	**Participants**: N=196 adults with a primary diagnosis of mild to moderate PTSD from one traumatic event **Setting**: NHS Mental Health Services (IAPT, primary and secondary care) **Green**	Follow-up at 16 and 52 weeks post-randomisation **Primary outcome:** • Clinician Administered PTSD Scale for DSM-5 (CAPS-5) at 16 weeks **Secondary outcomes:** • CAPS-5 at 52 weeks • Generalised Anxiety Disorder (GAD-7) • Work and Social Adjustment (WASA) Scale • The Patient Health Questionnaire Depression (PHQ-9) • EuroQol (EQ-5D-5L) **Green**	Good quality study. High number of participants with a very specific and relevant diagnosis. The outcomes are all within scope and there is a guided element to the use of the technology.

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Beating the Blues (6 studies)				
Study: Cavanagh 2011 **Location**: UK	**Design:** Pragmatic, open trial, pre-post design **Aim:** To test the generalisability of efficacy and effectiveness findings within the NHS to the implementation of CCBT in a service user-led, third sector Self Help Clinic **Comparator:** None **Therapist Involvement:** Therapist involvement not reported. Service volunteer offers support after each session **Amber**	**Participants**: N=351 completed baseline assessment (n=295 started BTB program) **Setting**: NHS Mental Health Services (Self Help Services – third sector) **Green**	Follow up after each session • PHQ-9 • GAD-7 Follow up at end of programme • Clinical Outcomes in Routine Evaluation-Outcome Measure (CORE-OM) • WASA • Patient Experience Questionnaire Numbers reaching caseness criteria (depression caseness criteria PHQ-9 ≥ 10; anxiety caseness criteria GAD-7 ≥ 8) **Green**	Moderate quality study. There is no comparator and therapist time is not reported. However, there is a good sample size and the outcomes are relevant to the scope.
Study: Cavanagh 2009	**Design:** Naturalistic, open trial	**Participants**: N=219 with anxiety and/or depression (191 (87%) completed the pre-treatment	Follow-up immediately posttreatment	Moderate quality study. Questionnaires/Measures used in the study do not align with the

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Location: UK	**Aim:** Acceptability of beating the blues for those with depression and/or anxiety **Comparator**: None **Therapist Involvement:** Programme completed within routine care setting (e.g., GP office, psychology service) Amber	measures and 84 (38%) completed treatment feedback questionnaire) **Setting**: NHS mental health services (primary and secondary care) Amber	• Opinions about Psychological Problems Questionnaire (OPP • Attitudes to CCBT Questionnaire (A-CCBT) • Patient Feedback Questionnaire for CCBT (PFQ-CCBT) Amber	IAPT measures and there are no clinical outcome measures. The diagnoses of the participants is also unclear. However, it was conducted within an NHS setting and has a good sample size.
Study: Cavanagh 2006 **Location**: UK	**Design:** Naturalistic, non-randomised, open trial **Aim:** To establish the generalizability of continuation and outcomes from the controlled setting of efficacy trials to routine care for depression and anxiety and to benchmark health gains associated with using computerized therapy against those achieved and maintained by patients receiving face-	**Participants**: N=219 with anxiety and/or depression (104 (47%) completed all 8 sessions of BtB and post-treatment measures – referred to as 'Research completers') **Setting**: NHS Mental Health Services (primary and secondary care) Amber	Weekly follow up • CORE-OM • WASA • Self-reported anxiety and depression scores Amber	Moderate quality study. The only anxiety measure is a self-report measure and there is no comparator. The diagnosis of participants is also unclear. However, it was conducted within an NHS setting with a good sample size.

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
	to-face counselling and psychological therapy **Comparator**: None **Therapist Involvement:** Programme completed within routine care setting (e.g., GP office, psychology service) **Amber**			
Study: Jonassaint 2020 **Location:** USA	**Design:** Secondary analysis of a three-arm randomized controlled clinical trial **Aim:** To study race differences in the impact of cCBT use on mental health outcomes among White and African American primary care patients **Comparator**: BtB plus internet support group (ISG) and usual care **Therapist Involvement:** Email and telephone	N=704 with anxiety and/or depression randomised to 3:3:1 ratio: • N=301 cCBT only • N=302 CBT+ ISG • N=101 Usual care **CBT+ISG group not included in these analyses** **Setting:** Primary care (mental health) **Amber**	Follow up at 3 and 6 months • Short form health survey (SF-12) • PROMIS-Anxiety • PROMIS depression Differences in PROMIS-Anxiety change between Caucasians and African Americans **Amber**	Moderate quality study as the outcome measures do not align with IAPT approved measures. A usual care comparator group was used but not defined. The diagnosis of patients is unclear and it was not conduced in a UK/IAPT setting but does have a good sample size. Acceptability results reported in this study are the same as those in an earlier study (Jonassaint 2020), unclear if same population in both studies but very possible.

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
	guidance and support from a care coach with mental health research experience **Amber**			
Study: Jonassaint 2017 **Location:** USA	**Design:** Secondary analysis of randomised controlled trial **Aim:** Examine differences in CCBT use and self-reported change in depression and anxiety symptoms among African Americans and white primary care patients **Comparator**: No comparator **Therapist Involvement:** Email and telephone guidance and support from a care manager with research experience **Amber**	Participants: N=590 with moderate anxiety and/or depression symptoms • N=91 African Americans • N=499 White Americans **Setting:** Primary care **Amber**	Follow up at 3, 6 and 12 months • GAD-7 • PHQ-9 App engagement **Green**	

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Study: Learmonth 2008 **Location:** UK	**Design:** Naturalistic study **Aims:** To evaluate the impact of Beating the Blues for the management of anxiety and depression, within an NHS CBT specialist healthcare centre **Comparator**: No comparator **Therapist Involvement:** Participants completed session material alone. Administrator available to manage concerns and alert therapeutic staff where needed **Amber**	**Participants**: N=555 (394 completed full follow-up; 'Research completers') with anxiety and/or depression symptoms **Setting:** NHS Mental Health Services (IAPT) **Amber**	Follow up at 6 and 8 weeks Reliable and clinically significant changes in: • Beck Depression Inventory II (BDI-II) • Beck Anxiety Inventory (BAI) **Amber**	
SilverCloud (7 studies)				

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Study: Chien 2020 **Location**: UK	**Design:** Cohort study **Aims:** To identify behaviour types based on how people engage with an internet-based cognitive behavioral therapy (iCBT) intervention for symptoms of depression and anxiety. **Comparator:** None **Therapist Involvement:** 8 weeks of guidance and feedback via asynchronous messages, monitors programme activity **Amber**	**Participants**: N=54604 adult patients assigned to the Space From Depression and Anxiety treatment program **Setting**: Not reported **Green**	Follow up at 14 week • PHQ-9 • GAD-7 Log data from user interactions with the iCBT program to inform engagement patterns over time. **Green**	
Study: Duffy 2020 **Location:** UK	**Design:** Uncontrolled feasibility design **Aim:** To investigate the potential impacts of using iCBT as a prequel for patients requiring high intensity treatment (HIT;	**Participants**: N=124 patients who were on the waiting list for high intensity face to face psychological treatment due to anxiety or depression **Setting:** NHS Mental Health Services	Changes in the following measures from baseline, iCBT exit and service exit: • GAD-7 • WSAS • PHQ-9	

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
	face-to-face) for depression and anxiety in IAPT **Comparators**: No comparator **Therapist Involvement:** Clinicians and Psychological Wellbeing Practitioners (PWPs) monitor clients' progress for 8 weeks and give feedback **Amber**	(IAPT) **Green**	Reliable change, recovery and reliable recovery **Green**	
Study: Jardine 2020 **Location:** UK	**Design:** Naturalistic randomised controlled trial **Aim**: To evaluate clients' expectations, experience, and context of usage of iCBT **Comparator**: Waitlist control **Therapist Involvement:**	**Participants**: N=361 randomised (n=183 completed all assessments) **Setting:** NHS Mental Health Services (IAPT) **Green**	Follow up at 4 and 8 weeks Patient expectations of their: • online treatment • experience of the intervention • context of their use of the intervention • their perception of the aesthetics employed	

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
	PWPs provides asynchronous feedback via written messages on the platform or telephone appointment **Amber**		**Green**	
Study: Palacios 2022(a) **Location:** UK	**Design:** Naturalistic, observational cohort study **Aim:** To compare treatment effects of three interventions, utilising four years' worth of routine clinical data **Comparator**: Guided self-help bibliotherapy (GSH) and psychoeducational group therapy (PGT) **Therapist Involvement:** PWPs provides encouragement, weekly online asynchronous written feedback for 6 – 8 weeks **Green**	**Participants**: N=21215 currently on step 2 of IAPT for anxiety and or depression • GSH n=12896 • iCBT n=6862 • PGT n=1457 **Setting:** NHS Mental Health Services (IAPT) **Amber**	Follow up at end of treatment • GAD-7 • WSAS • PHQ-9 Rates of reliable recovery **Green**	

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Study: Palacios 2022(b) **Location:** UK	**Design:** Secondary analyses from pragmatic RCT **Aims:** To investigate post-treatment relapse and remission rates 3, 6 and 9 months after completion of a clinician-supported internet delivered cognitive-behavioural therapy (iCBT) for anxiety and depressive symptoms, within a routine care setting **Comparator**: No comparator **Therapist Involvement:** PWPs trained in low intensity CBT monitors clients' progress, provides online or telephone reviews, feedback and guidance **Amber**	**Participants**: N=241 in intervention arm with anxiety and/or depression symptoms **Setting:** NHS Mental Health Services (IAPT) **Amber**	Follow up at 3, 6 and 9 months posttreatment • PHQ-9 • GAD-7 Durability of treatment effects Predictors of relapse at end of treatment **Green**	

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Study: Palacios 2018 **Location:** USA	**Design:** Open, non-randomised feasibility trial **Aim:** To assess feasibility, acceptability, effectiveness, and satisfaction of a supported iCBT intervention offering 3 programs on depression, anxiety, and stress to university students **Comparator**: Space from Depression; Space from Stress (SilverCloud) **Therapist Involvement:** Licensed psychologist or social worker provided web-based welcome message, encouragement, feedback and reviewed progress **Amber**	**Participants**: N=102 University students referred from either counselling services, mental health services or the international office **Setting:** US University mental health services **Amber**	Follow up at 8 weeks and 3 months • GAD-7 • Reliable Change Index (RCI) • PHQ-9 Satisfaction with Treatment **Amber**	
Study: Richards 2020	**Design:** Pragmatic randomised controlled trial **Aim:** To investigate the	**Participants:** N=361 • N=169 depressive disorder ○ N=111 SilverCloud ○ N=58 waiting list	Follow up at 8 weeks and 3, 6, 9 and 12 months • GAD-7 • PHQ-9	

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments

Location: UK	effectiveness and cost-effectiveness of iCBT when fully integrated within an IAPT settings
	
	Comparator: Waiting list
	
	Therapist Involvement: PWPs monitored and reviewed client's progress and provided weekly feedback over 8-weeks
	
	Green
		• N= 192 anxiety disorder
		  ○ N=130 SilverCloud
		  ○ N=62 waiting list
		
		Setting: NHS Mental Health Services (IAPT)
		
		Amber
			• M.I.N.I. diagnosis
			• WSAS
			
			App usage
			
			Safety
			
			Green	

iCT-SAD (2 studies)				
Study: Clark 2022 **Location:** UK	**Design:** Randomised controlled trial **Aim:** To compare internet and standard face-to-face delivery of individual cognitive therapy for social anxiety disorder (CT-SAD) with the same therapists, assessing the competence with which the face-to-face therapy is delivered and assessing the quality of the	**Participants**: N=102 patients with social anxiety disorder (SAD) - N=34 in each group (total 102) **Setting:** NHS Mental Health Services (IAPT) **Green**	Follow up mid-treatment, post-treatment and at 3 and 12 months **Primary outcome:** The social anxiety disorder composite - 6 independent assessor and patient self-report scales of social anxiety including ADIS, SPIN, LSAS, SPS, SIAS and FNE.	Waitlist control not in scope

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
	therapeutic alliances **Comparators**: CT-SAD or waitlist control **Therapist Involvement:** Weekly phone calls to review progress, assign new modules, deepen learning, and plan behavioural experiments **Amber**		**Secondary outcomes:** • GAD-7 • PHQ-9 • WSAS Recovery rates as defined by IAPT (Proportion of patients rated as meeting SAD criteria by independent assessor (score below cut-off on both PHQ 9 and SPIN)). **Green**	
Study: Stott 2013 **Location:** UK	**Design:** Pilot cohort study **Aim:** To develop an internet-based version of CBT that requires less therapist time **Comparator**: Face to face CBT **Therapist Involvement:** Clinical psychologist	**Participants**: N=11 with DSM-IV diagnosis of social anxiety disorder **Setting:** NHS Mental Health Services (IAPT) **Amber**	Follow up posttreatment • Liebowitz social anxiety scale (LSAS) • Social Cognitions Questionnaire (SCQ) • Social Behaviour Questionnaire (SBQ) • Social Attitudes Questionnaire (SAQ) • GAD-7 • PHQ-9	

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
	monitors clients' progress, uses secure messaging system, phone call once a week, and mobile SMS messages **Green**		Patient drop-out Rates of response and remission Therapist time **Green**	
iCT-PTSD (1 study)				
Study: Wild 2016 **Location:** UK	**Design:** Pilot cohort study **Aims:** To develop an Internet version of CT-PTSD that significantly reduces therapist contact time without compromising treatment integrity or retention rates **Therapist Involvement:** Advice, direction, and support via weekly telephone calls, SMS messages and follow-up	**Participants**: N=10 patients with DSM-IV diagnosis of PTSD **Setting**: NHS Mental Health Services (IAPT) **Amber**	Follow up posttreatment • PTSD checklist for DSM-V (PCL-5) • PTSD Symptom Scale Interview (PSS-I) • GAD-7 • PHQ-9 • WSAS • Rates of recovery as measured using the Impact of Events Scale – Revised (IES-R) • Rates of remission as defined by a loss of diagnosis on the PSS-I	

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
	emails Green		• Therapist time • Programme engagement • Patient drop out Green	
Koa Health (2 studies)				
Study: Wilhelm 2020 **Location:** USA	**Design:** Pilot feasibility and acceptability study **Aim:** To describe the development of the first smartphone-delivered individual CBT for BDD digital service ("Perspectives") and obtain data on feasibility, acceptability and treatment outcome **Comparator:** None **Therapist Involvement:** Participants had remote access to a licensed psychologist during treatment (phone call or	**Participants:** N=10 adults with primary BDD (based on DSM-5 criteria) **Setting:** No specific setting, participants recruited nationally through advertisement Green	Follow up at 6 and 12 weeks, and 3 months Feasibility, acceptability and satisfaction CSQ-8 • Yale–Brown Obsessive Compulsive Scale, Modified for BDD (BDD-YBOCS)_ • Brown Assessment of Beliefs Scale (BABS) score • PHQ-9 • Quality of Life, Enjoyment, and Satisfaction Questionnaire—Short Form (Q-LES-Q-S)	Low quality due to being a feasibility study with no comparator, small sample size and limited applicability of outcomes to the scope.

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
	secure, asynchronous messaging system) **Amber**		• Safety **Amber**	
Study: Wilhelm 2022 **Location:** USA	**Design:** Randomised controlled trial **Aim:** To provide an initial test of the usability and efficacy of coach-supported app-based cognitive behavioural therapy (CBT) for BDD **Comparator:** Waitlist **Therapist Involvement:** Coach provided encouragement and feedback, via calls and asynchronous in-app messages. Coaches followed a manual and were supervised by a licensed clinician **Amber**	**Participants**: N=80 participants • N=40 Perspectives • N=40 Waitlist **Setting**: Not reported **Green**	Follow up at 6 and 12 weeks **Primary Outcome** • Intent to treat analysis of difference in BDD-YBOCS scores between treatment and waitlist groups **Secondary Outcome** • BABS • QIDS-SR (Quick Inventory of Depressive Symptomatology – Self Report) • Q-LES-Q **Amber**	Moderate quality due to generalisability issues but indicative of positive outcomes.

Abbreviations: A-CCBT, Attitudes to CCBT Questionnaire; ADIS, Anxiety Disorders Interview Scale; BABS, Brown Assessment of Beliefs Scale; BAI, Beck Anxiety Inventory; BDD-YBOCS, Yale–Brown Obsessive Compulsive Scale, Modified for BDD; BDI-II, Beck Depression Inventory II; CAPS-5, Clinician Administered PTSD Scale for DSM-5; CORE-OM, Clinical Outcomes in Routine Evaluation-Outcome Measure; EQ-5D-5L, EuroQol; GAD-7, FNE, Fear of Negative Evaluation; Generalised Anxiety Disorder; IES-R, Impact of Events Scale – Revised; LSAS, Liebowitz Social Anxiety Scale; M.I.N.I., Mini-International Neuropsychiatric Interview; OPP, Opinions about Psychological Problems Questionnaire; PCL-5, PTSD checklist for DSM-V; PFQ-CCBT, Patient Feedback Questionnaire for CCBT; PHQ-9, Patient Health Questionnaire Depression; PSS-I, PTSD Symptom Scale Interview; QIDS-SR, Quick Inventory of Depressive Symptomatology – Self Report; Q-LES-Q-S, Quality of Life, Enjoyment, and Satisfaction Questionnaire—Short Form; RCI, Reliable Change Index; SAQ, Social Attitudes Questionnaire; SBQ, SIAS, Social Interaction Anxiety Scale; Social Behaviour Questionnaire; SPIN, Social Phobia Inventory; SPS, Social Phobia Scale; SF-12, Short form health survey; WASA, Work and Social Adjustment Scale

5 Clinical evidence review

5.1 *Quality assessment of included studies*

As outlined in the final protocol for the review, the EAG has taken a pragmatic approach to critical appraisal and quality assessment. This section outlines key information on factors such as study methodologies, potential risks of bias and key strengths and limitations of each of the included studies (Table 6). A summary comment is provided on EAG conclusions on the quality of the evidence for each condition.

There is no evidence for generalised anxiety disorder (as defined by ICD-10) instead much of the evidence relates to 'generalised anxiety' or 'symptoms of depression and anxiety' (n=13 studies covering 2 technologies only). Broadly the evidence indicates that use of either Beating the Blues or SilverCloud results in improvements in anxiety symptoms and, where reported participants were satisfied with the technologies, the quality of the evidence is variable (study design, interventions, comparators). Evidence for body dysmorphic disorder is limited to one technology (Koa Health) and only 2 studies. Although there is one randomised trial (Wilhelm 2022) showing favourable results for people using the Koa Health technology, the comparator is not within scope (waitlist control) and the measures used to assess BDD are not those used within IAPT. Additionally, although during the study users have access to a coach, the level of qualification for a coach may not meet the requirements set out for use within IAPT where step 2 interventions are supported by a psychological wellbeing practitioner (PWP). For both post traumatic stress disorder and social anxiety disorder the evidence was limited to 2 studies each. For social anxiety disorder, both studies related to iCT-SAD and included 1 RCT, however both were compared with waitlist control. For post-traumatic stress disorder, 1 study related to iCT-PTSD and 1 to Spring thus providing limited evidence for each of these technologies.

Table 6: Methodologies and Quality Assessment

Condition	Technology	Evidence Quality Comments	Quality conclusion
Body Dysmorphic	Koa Health	Randomised trial evidence	Positive results indicative of

Condition	Technology	Evidence Quality Comments	Quality conclusion
Disorder	(Perspectives)	available but • Overall limited studies available • Comparator not within scope. • Validated measures are used to assess BDD in study but they not aligned with the IAPT measures. • Therapist supported but unclear whether the level of qualification meets with IAPT requirements for step 2 interventions.	a benefit from using the technology but this should be balanced against the broader generalisability of the evidence to the UK setting however these could be addressed if the technology was used within a UK specific study setting or within an IAPT setting where data collection requirements can be clearly laid out.
Generalised Anxiety	Beating the Blues SilverCloud	13 published studies available however only 2 technologies addressed by published studies.	Positive results indicate a benefit to using Beating the Blues or Silvercloud to manage symptoms of anxiety however the extent of the benefit is difficult to quantify as for most studies, participants were included if they had symptoms of anxiety and depression and it is not possible to know the proportion of participants with anxiety symptoms. There was no evidence relating to generalised anxiety disorder (as defined by ICD-10) which is the condition included in the scope. Therapist time/involvement was not reported in any of the included studies.
Post-Traumatic Stress Disorder	iCT-PTSD Spring	Extremely limited evidence with only 2 published studies each using a different technology. • 1 non-comparative study including a small sample size • 1 study includes a large sample size of adults with PTSD and compares technology to face to face CBT	Positive findings indicative of a benefit however the evidence base is extremely limited.

Condition	Technology	Evidence Quality Comments	Quality conclusion
Social Anxiety Disorder	iCT-SAD	Two studies available however: • iCT-SAD compared with face to face CBT or waitlist control. • Both studies set in NHS mental health services and include a total of 112 patients though it should be noted that the sample size in one study included only 11 participants	Positive findings indicate improvements in SAD with iCT-SAD compared with face to face therapy. Evidence comparing the technology with waitlist control is outside of the scope.
Health Anxiety	None	None	None
Obsessive Compulsive Disorder	None	None	None
Panic Disorders with/without agoraphobia	None	None	None
Specific Phobias	None	None	None

5.2 *Results from the evidence base*

The IAPT manual recommends that PHQ-9 and WSAS tools are used as part of all assessments with condition specific measures recommended depending on the clinical condition being treated. Results for each anxiety disorder included in the scope are presented in this section. Table 7 shows each measure with a brief description.

Table 7: Included measures and description

Condition	IAPT Recommended Measure	Measure used in literature	Description
Body Dysmorphic Disorder	BIQ	BDD-YBCOS	Body dysmorphia disorder symptom scale
Health Anxiety	HAI	No evidence	Health anxiety scale
OCD	OCI	No evidence	Obsessive Compulsive Disorder Scale
Panic Disorder	PDSS	No evidence	Panic Disorder Severity Scale
PTSD	PCL-5	CAPS-5, PCL-5 and	Post-Traumatic Stress disorder symptom and cognition scales

		PSS-I [redacted]	
Social Anxiety Disorder	SPIN	LSAS	Social anxiety symptom scale
Generalised Anxiety	GAD-7	GAD-7, BAI, PROMIS-Anxiety	Anxiety symptom scales
Other Tools used	WSAS	WSAS	Work and social adjustment scale Used to measure the extent to which a person's mental health problem interferes with functioning
		CORE-OM	Global distress scale
		BABS	Delusions symptoms scale

Whilst the PHQ-9 was listed as an outcome in Table 5, the results from this will not be recorded as they relate to depression symptoms which is outside of the scope of this review.

5.2.1 Health Anxiety, Obsessive Compulsive Disorder, Panic Disorder with or without agoraphobia, Specific Phobia

Two included technologies (SilverCloud, Mind District) can be used for health anxiety. Two included technologies (SilverCloud, Mind District) can be used for OCD. Two included technologies (SilverCloud, Mind District) can be used for panic disorder. Two included technologies (SilverCloud, Mind District) can be used for phobia.

None of the identified evidence included reported results for health anxiety, OCD, Panic Disorder or specific phobias using any of the technologies of interest.

5.2.2 Body Dysmorphic Disorder

One included technology (Perspectives, Koa Health) can be used for BDD. Two relevant publications were identified relating to Perspectives: a pilot feasibility study including 10 participants (Wilhelm 2020) and a randomised trial including 80 participants (Wilhelm 2022). Table 8 summarises these results.

Table 8: Results for Body Dysmorphic Disorder

Study	Technology	Change in BDD scores	Change in BABS scores	Quality of Life	Remission and recovery	Drop out and App usage	Therapist Time
Wilhelm 2020	Perspectives, Koa Health	BDD-YBOCS scores decreased (Mean 45.27%)	BABS scores decreased (mean 67.08%)		90% of participants were treatment responders (≥30% reduction on BDD-YBOCS) Treatment response remained at 90% at follow-up RCI was 5.08 at posttreatment and 5.69 at follow-up (indicating reliable change)	Participants spent a mean of 398 minutes over 12 weeks using the service	
Wilhelm 2022	Perspectives, Koa Health	Mean BDD-YBOCS scores baseline and week 12 Perspectives: 29.9 to 16.8 Waitlist: 30.9 to 26.7, between group difference p<0.001	Mean BABS scores baseline and week 12: Perspectives: 15.1 to 8.3 Waitlist: 14.5 to 13.2	Mean Quality of life scores baseline and week 12: Perspectives:52.7 to 66.5 Waitlist: 48.3 to 55.2	Response rates for assessment completers at end of treatment: Perspectives: 68% Waitlist: 14% Full or partial remission: Perspectives: 52% (16/31)	Dropout rate: Perspectives: 23% (9/40) Waitlist: 8% (3/40) p=0.11 App usage Mean 130.2 mins in the app	Coach time Mean 26.9 mins speaking to participants on the phone (mean phone calls 2.1) Mean 1.5 mins per participant per week via chat

Study	Technology	Change in BDD scores	Change in BABS scores	Quality of Life	Remission and recovery	Drop out and App usage	Therapist Time
					Waitlist: 8% (3/37)	Mean 30.4 days Satisfaction 86% were very(14/28) or mostly (25/28) satisfied 89% would recommend Perspectives	

5.2.3 Generalised Anxiety

Six of the included technologies can be used for generalised anxiety (Beating the Blues, Cerina, Iona Mind, Resony, SilverCloud, and Wysa). Thirteen studies reported results for high levels of anxiety symptoms. It should be noted here that none of these used an ICD-10 or DSM-V diagnosis of Generalised Anxiety Disorder (GAD) and will be referred to as generalised anxiety for the rest of this review. Table 9 summarises these results for outcomes relevant to the scope. Therapist time was not reported in any of the included studies.

For Cerina, the company provided a short report (unpublished) and results from an unpublished pilot study providing limited information showing that mean GAD-7 scores before and after, completed by 20 out of 43 participants. Change from 10.2 to 9.2.

For Resony, the company provided a list of publications which were reviewed by the EAG and excluded as they were not considered relevant to the scope of this review. A real-world evidence report was also provided [redacted] and is therefore limited in its applicability to the current review. Resony also submitted results from one unpublished study after the final report was completed which included 86 participants. The aim of the study was to assess safety, clinical outcomes and engagement and treatment satisfaction. [redacted]

Table 9: Results for generalised anxiety

Study	Technology	Anxiety measures – GAD-7, BAI and self report measures	WSAS	CORE-OM	Recovery and remission	Acceptability and usage
Cavanagh 2006	Beating the Blues	Research completers • Self-reported anxiety score reduced from 5.47 at baseline to 3.64 post-treatment (p<0.001) Intention to treat analysis: • Self-reported anxiety score reduced from 5.23 at baseline to 4.00 post-treatment (p<0.001)	Research completers: • Mean score reduced from 23.14 at baseline to 18.51 post-treatment (p<0.001) Intention to treat analysis: • Mean score reduced from 22.39 at baseline to 20.05 post-treatment (p<0.001)	Research completers: • Mean score reduced from 1.88 at baseline to 1.27 post-treatment (p<0.001) Intention to treat analysis: • Mean score reduced from 1.81 at baseline to 1.53 post-treatment (p<0.001)		
Learmonth 2008	Beating the Blues	Research completers: A statistically significant mean BAI score difference was found between pre and post BtB treatment (difference = -5.9, p<0.001) Intention to treat analysis: A statistically significant mean BAI score difference was found between pre and post BtB treatment (difference = -4.9, p<0.001)			Of the 195 completers recording clinical caseness on the BAI measure, 44 (23%) showed reliable and clinically significant improvement, with 46 (19%) in the intention to treat population (n=238) Of the 394 who	

Study	Technology	Anxiety measures – GAD-7, BAI and self report measures	WSAS	CORE-OM	Recovery and remission	Acceptability and usage
					completed the program, 85 were referred on for further treatment. Of the 161 who did not complete the programme, 153 were referred for further treatment	
Cavanagh 2009	Beating the Blues					Mean pre-treatment total for the A-CCBT was 6.3 with all questions rated significantly higher than the midpoint score of 4 ($p<0.001$) Mean scores of CBT credibility were 1.8 which is significantly higher than the midpoint of 0 ($p<0.001$) Mean scores from the PFQ-CCBT showed the usefulness of the programme's introductory video were above the midpoint of 2.5 (Mean=3.3, $p<0.001$). Mean scores of the interactive, multimedia programme features were above the midpoint of 3 (mean = 4.0, $p<0.001$) Eighty-nine per cent of patients

Study	Technology	Anxiety measures – GAD-7, BAI and self report measures	WSAS	CORE-OM	Recovery and remission	Acceptability and usage
						providing feedback rated the programme overall as very (35%) or quite (54%) helpful, and averaged ratings of its usefulness were above the midpoint of 2.5 (mean =3.2, p <0.001)
Cavanagh 2011	Beating the Blues	Over the course of at least 2 treatment sessions mean GAD-7 scores reduced from 12.6 at baseline to 7.6 (p<0.001)	Over the course of at least 2 treatment sessions mean WASA scores reduced from 24 at baseline to 19.2 (p<0.001)	Over the course of at least 2 treatment sessions mean CORE-OM scores reduced from 19.6 at baseline to 14.5 (p<0.001)	At baseline, 226 (85.3%) of those who completed at least two sessions of CCBT (n=265) met caseness criteria for one of (n = 58, 21.9%) or both anxiety and depression (n = 168, 63.4%) Following treatment of at least 2 sessions, 142 (53.6%) no longer met caseness for either depression or anxiety, 41 (15.5%) continued to meet caseness for one, and 82 (30.9%) for both. Therefore 50.0% cases moved to recovery status	

Study	Technology	Anxiety measures – GAD-7, BAI and self report measures	WSAS	CORE-OM	Recovery and remission	Acceptability and usage
Jonassaint 2017	Beating the Blues	African Americans showed a similar level of decline in anxiety (estimated 8-session change: −5.3 vs. −5.6; P=0.80) over the course of the eight BtB sessions compared to white people Pharmacotherapy use at baseline was not a predictor of decline in GAD-7 scores over time (P=0.6713)				African Americans were less likely than white people to start session 1 of the CCBT programme (75% vs. 87%, P=0.01) African Americans completed slightly fewer sessions at 6 months (mean 4.7 vs. 5.5; P=0.03)
Palacios 2018	SilverCloud	Of those in the Space for Anxiety program, mean GAD-7 scores reduced from 10.9 at baseline to 7.5 at 8 weeks and 6.7 at 3 months.			On the GAD-7, for those with 8-week follow-up data, 17/53 (32%) decreased their scores by more than the RCI (4+), classed as reliable change; 30/53 (57%) had no reliable change and 6/53 (11%) had reliable deterioration (increase of 4 of more). At 3 months, 26/50 (52%) had reliable change,	

Study	Technology	Anxiety measures – GAD-7, BAI and self report measures	WSAS	CORE-OM	Recovery and remission	Acceptability and usage
					22/50 (44%) had no reliable change, and 2/50 (4%) had reliable deterioration	
Chien 2020	SilverCloud	Mean GAD-7 scores reduced from 11.85 at baseline to 4.01 at 14 weeks				5 different classes of engagement were suggested: • Class 1 – low engagers • Class 2 – late engagers • Class 3 – high engagers with rapid disengagement • Class 4 – high engagers with moderate decrease • Class 5 – high engagers Estimated engagement class specific mean GAD-7 change over 14 weeks: • Baseline/Class 1 = -4.72 • Class 2 = -4.18 • Class 3 = -6.36 • Class 4 = -4.98 • Class 5 = -5.56
Duffy 2020	SilverCloud	GAD-7 Post-hoc analysis of the linear mixed model: • Baseline to iCBT exit reduction of 3.226	WSAS Post-hoc analysis of the linear mixed model: • Baseline to iCBT		N=100 participants had full data at all time points. 58 showed reliable improvement from	

Study	Technology	Anxiety measures – GAD-7, BAI and self report measures	WSAS	CORE-OM	Recovery and remission	Acceptability and usage
		(p<0.001) • iCBT exit to service exit (completers) reduction of 3.985 (p<0.001) • iCBT exit to service exit (dropouts) increase of 0.164 (n.s.)	exit reduction of 2.426 (p<0.001) • iCBT exit to service exit (completers) reduction of 4.103 (p<0.001) • iCBT exit to service exit (dropouts) increase of 0.168 (n.s)		baseline to iCBT exit Ninety-nine participants were above clinical caseness threshold at baseline; 22 had achieved recovery by iCBT exit and 20 had achieved reliable recovery; 33 were in recovery at point of service exit all of which reliably recovered	
Jardine 2020	SilverCloud					General expectations theme: • 137 (75%) participants expected to develop self-management skills and learn how to practically deal with their condition/emotions/thoughts through use of the intervention • 42 participants (23%) had high or positive expectations of the treatment itself, for example 21 participants reported that they expected to feel supported,

Study	Technology	Anxiety measures – GAD-7, BAI and self report measures	WSAS	CORE-OM	Recovery and remission	Acceptability and usage
						understood and cared for via the online treatment. Fifteen expected it to be convenient and easy to use due to it being accessible in their own time, under their control • 42 (23%) of clients had negative expectations of the treatment; expected the experience to be challenging, emotionally confronting or feel strange or alien, while others expected online treatment to feel disconnected when compared to face-to-face therapy Practical expectations theme: • 69 (38%) participants expected to use the online treatment at a specific or routine time. • 50% of clients expected to use the platform when they were feeling low or anxious, or needed help or support Experience vs expectations

Study	Technology	Anxiety measures – GAD-7, BAI and self report measures	WSAS	CORE-OM	Recovery and remission	Acceptability and usage
						theme: • 71 (39%) participants reported that it was more helpful than they expected it to be • 11 (6%) of clients felt that their experience of online treatment was generally harder than they expected Experience of online treatment theme: • Only 66 (36%) participants reported developing self-management skills (compared to the 75% who expected it) • 93 (51%) participants stated that their overall experience of using the platform was a positive, enjoyable or pleasant one • For more than a third of clients in this sample, the flexibility and autonomy of online treatment were significant positive factors in their experience • 31 (17%) participants reported challenges with online treatment, such as

Study	Technology	Anxiety measures – GAD-7, BAI and self report measures	WSAS	CORE-OM	Recovery and remission	Acceptability and usage
						the treatment lacked adequate support and guidance, the platform was difficult to use or the content was repetitive • 16 (9%) participants felt the flexibility of the platform hindered their engagement with it as the lack of deadlines and structure meant it was easy to put off or forget about Study identified managing expectations, polarised preferences, momentary help-seeking and long-term support as important aspects of the experience to consider in future design
Jonassaint 2020	Beating the Blues	• African Americans in the cCBT group showed significantly greater decreases in PROMIS-Anxiety scores compared to those in the UC group (difference of 10.46 vs 4.81, p<0.01). • No significant difference between cCBT and UC				• White participants completed more BtB sessions on average than African Americans (5.5 vs 4.7, p = 0.03).

Study	Technology	Anxiety measures – GAD-7, BAI and self report measures	WSAS	CORE-OM	Recovery and remission	Acceptability and usage
		was seen in the white participants' group for PROMIS-Anxiety score (difference of 8.77 vs 7.37). • Compared to the white group, African Americans reported a greater benefit of the cCBT programme on PROMIS-Anxiety score only (p=0.05) • For white participants, the number of BtB sessions completed was associated with 6-month improvements PROMIS-Anxiety(p=0.01 - <0.01). For African Americans, more sessions showed a greater benefit on the PROMIS-Anxiety score only (p = 0.014)				
Richards 2020	Silvercloud	Paired comparisons showed in those who received Silvercloud, GAD-7 scores were reduced from baseline to 8-weeks more than in those who did not:			At 8-week follow-up 46.4% (90/194) of the intervention arm relative to 16.7% (15/90) control-arm participants recovered, with	

Study	Technology	Anxiety measures – GAD-7, BAI and self report measures	WSAS	CORE-OM	Recovery and remission	Acceptability and usage
		• Silvercloud = 12.7 vs. 8.2 • Waitlist = 12.5 vs. 10.8 8-week models suggested significant interaction effects of time-by-intervention-arm for GAD-7 (0.0001)			63.4% (123/194) intervention-arm relative to 34.4% (31/90) control-arm participants showing reliable improvement. Reliable recovery in the intervention-arm was 40.7% (79/194), and 13.3% (12/90) in the control arm. All between-group differences were significant ($p < 0.01$).	
Palacios 2022 (a)	SilverCloud	Mean GAD-7 score differences (pre, post): • iCBT = 12.4, 6.2 • GSH = 13.4, 7.9 • PGT = 11.4, 7.6 All differences between pre and post were significant at $p<0.001$	Mean WSAS score difference (pre, post) • iCBT = 15.6, 9.9 • GSH = 17.7, 11.9 • PGT = 16.8, 12.3 All differences between pre and post were significant at $p<0.001$		Overall reliable improvement rate was higher in the iCBT group (67%) compared to GSH (59%) and PGT (41%, $p<0.001$)	
Palacios 2022 (b)		GAD-7 scores decreased over the course of treatment then increased slightly over			Of the 89 participants included in analysis, 70.8% remained in	

Study	Technology	Anxiety measures – GAD-7, BAI and self report measures	WSAS	CORE-OM	Recovery and remission	Acceptability and usage
		9 months follow-up: • Baseline = 11.5 • End of treatment = 3.2 • 3 months follow-up = 4.5 • 6 months = 4.2 • 9 months = 4.5			remission whereas 28.2% had relapsed at the 9-month follow-up Of those who relapsed, 53.8% experienced a relapse of depression and anxiety, 7.7% depression only and 38.4% anxiety only Younger age, having a long-term condition, and residual symptoms of anxiety at end-of treatment were all significant predictors of relapse at end of treatment	

5.2.4 Post-traumatic Stress Disorder

Two included technologies can be used for PTSD (iCT-PTSD, Spring). Two relevant publications were included; one in relation to Spring and one in relation to iCT-PTSD. Table 10 summarises these results.

The company provided additional results from an unpublished randomised controlled trial however the study [redacted]

Comparative results are considered to be outside of the current scope as [redacted] and not included in the scope.

[redacted]

Table 10: Result for Post-Traumatic Stress Disorder

Study	Technology	PTSD specific measures: Change in CAPS-5, PCL-5 and PSS-I	Change in GAD-7	Change in WSAS	Rates of recovery and remission	Acceptability and usage	Therapist time
Wild 2016	iCT-PTSD	Mean PCL-5 scores decreased from 47.90 to 15.80 post treatment (p<0.001) Mean PSS-I scores decreased from 31.7 to 12.44 post treatment (p<0.001)	Mean scores decreased from 11.6 to 4.4 post treatment (p<0.01)	Mean scores decreased from 20.8 to 10.58 post treatment (p<0.05)	9 (90%) participants showed reliable change on the PCL-5, achieving a mean drop of 32.10 points 8 (80%) participants showed a drop of 20 points or more on the PCL-5, meeting criteria for clinically significant change At the end of the treatment, 8 (80%) participants were assessed as not having PTSD by an independent assessor on the PSS-I. The same eight patients met IAPT recovery criteria	Participants spent a mean of 21.7 hrs over a mean period of 9.6 weeks on the app	Therapists made a mean of 10.5 telephone calls during the course of treatment, which equated to a mean total telephone contact time of 3.2 h A mean of 20.7 emails 8 texts were sent to patients The total number of minutes therapists spent supporting patients in the course of the treatment was mean 4.1 h Indirect time spent reviewing case notes etc was comparable with face to face therapy
Bisson (2022)	Spring	CBT-TF group:	CBT-TF group:	CBT-TF group	Not reported		

Study	Technology	PTSD specific measures: Change in CAPS-5, PCL-5 and PSS-I	Change in GAD-7	Change in WSAS	Rates of recovery and remission	Acceptability and usage	Therapist time
		CAPS-5 scores decreased from a mean score of 35.6 at baseline to 13.0 at 16 weeks and 10.9 at 52 weeks GSH group: CAPS-5 scores decreased from a mean score of 34.6 at baseline to 13.1 at 16 weeks and 12.9 at 52 weeks	GAD-7 scores decreased from a mean of 13.4 at baseline to 5.3 at 16 weeks and 3.8 at 52 weeks GSH group: GAD-7 scores decreased from a mean of 13.9 at baseline to 5.6 at 16 weeks and 5.3 at 52 weeks	WSAS scores decreased from a mean of 20.9 at baseline to 10.4 at 16 weeks to 6.5 at 52 weeks GSH group: WSAS scores decreased from a mean of 21.1 at baseline to 8.9 at 16 weeks to 8 at 52 weeks			

5.2.5 Social Anxiety Disorder

Three included technologies can be used for SAD (iCT-SAD, MindDistrict and SilverCloud). No evidence was identified for the use of MindDistrict or Silvercloud for social anxiety. Two studies relating to iCT-SAD were relevant to this review; one non-comparative study (Stott 2013) and one RCT (Clark 2022). Table 11 summarises these results.

The company provided some limited real world results from [redacted]

Table 11: Results for Social Anxiety Disorder

Study	Technology	LSAS	GAD-7	WSAS	Recovery and remission	Drop out/ app usage	Therapist time
Stott 2013	iCT-SAD	LSAS scores reduced significantly from 80 to 39.8 ($p<0.001$) over the course of the treatment (mean 13.7 weeks)	GAD-7 scores reduced significantly from 9.3 to 4.3 ($p<0.01$) over the course of the treatment	Not reported	Nine patients (82%) were classified as treatment responders (improvement of 31% on the LSAS) and 7 (64%) were in remission	No patients dropped out during treatment	Mean iCT-SAD therapist time spent supporting the patient was 3.87 hours compared to mean face to face therapist time of 19.14 hours
Clark 2022	iCT-SAD	See therapist time	No significant between group differences found with mean GAD-7 scores at baseline, post treatment and 12 month follow-up: iCT-SAD = 9.82, 3.75, 3.46 CT-SAD = 8.72, 2.48, 2.41	No significant between group differences found with mean WSAS scores at baseline, post treatment and 12 month follow-up: iCT-SAD = 3.45, 1.77, 1.43 CT-SAD = 2.92, 1.14, 1.04	84% of iCT participants lost their SAD diagnosis at 12 months follow-up compared with 87% in the CT group 67% met me the IAPT recovery criteria in the iCT group compared to 75% in the CT group	2% (1/50) of patients in the digital therapy arm 0 patients in the fact to face therapy arm	Post treatment, iCT patients had dropped 45.5 points on the LSAS after an average of 6.45 h contact with their therapist. In CT, 15.8 h of therapist contact were required to achieve the same drop on the LSAS. iCT is therefore associated with 2.45 times more symptom change per hour of therapist contact time.

6 Adverse events

A search of the MAUDE database and MHRA (field safety notices/device safely information) did not identify any adverse events or safety concerns relating to any of the included technologies. Two included studies listed safety as an outcome (Richards 2020 and Wilhelm 2020). Neither of these reported any adverse events. One specialist committee member noted that digital therapies would not be suitable for moderate or high-risk clients as digital therapy review involves much less detailed safety review compared with one – to – one guided self-help.

7 Evidence synthesis

Where the studies have focused on one specific diagnosis such as PTSD, SAD and BDD, the results are much clearer and may be more reliable. Each condition had 2 relevant studies and reported for the following technologies; PTSD –one iCT-PTSD and one Spring, SAD – both iCT-SAD and BDD – both Perspectives. The non-comparative studies showed that the digital therapies reduced anxiety levels on both general scales such as the GAD-7 but also disorder specific measures. Further, these reductions did persist up to 1-year post treatment albeit with slight increases reported compared to immediately post treatment. Those studies with waitlist control as a comparator showed that these improvements in anxiety symptoms was greater in those that used the technologies. One study reported no difference between the digital therapy (iCT-SAD) group and cognitive therapy group (Clark 2020) indicating that digital therapy can achieve outcomes at least as good as face to face therapy.

Remission rates were also reported for these three conditions. In those with BDD one non-comparative study showed 90% of participants were classed as having responded to treatment (>30% reduction in BDD score) whilst one comparative study showed on 52% were in full or partial remission. However, this was compared to only 8% for the waitlist comparator group. In those with PTSD reporting for the ICT-PTSD technology, one non-comparative study reported 80% (8/10) were classed as in remission. Studies reporting for SAD

showed in the non-comparative study 64% were in remission at end of treatment. However, in the comparative study, levels of remission were slightly higher in the comparative group (face to face cognitive therapy) compared to iCT-SAD users.

There are 13 included studies that focused on generalised anxiety reporting for either Beating the Blues or SilverCloud technologies. Nine of these were non-comparative, 1 compared between African American and white groups,1 compared between African Americans and white groups and between intervention and comparator, 1 compared with 2 other treatments and 1 compared with a waitlist group. Eleven of these studies reported reduced levels of anxiety, as measured by the GAD-7, BAI and PROMIS-Anxiety, over the treatment sessions. Three studies reported reduction in WSAS scores over time and 2 reported reductions in the CORE-OM measure.

Six studies reported on remission and recovery. All showed reduced levels of ‘caseness’ or recovery increase following use of the guided technologies. However, Cavanagh 2011 (Beating the Blues) did not split the recovery rates by diagnosis. One study compared SilverCloud with GSH and PGT and another compared SilverCloud with a waitlist group (Richards 2020). Both found reliable recovery was higher in the Silvercloud group compared to the comparator groups.

Two studies looked at differences between African Americans and white participants in relation to anxiety measures and acceptability/usage of the guided technologies. African Americans showed a greater benefit from the Beating the Blues app in anxiety measures compared to usual care than white participants.

All studies that reported rates of drop out and amount of use of the technologies showed that there was little to no drop out when using the technologies. One study stated 89% of participants would recommend the app (Wilhelm, 2022). This suggests high levels of acceptability and ease of use across all patient groups. However, Jonassaint (2017) did find a slight

discrepancy between ethnic groups as white participants completed more sessions of BtB than African Americans in their study.

8 Interpretation of the clinical evidence

Reviewing the clinical evidence as a whole, it would appear that guided digital technologies do reduce anxiety symptoms (as measured by general and condition specific measures) across different anxiety disorders. In those that have a comparator group, the digital technologies create bigger reductions in anxiety symptoms, except in one study reporting results for SAD and iCT-SAD (Clark 2022). The evidence also suggests that the technologies are easy to use as they have high levels of usage and low levels of drop out across conditions, and tend to have comparable if not increased rates of remission and recovery following use, except again in one study reporting for SAD and iCT-SAD (Clark 2022)

The main limitation of the included evidence is that a large number of the populations reported within the studies are not fully aligned with the scope. There were no studies where participants had a clear DSM-V or ICD-10 diagnosis of GAD but had presented with, sometimes via self-referral methods, as having high levels of anxiety symptoms using the GAD-7 and/or depression symptoms on the PHQ-9. This does not constitute a diagnosis of either disorder and this is a major limitation of the included generalised anxiety studies as they cannot be wholly generalised to the IAPT pathway. Further, these studies grouped participants as those with anxiety and/or depression with results not split by either disorder/symptom group. It is therefore not known which participants showed a reduction in the GAD-7 score, those with anxiety symptoms, depression symptoms or both. Again, this makes the results hard to relate to the IAPT pathway.

There is a general lack of comparator groups within the included evidence and therefore it is hard to know whether the effects seen in these studies are typical or superior/inferior to standard practice or other technologies. Those that did have a comparator group generally used a ‘Waitlist’ comparator which is not within scope and therefore limits the applicability of this evidence.

There is also a lack of therapist or a guided element within the included research and, while for many studies it is indicated that there is a therapist guided element the details are not clearly reported and therapist time is only reported as an outcome in a small number of studies.

In terms of generalisability, the individual technologies have different information, use different methods to interact and apply to different conditions. The EAG considers therefore, it is not appropriate to consider evidence from one technology to be indicative of any clinical effectiveness with a different technology or to use existing data for one condition to infer generalisability to another condition. Many of the studies do not have comparators and do not report aspects such as therapist involvement sufficiently which further limits generalisability. An NIHR HTA report (Gega 2022) reported that to enable the appropriate analysis and meaningful interpretation of evidence syntheses, research studies need to describe in detail the comparators of digital interventions in accordance with existing frameworks for reporting complex interventions, including any support that participants have received in a waitlist or usual care and the EAG would agree with this.

The purpose of the EVA was not to compare technologies with each other, therefore where evidence is available for more than one technology for the same condition, no judgement can be made on which technology (if any) is better.

8.1 *Integration into the NHS*

The adoption of these technologies into the IAPT pathway would not require significant change as IAPT currently facilitates the use of digitally enabled therapies.

Several of the included studies were reporting from within an NHS IAPT setting and these were in relation to specific conditions; PTSD, SAD and BDD. In relation to generalised anxiety, study settings were a mix of NHS-

IAPT and non NHS/UK which makes these some of the included studies much less generalisable.

The main issues to consider when deciding whether to use any of the technologies would be the evidence available, specifically around place in the stepped pathway and therapist time required. If adopted, it is possible that use of digitally guided technologies could reduce the amount of therapist time needed for face to face sessions however this is not currently supported by the available evidence. For generalised anxiety disorder specifically, use of technologies should be weighed against the fact that the evidence available is related to generalised anxiety or symptoms of anxiety and depression.

Limited evidence suggests that digitally enabled therapies are acceptable to patients and therefore adoption of these technologies into IAPT may give patients more control over their treatment.

8.2 *Ongoing studies*

Searches identified a total of 6 potentially relevant ongoing studies with detailed summaries reported in Table 12.

Table 12: Ongoing Studies

Study	Technology	Condition	Design	EAG Comment
NCT03271645 Internet-delivered Interventions for Stress, Anxiety and Depression in the Workplace	SilverCloud	Stress, anxiety and depression	Open label, non-randomised trial	• Study has been withdrawn for logistic reasons. • Study setting was the workplace
NCT04622930 Waitlist-Control Trial of Smartphone CBT for Social Anxiety Disorder (SAD)	Koa Health Perspectives	SAD	Randomised, open-label, parallel assignment	
NCT04034693 Waitlist-Control Trial of Smartphone CBT for Body Dysmorphic Disorder (BDD)	Koa Health Perspectives	BDD	Randomised crossover assignment	Information from the company suggests this study has been completed and results reported in Whilhelm 2022.

Study	Technology	Condition	Design	EAG Comment
ISRCTN12462559 A study of the implementation of Internet-based Cognitive Therapy for Post-Traumatic Stress Disorder within NHS Improving Access to Psychological Therapies (IAPT) services	iCT-PTSD	PTSD	Interventional multi-centre implementation study	
ISRCTN16806208 A randomiSed controlled Trial of therapist-assisted Online Psychological therapies for Post-Traumatic Stress Disorder	iCT-PTSD	PTSD	Randomised Controlled Trial	Listed as ongoing, however company has provided confidential results for consideration and are reported in section 5.2.4 and section 10
ISRCTN72832736 A study of the implementation of internet-based cognitive therapy for Social Anxiety Disorder within NHS Improving Access to Psychological Therapies (IAPT) services (Overcome-SAD)	iCT-SAD	SAD	Interventional multicentre non-randomized implementation study	Listed as ongoing, however company has provided confidential results for consideration and are discussed in section 5.2.5 and section 10.

9 Economic evidence

9.1 *Key economic evidence for anxiety in adults*

A previous early value assessment report has summarised economic evaluations of guided digital therapies for treatment of symptoms of anxiety for both adults and children (GID-MT580). Therefore, any searching outside the topic scope was limited to information on different modelling approaches. In order to consider the optimum modelling approach, a rapid review was carried out to identify key economic evaluations that used a modelling approach for anxiety in adults. We identified 8 published economic modelling studies for any interventions in the management of anxiety (not limited to digital interventions) (You 2022, Baumann 2020, Stiles 2019, Jankovic 2022, Mavranezouli 2015, Najafzadeh 2017, Gega 2022, Health Quality Ontario 2019), including 2 HTA reports (Gega 2022 (NIHR); Health Quality Ontario 2019) These studies were conducted in the UK (n=3), Australia, Germany, US, Canada and Hong Kong.

In addition, the EAG also considered the economic modelling used in the following clinical guidelines:

- CG159 Social anxiety disorder: recognition, assessment and treatment
- CG113 Generalised anxiety disorder and panic disorder in adults: management
- NG222 Depression in adults: treatment and management (in particular the model for treating new episodes of depression).

The economic models varied in terms of the model type and structure. Both decision tree and markov models were seen, as well as modelling that combined both methods, and one discrete event simulation (Najafzadeh 2017). The time horizon varied significantly, from 7 months, 3-5 years to lifetime. Perspectives undertaken were either societal or health system. The acceptance and adherence rate of internet-based CBT was only explicitly incorporated into the decision model by You et al. Many of the models were non-specific to a particular anxiety disorder, and the majority included only one intervention per arm, without referral to an additional intervention, other than medication.

The NIHR HTA report (Gega 2022) undertook a Markov model with 3-month cycles (adapted from Jankovic 2021) over a lifetime horizon to evaluate the cost-effectiveness of digital interventions in GAD. Health states included in the model were: no anxiety, mild, moderate or severe anxiety. However, Health Quality Ontario (2019), considering digital interventions for anxiety, conducted a short-term simplified decision tree model of 12-month time horizon, and subsequently combined this with a Markov microsimulation model.

This approach is more in line with the economic modelling described in NICE clinical and national guidelines for SAD and depression which use a decision tree for short term modelling of the pathway, and links this with a longer-term Markov model to consider the movement between no anxiety and different anxiety levels over a number of years. The EAG consider that this approach had a number of benefits, although most were not implemented within existing models due to lack of data:

- More explicit pathway during early stage of the model
- Ability to model treatment switching during the early stage of the model
- Ability to model changes in effectiveness due to treatment position in pathway (e.g. effectiveness might be different for group therapy delivered as first intervention, or group therapy after digitally enabled therapy)
- Ability to model combined therapies e.g. medication together with therapeutic approach.

A short narrative summary of the key findings and limitations of modelling reported by the two HTA reports and two NICE guidelines for anxiety is presented in Table 13. These report evidence for generic categories of interventions rather than specific technologies, and the Health Quality Ontario (2019) report is across all anxiety disorders. They all consider digital interventions as part of their evaluation. Health Quality Ontario (2019) is the only one that considers a stepped pathway or any treatment switching, and this is reported as a secondary exploratory analysis. Although others models have extended time horizons, up to a lifetime, they are restricted to a single intervention delivered once per pathway arm (with the exception of medication in some cases).

The NIHR HTA report (Gega 2022) considered 76 economic evaluations and found that they did not capture all relevant comparators or long-term impacts, and that the complex nature of the interventions presented significant challenges. In general, the review (work package 1) found that digital interventions were likely to be cost effective if compared to no intervention or non-therapeutic interventions. They reported that this was less clear where the comparator was face to face therapy or printed manuals.

A network meta-analysis of RCTs (work package 2) found that uncertainty was too great to draw conclusions on digital interventions compared to no intervention, non-therapeutic active control or group therapy.

Modelling (work package 3) found that digital interventions (for GAD) had lower NMB than medication or group therapy, but greater NMB than non-

therapeutic interventions or no intervention. They found that this was driven by clinical outcomes rather than intervention costs. Value of Information analysis suggested that treatment effect had the greatest value, at £12.9 Billion.

Table 13: Summary of HTA and NICE Guidance

	Interventions and population	Modelling approach	Key findings	Key limitations
Gega 2022 (NIHR)	GAD Supported and unsupported therapy, face to face individual and group therapy, medication and usual care	Markov model, lifetime horizon (Jankovic 2022)	Effectiveness results were inconclusive due to uncertainty about appropriate comparators. Digital interventions were likely to be cost effective compared to no intervention, or non-therapeutic controls. This was less clear compared to face to face therapy or printed manuals. Cost effectiveness was driven by how effective technologies were, rather than how much they cost. Clinical effectiveness was also a key driver of uncertainty.	Pooled evidence for similar interventions Single treatment only per pathway Likely to be heterogeneity in patient pathway
Ontario HTA	Usual care vs interventions including guided digital CBT and face to face CBT. Depression and anxiety (modelled separately)	Decision tree (12 months) and Markov. 1 week cycle, lifetime horizon	Guided digital CBT was likely to be good value for money compared to waiting list, but effectiveness was uncertain compared to face to face or group CBT. Exploratory analysis of digitally enabled therapies in a stepped care model appeared to present good value for money compared to usual care (including medication and GP follow up)	Pooled evidence for similar interventions Primary modelling was for a single intervention during pathway. Secondary modelling considered a stepped pathway
CG113	GAD Considers low and high intensity psychological interventions. Modelling is for	Cost analysis: decision tree (35 weeks) for low intensity intervention	Digitally delivered CBT was found to be cost effective compared to a waitlist. It was noted that this does not represent routine practice in the NHS for GAD.	Single treatment only per pathway Waitlist comparators in clinical studies Study population with mixed anxiety disorders

	Interventions and population	Modelling approach	Key findings	Key limitations
	low intensity psychological interventions compared to waiting list.	s		Study reporting: use of continuous outcomes and inconsistent definitions of response and remission
CG159	SAD Compares psychological and pharmacological interventions	Hybrid model, decision tree (12 weeks) and Markov (5 years) (Mavranezouli 2015)	CT (Clark & Wells) was most cost effective due to higher effectiveness and lower risk of relapse compared ot medication. For interventions ranked by NMB, Internet based self help ranked 7th (with support) and 20th (without support)	Single treatment only per pathway Limited data available for recovery Lack of robust evidence on the relative risk of relapse

9.2 *Key economic evidence for Digitally enabled therapies delivered with support, for anxiety in adults*

The EAG conducted a combined literature search for both clinical and economic evidence (see Section 4.1). Additional economic studies were identified from the references of a similar report: Guided dCBT for CYP with mild to moderate anxiety or low mood: an Early Value Assessment (MT580). The economic searches from this report were updated to identify any literature published since August 2022. The economic literature searches returned a total of 53 records. Details of the EAG economic searches are provided in Appendix A.

Four studies were identified that were for the intervention technologies included in the scope (McCrone 2004, Richards 2020, Bisson 2022, [redacted]), however only one reports a comparator that is within the scope. All are within trial analyses, and are grouped by indication and summarised in Table 14. The digitally enabled therapies that were evaluated were cost-effective when compared to usual care, waitlist or a non-IAPT comparator, but were less conclusive compared to face to face therapy.

Generalised anxiety, and non-specified anxiety disorders

Two studies (McCrone 2004, Richards 2020) looked at mixed populations of people with depression, mixed depression and anxiety or anxiety disorders. Neither presented economic results for patients with anxiety alone or with mixed depression and anxiety as sub-group analysis. Both of these found the intervention to be cost-effective compared to either waiting list or usual care. Neither reported cost-effectiveness compared to interventions at a similar stage of the IAPT pathway.

McCrone et al (2004) report within trial cost effectiveness of Beating the Blues in addition to usual care compared to usual care alone for people with a diagnosis of depression (39%), mixed depression and anxiety (49%) or anxiety disorders (12%). The primary outcomes for clinical reporting and for cost-effectiveness are based on outcome measures for depression, and there is no sub group analysis comparing a population with a primary descriptor of anxiety. The paper reports a 99% probability of cost effectiveness, compared to usual care alone, at a £15,000 WTP threshold. This is based on 8 months follow up post randomization, and using depression free days to estimate QALYs. This is unlikely to be the most appropriate outcome for people with anxiety. The use of health care resources is listed for both study arms, however there is no clear description of usual care, and it is unclear if the healthcare resource includes interventions for anxiety or depression. The provision of usual care alongside the digitally enabled therapy is likely to impact effectiveness compared to the use of digitally enabled therapy on its own.

Richards et al (2020) report within trial cost effectiveness of SilverCloud with waiting list for people who are newly referred to IAPT and meet the "caseness" threshold for either GAD-7 or PHQ-9 with 290 people having a diagnosis at baseline (52% major depressive disorder, 64% anxiety, including mixed depression and anxiety). The primary outcomes include GAD-7 and PHQ-9 and cost effectiveness is calculated using QALYs collected from EQ-5D-5L with a cross walk, as recommended in the NICE reference case. The waiting list comparator is not within scope, and will result in a greater incremental effectiveness than comparison to other step 2 interventions. Data

was only collected for 8 weeks in the waiting list group, with longer term results based on extrapolation for the comparator. Data for SilverCloud was collected for 1 year. The authors reported a 47% probability of being cost effective at 8 weeks, with a WTP of £30,000, or a 91% probability of being cost effective at 1 year.

Post Traumatic Stress Disorder

Bisson et al (2022) report within trial cost effectiveness outcomes for an RCT comparing Spring internet delivered trauma focused CBT (CBT-TF) with face to face delivery of similar content. The population was adults with a primary diagnosis of mild to moderate PTSD. The study was a non-inferiority study, and the clinical findings were that the internet delivered CBT-TF was acceptable and non-inferior at 16 weeks, while being inconclusive in favour of face to face CBT at 52 weeks. The study collected EQ-5D-5L data, cross walked to give utilities (NICE reference case), resulting in a non-significant decrease of 0.04 QALYs at 1 year for the internet CBT-TF when compared to face to face delivery. Therefore, although the internet delivery was significantly cheaper than face to face (£277 vs £729 for the two interventions) it resulted in poorer outcomes. Additional unpublished submissions reported that there was a [redacted] The authors suggest that the use of guided self help is appropriate due to the reduction in therapist time leading to an increased availability of therapy.

It was noted that all therapy was delivered by experienced psychological therapists working in high intensity IAPT services or psychological services, experience of delivering CBT-TF for PTSD and additional training in the interventions. The company explained that at present in normal practice 50% of therapists delivering Spring are band 5, and not fully accredited face to face cognitive behavioral therapists, and this is expected to increase to100%. It is possible that this change in delivery could impact on real world effectiveness seen compared to that reported in the paper.

[redacted]

The details of the clinical studies are reported separately in Table 5 to Table 11. Key outcomes from economic analysis are reported in the Table 14, however in most cases there are large amounts of data available either within the paper or as supplementary information that is not included in these tables.

Table 14: Economic Studies

Study name and location	Study Design, intervention(s) and comparator	Economic approach, time horizon	Selected Health Outcomes	Costs	Cost effectiveness	EAG comments
SilverCloud						
Richards 2020. UK *(See also tables 5 and 9)*	**Design:** RCT **Participants:** People with depression, anxiety, and comorbid anxiety and depression **Intervention:** SilverCloud 8 week, total follow up 1 year (n=241) **Comparator:** waitlist control limited to 8 week follow up (n=120)	Within trial ITT analysis at 8 weeks. Use of extrapolation to model comparator, allowing comparative analysis of intervention data at 1 year. NHS perspective Complete case reported in addition	GAD-7 mean (SD) Intervention: 0 week: 12.66 (4.69) 8 week: 8.2 (5.31) 1 year: 6.08 (4.81) Waitlist: 0 week:: 12.54 (4.18) 8 weeks 10.79 (5.12) EQ-5D-5L cross walk mean (SE) Intervention: 0 week: 0.657 (0.013) 8 week: 0.724 (0.012) 1 year: 0.7622 (0.013) Waitlist: 0 week: 0.645 (0.020) 8 weeks 0.676 (0.024)	Mean cost(SE) Intervention: 0 week: £122.91 (£18.24)	For WTP of £30,000/QALY At 8-weeks, 46.6% probability cost-effective At 1 year 91.2% probability cost effective	Limited direct applicability due to comparator choice and heterogenous population. There is no sub-group reporting of patients with a diagnosis of anxiety. Use of waitlist control will result in higher incremental effectiveness than if the comparator were group CBT. This may result in a higher probability of cost effectiveness, as identified by study authors.
Spring						
Bisson	**Design:** RCT, non-	Within trial	ITT CAPS-5 Mean (SD)	Mean cost (95%	Incremental cost: −£572.55	This paper is within

Study name and location	Study Design, intervention(s) and comparator	Economic approach, time horizon	Selected Health Outcomes	Costs	Cost effectiveness	EAG comments
2022 UK *(see also tables 5 and 10)*	inferiority **Participants:**Adults with primary diagnosis of mild to moderate PTSD (n=196) **Intervention:** Spring internet delivered CBT-TF (and 4 x 30 min Face to face plus 4 phone calls; n=97) **Comparator:**: Face to Face individual CBT-TF (12 x 60-90 min; n=99)	analysis NHS perspective, 1 year time horizon.	Intervention: 0 weeks: 34.6 (6.8) 1 year: 12.9 (11.6) Comparator: 0 weeks: 35.6 (6.7) 1 year: 10.9 (11.1) EQ-5D-5L (utilities) mean (SD) Intervention: 0 weeks: 0.5 (0.3) 1 year: 0.7 (0.3) Comparator: 0 weeks: 0.6 (0.2) 1 year: 0.8 (0.2)	CI) Intervention: £277 (£253 to £301) Comparator: £729 (£671 to £788) P<0.001 Total NHS Cost (95% CI) Intervention: £1,325 (£942 to £1,709) Comparator: £1,898 (1,565 to £2,231)	(−£1080.14 to −£64.96) Incremental QALYs −0.04 (−0.10 to 0.01) Incremental NMB(£) at £30kQALY −£460.41 (−£2,143.27 to £1,222.45) [redacted]	scope for both the intervention, comparator and population. Therapy was carried out experienced psychological therapists, however in the submission the intervention is described as being delivered by trained therapists at band 4 and 5. Additional information was provided in the form of an accepted HTA report chapter, this is marked AiC
Beating the blues						
McCrone 2004. UK Study reported in Proudfoot 2004	**Design:** RCT **Participants:** Adults with depression, anxiety, or mixed depression and anxiety **Intervention:**	Within trial analysis. 8 month time horizon. Perspective not clearly stated, costs are for healthcare and for loss of		Total NHS cost (1999-2000) Mean (SD) Intervention: 6 months pre: £203 (£262) 8 months post: £397 (£589) Comparator:	Incremental cost £40 at 8 months (excluding employment) Authors report over 99% change of cost effectiveness at a WTP threshold of £15,000	Limited direct applicability due to comparator choice and heterogenous population. There is no sub-group reporting of patients with a diagnosis of anxiety. Quality of life is not

Study name and location	Study Design, intervention(s) and comparator	Economic approach, time horizon	Selected Health Outcomes	Costs	Cost effectiveness	EAG comments
	Beating the Blues, iCBT (n=146) **Comparator:** Usual care including GP, referral to counselling, practice nurse, or mental health professional, and treatment of physical conditions (n=128)	productivity.		6 months pre: £236 (£404) 8 months post: £357 (£575)		directly measured, effectiveness is given per unit of the Beck Depression Inventory, and depression free days are used to estimate QALYs.
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Limited direct applicability. The comparator is also not a routinely offered treatment for PTSD and is therefore not within scope. There are some difficulties in interpreting the results due to pre-publication summaries without the same level of detail as a full paper. Also, the results are presented in blinded format.

Study name and location	Study Design, intervention(s) and comparator	Economic approach, time horizon	Selected Health Outcomes	Costs	Cost effectiveness	EAG comments
						The EAG were unable to verify ICER calculations from the results presented.

9.3 *Conceptual modelling*

Existing models have a variety of structures and there is not one single version that is widely accepted. There are however a number of factors that would ideally be included in any model:

- The long-term nature of anxiety disorders
- The possibility that recovery may be followed by relapse or recurrence
- The impact that previous or adjunct treatment may have on the efficacy outcomes (this could be IAPT interventions, medications or others)
- Healthcare and personal social service costs incurred other than direct interventions for anxiety, including those outside the IAPT pathway
- Align with IAPT pathways and definitions, where used for decision making in the IAPT pathway.

Ideally clinical data used in the inputs will:

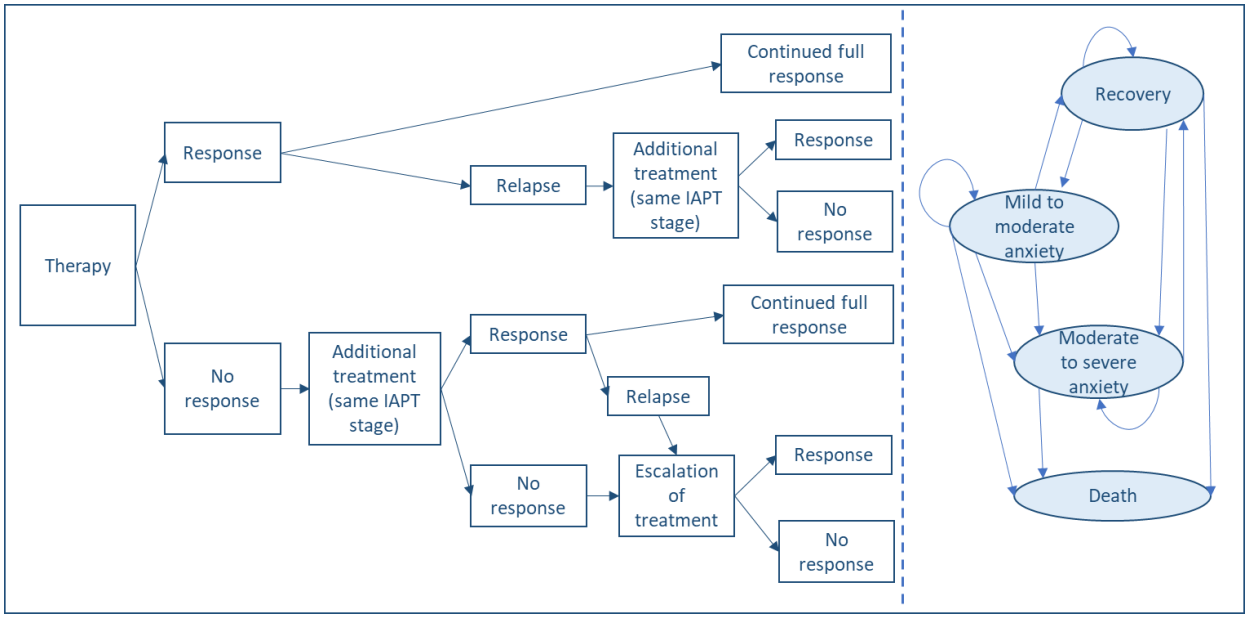
- be for the anxiety descriptor that is under consideration
- use interventions that are delivered in the same way as described by IAPT (e.g therapist guiding time included)
- be reported using IAPT defined terms, such as caseness thresholds, recovery and reliable recovery
- use of longer term data to demonstrate continued recovery or relapse, with reporting at multiple time points (short and longer-term)
- report ITT results, or according to IAPT manual methods, so that those who drop out, or are missing from the final results are assumed not to experience recovery.
- Include comparators that reflect the most appropriate current treatment, or mix of treatments, usually on the IAPT pathway. These should also be reported fully in any clinical studies.

A potential solution to capture the stepped IAPT pathway is to use a decision tree for a fixed duration, and follow this with a markov model over a longer time horizon. This approach has been demonstrated in previous models (You 2022, Mavranezouli 2015, Health Quality Ontario 2019). Although most previous models have not attempted to include subsequent treatments (either repeating the first intervention, or switching to an alternative approach), the EAG feel this could be used to model one or two subsequent treatments on the pathway. One other model that was identified considered a stepped pathway (Stiles 2019), limiting the time horizon to 12 months and using a decision tree only.

Having captured the initial costs and effectiveness of initial steps on the pathway, the Markov component would consider longer term impacts of future relapses or changes in health state of each intervention, using state based costs, transitions and utilities.

Different modelling approaches could be used to satisfy these requirements, but an example of how such a model may appear is given below. Any new model is unlikely to require the same pathway or approach for all anxiety disorders, as there will be differences in the likelihood of a second or third intervention at the same IAPT stage, or immediate escalation. Preparation of a model for a specific disorder would require further consultation with clinical experts and incorporation of IAPT recommendations specific to that population and pathway.

Figure 2: Theoretical hybrid model for anxiety



Modelling used by EAG for this report

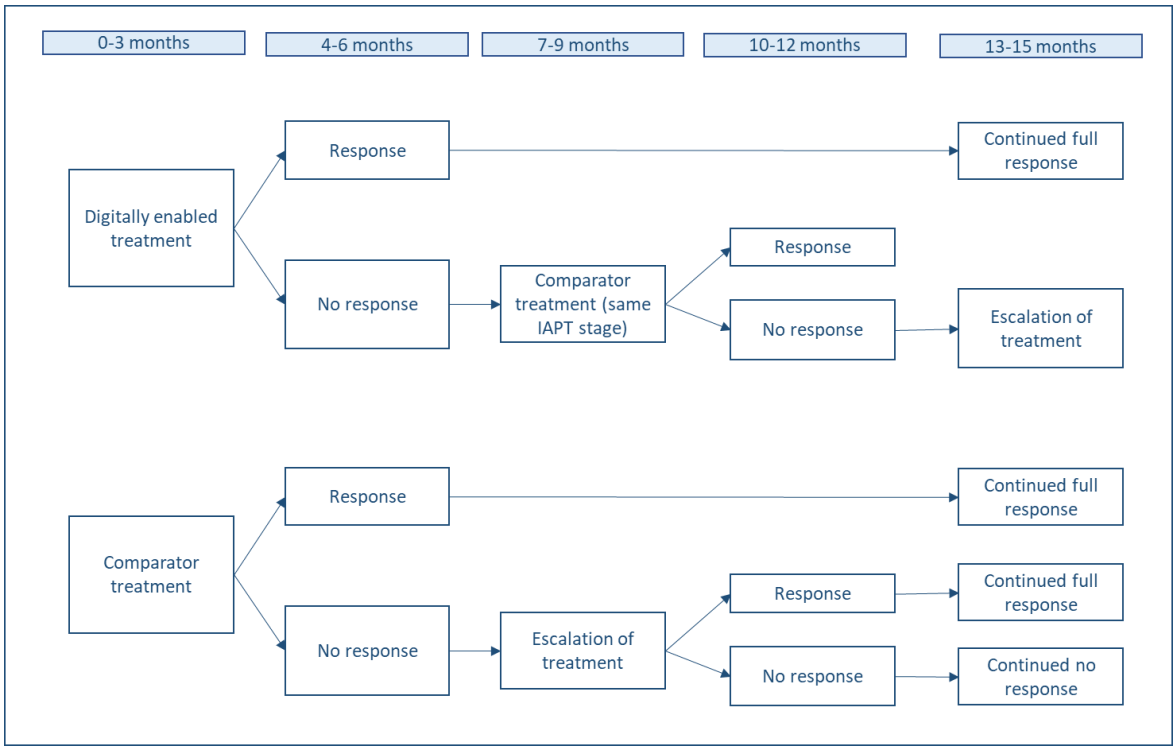
The model used is a 15-month cost effectiveness model using a decision tree structure and taking an NHS and personal social services perspective. The time horizon has been chosen as a short duration that allows progression from the initial intervention, to a second intervention at the same IAPT stage, and further escalation if needed, given the assumptions listed below. The model structure is limited by the amount and type of data available, and numerous assumptions have been made in order to populate it. For these reasons it should be seen as an initial exploration of the economic impact of the technologies, and extreme caution taken in interpreting the results.

The model compares digitally enabled therapy with the alternative therapy that would normally be offered at that stage (i.e. group CBT for stage 2 or individual CBT for stage 3). It assumes that those patients treated with digitally enabled technology either respond, and need no further treatment within the time horizon, or do not respond and are offered the comparator treatment at the same stage. If they do not respond to this then treatment is escalated. The model does not include outcomes from this third treatment due to the short time horizon. The structure is intended to capture the impact of both successful treatments using digitally enabled therapies, and the impact of offering additional treatments to those patients who do not respond.

The model is split into three-month periods, with one intervention occurring within a three-month period, followed by a three-month period of assessment or waiting list during which time there is no intervention, before any additional intervention is provided. Utility values remain static during the intervention period, but then increase if there is a response.

Net benefit was reported at a willingness to pay threshold of £20,000 per QALY and confidence intervals were calculated using probabilistic sensitivity analysis using 10,000 simulations.

Figure 3: EAG simple decision tree model



Assumptions and limitations

A number of simplifications were required to allow the model to be built using available data, and to approximate a number of different pathways. These simplifications may not completely reflect actual patient pathways or clinical realities, and this is discussed in table 15.

Table 15: Assumptions and limitations of the simple model

Assumption	Discussion
Patients are grouped into response and no response	In reality this will be partial responses, some of which will also require additional treatment.

Assumption	Discussion
Patients treated with stage 2 interventions comprise 50% mild and 50% moderate anxiety	The IAPT description is for people with mild to moderate anxiety. This assumption is used to estimate the utility values for this group, which are available for mild, moderate and severe anxiety.
Patients treated with stage 3 interventions comprise 50% moderate and 50% severe anxiety	The IAPT description is for people with moderate to severe anxiety. This assumption is used to estimate the utility values for this group, as in the comment above.
Patients receiving comparator treatments are expected to receive the same benefits regardless of having prior digitally enabled therapies or not	We cannot know the impact of this assumption. It is possible that prior exposure to digitally enabled therapies may make patients more receptive to subsequent treatment. It is also possible that those patients who did not respond to digitally enabled therapies are a subgroup who are also less likely to respond to alternative treatments.
The proportion and impact of patients with other previous or adjunctive treatments is assumed to be the same in each arm.	We know that many patients receive multiple different treatments, and that these include medicines that are prescribed outside the IAPT pathway. There is not sufficient information to group patients according to previous or adjunctive treatment, however it is likely to have an impact on the outcomes experienced.
Study data for interventions reflects real word sufficiently to use the IAPT database as a comparator	Study data may be expected to be somewhat more positive than real world data if patients are engaged with the study having consented, protocols may be more rigorously adhered to and more data collected. Only one intervention had a comparator that was appropriate for modelling, and therefore we have used IAPT data due to the large numbers and availability. This may exaggerate the impact of the intervention. The IAPT database also has limitations, which are discussed in the clinical inputs section
Time durations between treatments are fixed	It is assumed that the initial treatment lasts for 3 months, and if it is not successful then another treatment is offered following a 3 month wait or assessment period.
Treatment response has a duration of at least 1 year	Those people who respond to treatment are assumed to remain at that response level for the remainder of the model. There is no modelling of relapses.
Recovery rates are applicable across different descriptors	For all interventions that can be used for different anxiety descriptors, the recovery rate is obtained from studies that are for a population with mixed anxiety descriptors, and in most cases also depression descriptors (with or without anxiety).
No spontaneous recovery	The model does not allow for patients whose condition may improve without intervention.
Interventions are assumed to be delivered over 3 months	Actual therapist input is based on more detailed data, however for the decision tree process a three month period is assumed, which is used to calculate utilities. There is a 3 month assessment / waiting period before a further intervention is delivered
Utilities change at the end of	In reality utilities may change throughout the intervention

Assumption	Discussion
the intervention period	period, and the modelling is a simplification.
No costs other than those of delivering IAPT interventions are included	Patients who do not experience improved symptoms following the modelled interventions may seek other healthcare resources such as GP appointments, or potentially may deteriorate further and require more intensive interventions.
No costs are included for hardware to support the intervention	It is assumed that services have sufficient internet and computing capability and patients would use existing personal devices and internet connections. There may be situations where devices are provided to enable participation for patients, however this is unlikely to be common practice in the NHS. Inclusion would be unlikely to change any of the report conclusions.

Main clinical parameters

Effectiveness in previous models is either shown by movement between recovery / non-recovery, (which would be defined using the GAD-7 threshold) or by group patients into mild, moderate and severe anxiety states, for which GAD-7 thresholds of 5,10 and 15 are widely accepted. Both have been used in previous models, and lend themselves somewhat to decision tree and Markov model structures respectively (but not exclusively). The EAG has used the recovery / non-recovery approach within the model. Reliable recovery could also be used, and is reported in the IAPT database and some of the clinical studies, but would have reduced the number of technologies with evidence. In designing future studies and modelling, use of reliable recovery may be more robust, however additional clinical advice could be sought for the relevant indication.

Effectiveness for the digitally enabled therapies has been taken from available clinical studies, which share a number of serious limitations.

Many of the trials group patients with anxiety descriptors and depression descriptors together in the results, and also group sub-descriptors of anxiety together. The information in the IAPT database indicates that responses to one therapy type for patients with different descriptors may not be equivalent.

The majority of papers in the clinical evidence use mean cohort score at two time points as their primary outcome, or they may use the mean change per patient between two time points. Both of these are problematic for economic

modelling, as we do not have information on the distribution within the trial population in order to calculate progression to other treatments or appropriate utilities.

The studies used for individual technologies are presented in Table 14, and are also presented in more detail in the clinical evidence section.

Use of IAPT database as a comparator

Only one of the economic analysis papers has an appropriate comparator for the scope of this report. Therefore, the IAPT database has been used as a large source of real-world evidence.

There are limitations in using the IAPT database for this purpose including:

- Studies carried out under trial conditions may experience higher response rates than those reported in real world data, due to strict inclusion criteria, more complete reporting and higher motivation for both staff and participants. As digitally enabled therapies are modelled using trial data, this may increase the resultant cost-effectiveness.
- IAPT data requires two datapoints to be able to report recovery, and therefore patients who don't engage for a first or second appointment are not included in the recovery data. Trial participants will be included in an intention to treat analysis even if they do not engage with the therapy, however they have to have already engaged at some level to have consented to participate. The net effect of this is unknown.
- CBT can be delivered in a group or individual setting; however, these are grouped together within the IAPT database. These have different cost implications and may be delivered within different IAPT stages.

The EAG model is based on supplementary IAPT data that allows us to model a stepped pathway including recovery rates for step 2 and step 3 treatments, but analyses data in a slightly different way.

The main IAPT database and report looks at complete episodes of care and considers changes from the initial assessment to the final appointment. This may involve more than one therapy, and these may be delivered at one or more IAPT steps.

The IAPT data used for the EAG base case analysis breaks down recovery results by therapy type. This data considers only instances within an overall episode of care where there were at least two session coded as the same therapy type. The means that the initial assessment is not captured and this may have a therapeutic effect prior to the start of the first recorded therapy session. It is likely that intervention trial data will include this initial assessment at the start of the trial, and this may result in higher clinical effectiveness being shown for the trial data than within the IAPT secondary analysis.

We have included an additional scenario that considers the use of overall recovery rates from the main IAPT database. It should be noted that there are also very significant limitations of this approach. The data is presented for a complete episode, and the model uses the same clinical effectiveness for each treatment iteration. This scenario is an exploration of possible impact, and should not be taken as a final result.

Table 16: Main Clinical Parameters

Variable	Value	Distribution	Source	EAG commentary on availability, quality and reliability of the source/s
Recovery rate, digitally enabled therapies				
Beating the blues	0.5	B(113, 113)	Cavanagh 2011	Heterogenous population. Intervention was not guided. Overall recovery reported as 50%, however this number may include participants who were not at caseness at baseline
Cerina	n/a		Cerina Short Report	No data available on recovery rate. Unpublished data made available on a small pilot study showing mean GAD-7 scores before and after, completed by 20 out of 43 participants. Change from 10.2 to 9.2
iCT-PTSD	[redacted]	[redacted]	Company submission, unpublished data	[redacted] Authors note that the recovery criteria require a reduction below the clinical threshold for both PTSD and depression symptoms, and that those who drop out of the study are assume not to have recovered.
iCT-SAD	0.67	B(33, 16)	Clarks et al., 2022	All participants have a diagnosis of SAD. Intervention was guided. IAPT recovery at 12 months, patients who have moved from caseness and below clinical threshold for both SAD (SPIN score) and PHQ-9. Missing data assumed non-recovered
Iona Mind	n/a			There is no available data for this product.
MindDistrict	0.72	B(27, 0.03)	Manufacturer submission	Heterogenous population. Guiding unknown Manufacturer submitted 72% recovery rate based on data from two IAPT providers. This includes all use of MindDistrict supported modules and for all users of the platform. There is no additional data to allow EAG critique. For these reasons, this should be treated with additional caution.
Perspectives	0.516	B(16, 15)	Wilhelm et al., 2022	All participants had a primary diagnosis of BDD. Intervention was guided. This is based on an assessment at 12 weeks of full or partial remission in those who completed the follow up assessment: Perspectives: 52% (16/31) from total of 40 randomised Waitlist: 8% (3/37) from total of 40 randomised This is not an IAPT definition, and we cannot be certain how many would fulfil the

Variable	Value	Distribution	Source	EAG commentary on availability, quality and reliability of the source/s
				IAPT criteria for recovery, therefore should be treated with additional caution.
Resony	n/a			There is no evidence available that would allow us to complete the model for Resony.
SilverCloud(all)	0.464	B(90, 104)	Richards et al., 2020 (recovery rate at 8 weeks, reliable is available)	Richards: Heterogenous population. Intervention was guided. At 8-week) follow-up 46.4% (90/194) of the intervention arm relative to 16.7% (15/90) control-arm participants recovered. Amongst 3-month M.I.N.I. interview completers (total n = 179) 50% (24/48) with anxiety, and 46% (30/65) with comorbid depression and anxiety diagnoses, did not meet diagnostic criteria anymore at 3-months. Alternative, Duffy: N=100 participants had full data at all time points. 99 participants were above clinical caseness threshold at baseline; 22 (22%) had achieved recovery by iCBT exit and 20 (20%) had achieved reliable recovery; 33 were in recovery at point of service exit all of which reliably recovered.
Spring (PTSD)	0.818	B(63, 14)	Bisson et al., 2021 (recovery rate, reliable not available)	All participants had diagnosis of PTSD. Intervention was guided. At 16 weeks,14 of 77 participants (18%) using iCBT were still classed as PTSD at end, comparator was 12 out of 83 participants (15%). For an ITT approach that assumed no recovery for those who are lost to follow up, this would be 35% (34/97) for intervention and 28% (28/99) for comparator).
Wysa	n/a			There is no evidence available that would allow us to complete the model for wysa.
Recovery rate, IAPT pathway				
IAPT Step 2, GAD	0.511	B(24188, 23157)	IAPT database 2021-2	Weighted recovery rate of each Step 2 interventions for GAD
IAPT Step 2, other	0.396	B(6233, 9493)	IAPT database 2021-2	Weighted recovery rate of each Step 2 interventions
IAPT Step 3, PTSD	0.131	B(2560, 16928)	IAPT database 2021-2	Recovery rate of IAPT CBT for PTSD

Variable	Value	Distribution	Source	EAG commentary on availability, quality and reliability of the source/s
IAPT Step 3, Social Phobia (SAD)	0.375	B(3903, 6517)	IAPT database 2021-2	Recovery rate of IAPT CBT for Social Phobia
IAPT Step 3, BDD	0.482	B(104,112)	IAPT database 2021-2	Recovery rate of IAPT CBT for BDD (note that the number in database is low)

Resource identification, measurement and valuation of expected key cost drivers

Table 17: Key Cost Parameters

Variable	Value	Distribution	Source	EAG commentary on availability, quality and reliability of the source/s
dCBT licence cost (per user)				
Beating the blues	[redacted]	[redacted]	Company	Costs are based on the company submissions in each case, using pricing based on an assumption of 1,000 licences for those that have a volume-based pricing structure, with additional assumptions due to different price structures between devices. Some products are not currently provided commercially, therefore costs are estimated only.
Cerina	[redacted]	[redacted]	Company	
iCT-PTSD	[redacted]	[redacted]	Company	
iCT-SAD	[redacted]	[redacted]	Company	
Iona Mind			Not commercialised in UK	
MindDistrict	[redacted]	[redacted]	Company	
Perspectives	[redacted]	[redacted]	Company	
Resony	[redacted]	[redacted]	Company	
SilverCloud	£49.90	U(40, 50)	Company	
Spring	£40.00	U(40, 50)	Assumption	
Wysa	[redacted]	[redacted]	Company	

Variable	Value	Distribution	Source	EAG commentary on availability, quality and reliability of the source/s
Therapist cost calculations				
Therapist unit costs in dCBT (per hour)				
Psychological wellbeing practitioner	£38		PSSRU (2021)	Mean of band 4 (£35) and band 5 (£41), community based scientific and professional staff, not including qualifications.
High Intensity Therapist (HIT)	£60		PSSRU (2021)	Mean of band 6 (£54) and band 6 (£65), community based scientific and professional staff, not including qualifications.
Step 2 interventions, assume delivered by PWP, bands 4 & 5				
Individual non-facilitated self-help	£0		IAPT guidance, PSSRU (2021)	Minimal
Individual guided self-help	£95		IAPT guidance, PSSRU (2021)	IAPT guidance is 5-7 weekly or fortnightly face to face or telephone sessions, each 20-30min. Assume 6 x 25 minutes.
Psychoeducational groups	£38		IAPT guidance, PSSRU (2021)	IAPT guidance is ratio 1 therapist to 12 participants, 6 weekly sessions, each 2 hours.
Brief individual CBT + self-help materials or telephone support	n/a		IAPT guidance, n/a	IAPT guidance is up to 10 therapist hours per patient, assume 10 hours. Not included, as information on uptake not possible to disaggregate from IAPT database.
Group CBT	n/a		IAPT guidance, n/a	May receive >10 hours per patient. Not included, as information on uptake not possible to disaggregate from IAPT database.
Step 3 interventions, assumed delivered by HIT, bands 6 & 7				
GAD	£833		IAPT guidance, PSSRU (2021)	Individual high-intensity psychological intervention, 12-14 sessions x 1 hour. Assume 14 hours
PTSD	£595		IAPT guidance, PSSRU (2021)	Individual high-intensity psychological intervention, 8-12 sessions x 1 hour. Assume 10 hours
SAD	£803		IAPT guidance, PSSRU (2021)	Mean of: book based sessions, support for total of 3 hours, or 14 sessions of 90 min, or

Variable	Value	Distribution	Source	EAG commentary on availability, quality and reliability of the source/s
				15 sessions of 60 min and 1 of 90 min.
BDD	£595		IAPT guidance, PSSRU (2021), Assumption	Mix of group and individual CBT is offered initially, but no guidance on therapist time or number of sessions. Both individual and group CBT can be offered at approx. 10 hours per patient (see PTSD and Group CBT information above). Therefore, assumption of 10 hours with high intensity psychological intervention.
Mean IAPT costs (therapist time)				
Step 2, GAD	£86	N(88, 9)	IAPT database, 2021-2, NICE GAD guideline	Weighted mean of provided stage 2 interventions (IAPT database) with calculated cost based on estimated therapist time of each intervention NICE GAD guideline, IAPT database)
Step 2, Others	£84	N(84, 8)	IAPT database, 2021-2	Weighted mean of provided stage 2 interventions (IAPT database) with calculated cost based on estimated therapist time of each intervention NICE GAD guideline, IAPT database)
Step 3, PTSD	£595	N(595, 60)		Calculated cost based on estimated therapist time for IAPT Step 3 therapy (NICE PTSD guideline)
Step 3, SAD	£803	N(803, 80)		Calculated cost based on estimated therapist time for IAPT Step 3 therapy (NICE SAD guideline)
Step 3, BDD	£595	N(595, 60)		Calculated cost based on estimated therapist time for IAPT Step 3 therapy using the NICE PTSD guideline, as no guidance for BDD available
Step 3, others	£833	N(833, 83)		Calculated cost based on estimated therapist time for IAPT Step 3 therapy (NICE SAD guideline)
Medication cost per day	£1.13	U(1, 2)	BNF, 2022	Assumed sertraline 100mg per day was prescribed. (50-200mg/day as range) Applied as adjunct to step 3 therapy, following no response to initial step 3 intervention.
Therapist costs as part of guided therapy for intervention arms (adjunct to intervention cost)				
Step 2	£95	U(88, 103)		Estimated using recommended therapist time in IAPT Step 2 guided therapy, delivered by PWP. IAPT guidance is 5-7 weekly or fortnightly face to face or telephone sessions, each 20-30min.

Variable	Value	Distribution	Source	EAG commentary on availability, quality and reliability of the source/s
				Assume 6 x 25 minutes.
Step 3, PTSD	£238	U(216, 260)	Ehlers et al., 2020	Estimated using trial protocol, 4 hours per participant (iCT-PTSD: 12 weekly phone calls (average 4 hours per participant), Spring: 3 hours face to face + 4 short phone calls), delivered by HIT
Step 3, SAD	£384	U(348, 419)	Clarks et al., 2022	Estimated using trial data (Average 6.45 hours per participant)
Step 3, BDD	£238	U(216, 260)	Assumption	Trial reported 1 hour therapist support, but within IAPT this may be closer to other Step 3 interventions. Therefore the value for PTSD has been assumed.

Table 18: Key Utility Parameters

Variable	Value	Distribution	Source	EAG commentary on availability, quality and reliability of the source/s
Utilities used to calculate model inputs				
No anxiety	0.720	B(14, 5)	NIHR HTA report (Gega 2022)	These are reported in the HTA report (Gega 2022), but are derived from Revicki et al 2012 and Revicki et al. 2008. There is limited information on how the utilities reported in the paper were valued.
Mild anxiety	0.640	B(14, 8)		
Moderate anxiety	0.600	B(14, 9)		
Severe anxiety	0.530	B(13, 11)		
All anxieties other than SAD and PTSD				
Prior to treatment	0.620			Mean of mild and moderate anxiety
Responded to treatment	0.680			Mean of mild and no anxiety
Did not respond to treatment	0.620			Mean of mild and moderate anxiety
PTSD and SAD				
Prior to treatment	0.565			Mean of moderate and severe anxiety
Responded to treatment	0.620			Mean of mild and moderate anxiety
Did not respond to treatment	0.565			Mean of moderate and severe anxiety

9.4 *Results from the economic modelling*

Exploratory results are presented below, based on a purchase of 1,000 licences, over a 15-month period, and using IAPT database reported recovery to illustrate current normal treatment outcomes. Insufficient evidence on efficacy was available for Cerina, Iona Mind, Resony and Wysa, and therefore their cost-effectiveness could not be modelled, and no conclusions can be drawn for these technologies. Cerina have some small unpublished evidence demonstrating improved clinical scores over time, but these do not include for recovery. Wysa have a number of published studies, but not in applicable patient groups or settings. Beating the Blues, MindDistrict and SilverCloud efficacy data is based on a mixed population with depression, mixed anxiety and depression and other anxiety descriptors. Therefore, the model may not represent outcomes appropriately for the stated anxiety descriptors.

The initial interventions for BDD are group or individual CBT, and the appropriate costs to apply for both the IAPT comparator and the guided element of the intervention are unclear. Assumptions have been stated in the model input tables. Although there is uncertainty in the exact costs, the general direction of the results is likely to be robust.

Table 19:Generalised Anxiety Disorder

GAD	IAPT current pathway	Beating the blues	MindDistrict	Silver Cloud
Cost	£494	[redacted]	[redacted]	£410
QALYs	0.81	0.81	0.82	0.81
NMB @ £20,000/QALY	£15,771	[redacted]	[redacted]	£15,811
NMB CI (95%)	12707, 18615	12828, 18724	13357, 19546	12641, 18714

Table 20: Body Dysmorphic Disorder

Body Dismorphic Disorder	IAPT current pathway	Koa Health
Cost	£1,009	[redacted]
QALYs	0.74	0.74
NMB @ £20,000/QALY	£13,783	[redacted]
NMB CI (95%)	10,639, 16661	10,930, 16,978

Table 21: Other Anxiety Descriptors

Other anxiety descriptors that are initially treated within IAPT Step 2	IAPT current pathway	MindDistrict	Silver Cloud
Cost	£587	[redacted]	£459
QALYs	0.81	0.82	0.81
NMB @ £20,000/QALY	£15,538	[redacted]	£15,725
NMB CI (95%)	12459, 18455	13306, 19573	12540, 18625

Table 22: Post traumatic stress disorder

PTSD	IAPT current pathway	iCT-PTSD	Spring
Cost	£1,289	[redacted]	£496
QALYs	0.72	0.74	0.75
NMB @ £20,000/QALY	£13,044	[redacted]	£14,542
NMB CI (95%)	9807, 16214	11167, 17097	11362, 17444

Table 23: Social anxiety Disorder

SAD	IAPT current pathway	iCT-SAD	MindDistrict	Silver Cloud
Cost	£1,433	[redacted]	[redacted]	£1,168
QALYs	0.73	0.75	0.75	0.74
NMB @ £20,000/QALY	£13,233	[redacted]	[redacted]	£13,578
NMB CI (95%)	10060, 16141	10938, 17006	11549, 17824	10520, 16519

One-way sensitivity analyses

Net monetary benefit was sensitive to the recovery rate of each intervention, where it varied significantly with the change in recovery rate across all anxiety descriptors ([redacted]4).

[redacted]

[redacted]	
[redacted]	[redacted]
[redacted]	
[redacted]	[redacted]
	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Scenario analysis

This scenario is based on the use of overall recovery rate from the main IAPT database. The interventions all remain at a lower cost to the comparator, and a similar level of QALY gain, however the uncertainties in the results remain.

Table 24: Generalised Anxiety Disorder

GAD	IAPT current pathway	Beating the blues	MindDistrict	Silver Cloud
Cost	£446	[redacted]	[redacted]	£384
QALYs	0.82	0.81	0.82	0.81
NMB @ £20,000/QALY	£15,883	[redacted]	[redacted]	£15,855

Table 25: Body Dysmorphic Disorder

Body Dismorphic Disorder	IAPT current pathway	Koa Health
Cost	£1,008	[redacted]
QALYs	0.74	0.74
NMB @ £20,000/QALY	£13,786	[redacted]

Table 26: Other Anxiety Descriptors

Other anxiety descriptors that are initially treated within IAPT Step 2	IAPT current pathway	MindDistrict	Silver Cloud
Cost	£517	[redacted]	£422
QALYs	0.81	0.82	0.81
NMB @ £20,000/QALY	£15,708	[redacted]	£15,789

Table 27: Post traumatic stress disorder

PTSD	IAPT current pathway	iCT-PTSD	Spring
Cost	£1,063	[redacted]	£460
QALYs	0.73	0.75	0.75
NMB @ £20,000/QALY	£13,560	[redacted]	£14,606

Table 28: Social anxiety Disorder

SAD	IAPT current pathway	iCT-SAD	MindDistrict	Silver Cloud
Cost	£1,457	[redacted]	[redacted]	£1,179
QALYs	0.73	0.75	0.75	0.74
NMB @ £20,000/QALY	£13,180	[redacted]	[redacted]	£13,560

Value of information analysis

Estimated population-level value of perfect information (EVPI) was derived based on 330,000 people per year (estimated using the GAD incidence in England, 4.9% and 10% of patients receive intervention) (Jankovic 2022, Kumar 2018) and the lifetime of the intervention was 5 years. The analyses were conducted using SAVI interface (http://savi.shef.ac.uk/ SAVI/) (Strong 2014).

Table 29: Population EVPI over 5 years

	Population EVPI over 5 years (£)
GAD	
Beating the Blues	4,065,153
MindDistrict	20,015,447
Silver Cloud	26,066,628
Other anxiety descriptors that are initially treated with IAPT Step 2	
MindDistrict	30,069,717
Silver Cloud	517,143
BDD	
Koa	8,037,210
PTSD	
iCT-PTSD	20,651,596
Spring	29,945,591
SAD	
iCT-SAD	1,442,974
MindDistrict	5,518,988
Silver Cloud	108,611

9.5 *Interpretation of the economic evidence*

Published HTA reports and guidance (Gega 2022, Health Quality Ontario 2019) for guided digital therapies in anxiety found that there was insufficient evidence to draw conclusive results on cost-effectiveness when compared to face to face therapy or printed manuals. It was likely to be cost effective compared to waiting lists. NICE CG113 considered modelling that compared digitally delivered CBT to waitlist for patients with GAD, but noted this did not reflect NHS practices. NICE CG159 reported limitations, but ranked interventions for symptoms of SAD by NMB and found that guided digital therapies were ranked 7th, after different forms of face to face cognitive therapy and some medication.

Economic analysis for technologies within the scope were all within trial analysis. All four studies found the interventions to be cost saving, and three were reported as cost effective; however this is based on either waiting list comparators (Richards, 2020), treatment as usual that is poorly reported and may include waiting list (McCrone, 2004), or other [redacted]These cannot be interpreted as implying cost-effectiveness in the IAPT pathway. Only Bisson (2022) report an economic within study analysis where the comparator is appropriate for treatment within the IAPT pathway. They found cost savings for the intervention, but a slightly lower improvement in QALY values for the intervention compared to face to face CBT.

There are two key limitations to the published economic evidence also apply more widely to the clinical evidence. These are the broad, heterogenous population for unspecified anxiety descriptors (Richards 2020, McCrone 2004), and the inappropriate comparator for IAPT (Richards 2020, McCrone 2004, [redacted]).

EAG modelling required simplification of a complex pathway, and was limited by the available evidence. As a result, they should be seen as exploratory only.

Across all the interventions the model finds that they are slightly less costly at 15 months than the modelled IAPT equivalent, with some at stage 3 (PTSD, SAD) having a slightly larger cost saving. The model found similar QALY gains for the interventions and the comparator, with only small differences across the different interventions and technologies. The key driver of the model is clinical effectiveness, meaning that all the limitations noted for the clinical evidence also impact on the model.

Efficacy inputs to the model show the interventions to be more effective than standard IAPT treatment, and this drives a reduced cost, due to fewer additional therapies, and a small increase in accumulated QALYs. However, this should be interpreted with extreme caution, due to the issues discussed in “Main Clinical Parameters”. The IAPT reflects normal care, whereas intervention efficacy is based on trial data, and there are differences in how results are obtained. In addition, there

are limitations in how both IAPT and study data relate to the patient groups being modelled.

The direct cost of providing any of the digitally enabled interventions is the licence cost (and any other fees to the supplier) and therapist time for delivering and guiding the therapy. In all cases the therapist time is the largest element of this cost. For most IAPT stage 2 interventions, therapist time is assumed to be driven by IAPT protocol, and therefore therapist costs are the same for all IAPT stage 2 digitally enabled therapies considered for any given indication. PTSD and SAD therapist time are estimated based on study date, but this the same cost is applied to any digitally enabled therapy used for that indication. This means there is little difference in the cost to deliver each digitally enabled therapy for a given indication, and the key driver for costs is the clinical effectiveness of each intervention.

10 Evidence gap analysis

The primary evidence gap relates to a lack of evidence for specific technologies and for specific conditions included in the scope. Five of the technologies (Cerina, Iona Mind, Mind District, Resony and Wysa) and 4 specific conditions (health anxiety, obsessive compulsive disorder, panic disorder and specific phobias) have no relevant published clinical evidence available. It is therefore not possible to comment on the clinical effectiveness of these technologies or to know whether using digitally enabled technologies can positively impact outcomes for adults with health anxiety, obsessive compulsive disorder, panic disorder and specific phobias. It was also not possible to calculate the cost effectiveness associated with the use of digitally enabled therapies for these specific conditions. Ideally evidence for the economic model would come from a study with a comparator that is relevant to the model i.e. an IAPT pathway intervention.

The EAG identified a number of ongoing studies (table 12) that may contribute to identified evidence gaps.

Table 30 to Table 33 summarises what the evidence gaps are for those conditions and technologies where there was some evidence available.

Table 30:Post traumatic Stress Disorder Evidence Gap Analysis

	iCT-PTSD	Spring
Clinical Studies		
Comparator IAPT pathway	No studies *Red*	Yes – One RCT *Green*
Clinical outcome: Symptom severity	Yes – One non-comparative study and data from one unpublished study *Amber*	*Yes – One RCT* *Green*
Clinical outcome: Remission and recovery	Yes – One non-comparative study and data from one unpublished study *Amber*	Partially reported *Amber*
Intermediate outcome: Acceptability and usage	Yes – One non-comparative study *Amber*	No studies Red
Intermediate outcome: Therapist time	Yes – One non-comparative study *Amber*	No studies Red
Intermediate outcome: Adverse events	No studies Red	No *Red*
Economic outcome: utilities	Yes Green	Yes – One RCT Green
Economic within trial analysis	One economic analysis of an RCT, comparator is another digital therapy that would not be provided on the IAPT pathway. Amber	One economic analysis of a non-inferiority RCT, with face to face therapy as the comparator. Green
Real World Evidence No real world evidence identified for Spring  Amber		
Ongoing studies / Unpublished Studies Two ongoing studies were identified by the EAG, both relating to iCT-PTSD. Although these studies have not yet been published in the public domain, the company provided the results to the EAG and these are discussed in the report. No additional ongoing studies have been identified.		

Table 31: Social Anxiety Disorder Evidence Gap Analysis

	iCT-SAD	MindDistrict	Silver Cloud
Clinical Studies			
Comparator:	No studies	No studies	No studies

IAPT pathway	*Red*	*Red*	*Red*
Clinical outcome: Symptom severity	Yes – One non-comparative study and one RCT *Green*	No studies *Red*	No studies *Red*
Clinical outcome: Remission and recovery	Yes – One non-comparative study and one RCT *Green*	No studies *Red*	No studies *Red*
Intermediate outcome: Acceptability and usage	Yes – One non-comparative study *Amber*	No studies *Red*	No studies *Red*
Intermediate outcome: Therapist time	Yes – One non-comparative study and one RCT *Green*	No studies *Red*	No studies *Red*
Intermediate outcome: Adverse events	Yes – One RCT *Green*	No studies *Red*	No studies *Red*
Economic outcome: Utilities	No *Red*	No studies *Red*	No studies *Red*
Economic within trial analysis	No *Red*	No studies *Red*	No studies *Red*

Real World Evidence

No real world evidence identified for MindDistrict or SilverCloud

[redacted]

Amber

On-going studies / Unpublished Studies

One ongoing study relating to iCT-SAD was identified. Although this study has not yet been published in the public domain, the company provided the results to the EAG and these are discussed in the report.

One ongoing study relating to Koa Health (Perspectives) was identified and study completion is anticipated in 2025. The study is randomised but does not use IAPT recommended tools to measure symptoms (LSAS) and the comparator for this study is waitlist which may limit the applicability of evidence from this study.

Table 32: Body Dysmorphic Disorder Evidence Gap Analysis

	Perspectives, Koa Health
Clinical Studies	
Comparator: IAPT pathway	No studies *Red*

Clinical outcome: Symptom severity	Yes – One non-comparative study and one RCT Green
Clinical outcome: Remission and recovery	Yes – One non-comparative study and one RCT *Green*
Intermediate outcome: Acceptability and usage	Yes – One non-comparative study and RCT *Green*
Intermediate outcome: Therapist time	Yes – One RCT *Amber*
Intermediate outcome: Adverse events	Yes – one non-comparative study *Amber*
Economic outcome: Utilities	Quality of life scores are reported (Quality of Life, Enjoyment, and Satisfaction Questionnaire—Short Form (Q-LES-Q-S) *Amber*
Economic within trial analysis	No Red
Real World Evidence No real world evidence identified *Red*	
On-going Studies / Unpublished Studies One ongoing study relating to Koa Health (Perspectives) was identified with study completion date anticipated to have been January 2022. Information from the company suggests this study has completed and reported in Wilhelm 2022 which is included in the evidence.	

Table 33: Generalised Anxiety Evidence Gap Analysis

	Beating the Blues	Cerina	Iona Mind	Mind District	Resony	Silver Cloud	Wysa
Clinical Studies							
Comparator: IAPT pathway	No *Red*	No *Red*	No *Red*	No *Red*	No *Red*	Yes – one study comparing with guided self-help and group therapy. *Green*	No *Red*
Clinical outcome: Symptom severity	Yes – 5 studies All included studies reported a baseline anxiety score however this was not specifically reported as a symptom severity outcome and the tools used in each study varied *Amber*	No *Red*	No *Red*	No *Red*	No *Red*	Yes – 6 studies All included studies reported a baseline anxiety score as measured using GAD 7 *Green*	No *Red*
Clinical outcome: Remission and recovery	Yes – 5 studies All included studies reported the change from baseline anxiety score in some format. Studies reported changes at different timepoints to indicate change (improvement) over time however this was not specifically reported as remission/recovery *Amber*	No *Red*	No *Red*	No *Red*	No *Red*	Yes – 6 studies All included studies reported the change from baseline anxiety score as measured using GAD 7 Studies reported changes at different follow-up timepoints to indicate change (improvement) over time however this was not specifically reported as remission/recovery	No *Red*

Intermediate outcome: Acceptability and usage	Yes – 2 studies One randomised trial reporting the acceptability of using the technology in two user groups One non-comparative study reporting patient feedback on usefulness/helpfulness of technology *Green*	No *Red*	No *Red*	No *Red*	No *Red*	Yes – 2 studies One non-comparative study reporting engagement rates One comparative study (comparing to waitlist control) reporting participants expectations of technology including experience versus expectation *Green*	No *Red*
Intermediate outcome: Therapist time	No *Red*	No *Red*	No *Red*	No *Red*	No *Red*	No *Red*	No *Red*
Intermediate outcome: Adverse events	No *Red*	No *Red*	No *Red*	No *Red*	No *Red*	Yes – one study included adverse events as an outcome. *Green*	No *Red*
Economic outcome: Utilities	Yes *Green*	No *Red*	No *Red*	No *Red*	No *Red*	Yes *Green*	No *Red*
Economic within trial analysis	Yes, but not relevant comparator *Amber*	No *Red*	No *Red*	No *Red*	No *Red*	Yes, but not relevant comparator *Amber*	No *Red*
Real World Evidence No real world evidence identified *Red*							
Ongoing Studies / Unpublished Studies One ongoing study relating to SilverCloud was identified however the trial record indicates this study has been withdrawn due to logistic reasons and will therefore not provide any data to inform the evidence gaps.							

Confidential results from one unpublished study were provided for Resony which report [redacted]

10.1 *Summary and conclusions of evidence gap analysis*

The largest volume of evidence was available for Beating the Blues and SilverCloud and related to generalised anxiety. Limited evidence from one technology each was available for body dysmorphic disorder (Koa Perspectives), and Social anxiety disorder (iCT-SAD) and from two technologies for PTSD (iCT PTSD, Spring).

Across all technologies for both clinical and economic evidence, the key relevant clinical outcomes are for remission and recovery, and longer-term outcomes including relapse which require well conducted clinical studies to generate reliable results. Where there is available evidence for specific technologies, a key evidence gap relates to use of a valid comparator within IAPT pathway. For economic analysis, additional data such as costs and utilities may be collected during the study, but may also be based on IAPT guidance and published literature. Real world evidence generation might be possible, particularly within the current IAPT database however currently, the publicly available information does not report on specific details of technologies used where a digital intervention is used. One company provided limited data from real world evidence collection for iCT-PTSD and iCT-SAD which suggests that real world evidence generation is possible and may provide useful and informative results.

Specifically related to generalised anxiety, a second key evidence gap relates specifically to different anxiety descriptors and the separate reporting of depression, anxiety, and separate anxiety descriptors where appropriate.

One additional gap to be considered relates to the use of validated tools / measures to assess conditions. For example, the body dysmorphia studies use BDD-YBCOS to measure symptoms whereas the recommended tool / measure in the IAPT manual is the Body Image Questionnaire.

For many of the technologies, it is impossible to know if the reported effect size is relevant to the anxiety descriptor being discussed, or even to anxiety in its broadest sense.

10.2 *Key areas for evidence generation*

Evidence generation should focus on larger scale randomised controlled trials without a 'Waitlist' comparator group but rather a different technology or ideally a current practice comparator group. They should focus on the technologies with no current evidence and anxiety disorders with no current evidence. Further, those referring to GAD should make it clear whether participants have a defined DSM-V or ICD-10 diagnosis of GAD or are experiencing high levels of anxiety as assessed (usually self-assessed) by the GAD-7 questionnaire. More studies need to be conducted within the UK and preferably within an NHS IAPT setting so that results generated can be readily generalised to the IAPT pathway.

Table 34: Evidence Generation

Population	• Studies should clearly report on participant diagnosis - focusing on actual diagnoses of GAD, or differentiating from anxiety symptoms as reported from the GAD-7 • Reporting of results should be split by diagnosis or descriptor – rather than grouping people who are experiencing anxiety and/or depression symptoms • Use of IAPT recommended tools / measures to assess caseness
Interventions	• Some interventions are lacking in any clinical evidence, and others have very limited evidence, or no relevant comparative evidence • Clear reporting of therapist involvement and level of qualification • Consistent use of guided element as per IAPT protocol
Comparators	• Lack of comparators based on appropriate treatments (rather than waiting list, or treatment as usual that includes waiting list, or has little specification of treatments) •
Outcomes	• Reporting of recovery or reliable recovery data • Consistent reporting of ITT, or based on IAPT criteria • Relapse rates and longer term follow up • Consistent use of guided element as per IAPT protocol • Safety/Adverse Events
Economic	• Robust clinical evidence as outlined above • Inclusion of quality of life outcomes and utilities

11 Conclusions

11.1 *Conclusions from the clinical evidence*

Where available, the clinical evidence (n=19 studies) suggests that guided digital therapies can reduce anxiety symptoms across a range of conditions and that reductions can persist up to 12 months post treatment. Limited comparative evidence indicates the reduction in anxiety symptoms was larger in those using the guided therapies, compared to waiting list or usual care. There is no evidence that the technologies lead to any adverse events nor is there evidence of any safety concerns with any of the technologies. Where reported, users seem satisfied with the technologies they are using suggesting that digitally enabled technologies are an acceptable however it should be noted that user acceptability measures are largely before and after technology use and therefore it is not clear whether digitally enable technologies are an acceptable alternative to face-to-face CBT.

It is possible that use of digitally enabled technologies may reduce the amount of therapist time needed however studies did not always clearly report whether there was therapist involvement and if so what the role of the therapist and the qualification level of the therapists involved.

None of the identified evidence included reported results for health anxiety, OCD, Panic Disorder or specific phobias using any of the technologies of interest and therefore no conclusion can be made on the effectiveness of these technologies. In addition, it was not the purpose of the review to compare technologies with each other therefore no conclusions can be made on the relative effectiveness of technologies that can be used for the same conditions.

The EAG concludes that digitally enabled technologies show promise but additional evidence is needed for recovery, remission and relapse rates, over longer periods, for a specific population and using appropriate comparators.

11.2 *Conclusions from the economic evidence*

The economic findings are dependent on clinical evidence for very heterogenous groups, with delivery methods that may not align to the planned IAPT delivery, and comparator data that is not appropriate for an IAPT pathway.

The EAG model attempts to summarise, and standardise, a complex pathway across multiple indications, which, by necessity, involves simplifications and assumptions. The limited quality and applicability of the evidence base, combined with the simplified pathway means that any results should be seen as exploratory, and conclusions should be reached with caution.

Across all the interventions the model finds that they are slightly less costly at 15 months than the modelled IAPT equivalent, with some at stage 3 (PTSD, SAD) having a slightly larger cost saving. The model also calculates a similar QALY gain to the comparator, with only small differences across the different interventions and technologies. It should however be noted that the only economic study that used an appropriate treatment-based comparator found that the digitally enabled therapy for PTSD resulted in a slightly lower QALY gain than the standard face to face intervention.

The key driver for the model is clinical effectiveness, and this is similar to findings from other modelling studies for digitally enabled technologies (Gega 2022). The EAG key evidence gaps are also similar to those identified in previous economic modelling work for interventions for digitally enabled therapies for anxiety (Gega 2022, Health Quality Ontario 2019, CG113).

Additional evidence is needed for recovery, remission and relapse rates, over longer periods, for a specific population and using appropriate comparators.

12 Summary of the combined clinical and economic sections

There is a lack of relevant evidence for some of the included technologies, and a lack of evidence that focuses on specific anxiety descriptors (health

anxiety, obsessive compulsive disorder, panic disorder and specific phobias). Therefore, the EAG are unable to draw any clinical or economic conclusions in these areas.

There are a number of RCTs published, including within trial economic evaluations, for digitally enabled therapies in the unspecified anxiety disorders, PTSD, SAD and BDD. There are no studies that look specifically at GAD, and populations often include depression making interpretation of results difficult. Almost all comparative studies use waiting list or usual care (that may be poorly defined and includes wait list) and are not relevant to a decision based on the IAPT pathway.

Economic evidence is subject to the same limitations and economic modelling is highly driven by the quality of the clinical evidence.

Technologies are likely to be cheaper to deliver than many other IAPT interventions at a similar stage, and are likely to provide better outcomes than waitlist. Modelling shows lower costs and similar outcomes at 15 months compared to IAPT interventions at the same stage, but has a high degree of uncertainty.

Additional evidence is needed for recovery, remission and relapse rates, over longer periods, for a specific population and using appropriate comparators. Other assessments that were not focused on specific technologies, but took a broader view of digitally enabled therapies also noted similar limitations and evidence gaps.

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14 Appendices

Appendix A: Search Strategies

Appendix A: Clinical data search strategy.

The EAG conducted a search for both clinical and economic evidence as directed by the scope. Eleven bibliographic databases were searched from inception to 23rd November 2022, using a range of free text terms and, where appropriate, indexed terms. The searches were not restricted by language of publication. Two clinical trial registries were also searched for ongoing and unpublished trials; the companies' websites were also searched for additional literature. The MHRA's medical device alerts and field safety notices and the FDA MAUDE database were searched for adverse events.

Additionally, economic studies were identified from the references of a similar report: Guided dCBT for CYP with mild to moderate anxiety or low mood: an Early Value Assessment (MT580). The economic searches from this report were updated to identify any literature published since August 2022.

Clinical and economic searches

Date	Database Name	Total Number of records retrieved	Total number of records from database after de-duplication
23/11/22	Medline ALL (includes Medline In Process & Medline Epub Ahead of Print)	247	
23/11/22	EMBASE	362	
23/11/22	PsycInfo	398	
23/11/22	Cochrane Library CDSR CENTRAL	 89 152	
23/11/22	CRD DARE HTA NHS EED	 13 6 1	
23/11/22	INAHTA	13	

Date	Database Name	Total Number of records retrieved	Total number of records from database after de-duplication
23/11/22	PubMed	313	
23/11/22	Epistemonikos	100	
21/06/22	Company websites: Beating the Blues Cerina Iona Mind MindDistrict SilverCloud Spring Wysa Koa Health/Perspectives Oxcadat Resony Deprexis	 13 0 0 13 67 0 1 0 14 0 8	
22/06/22	MHRA	0	
27/06/22	FDA MAUDE	0	
21/06/22	Clinical Trials.gov	55	
22/06/22	ICTRP	75	1250 records after manual deduplication

Economic searches

Date	Database Name	Total Number of records retrieved	Total number of records from database after de-duplication
29/11/22	ScHARRHUD	0	
29/11/22	CEA Registry	6	
29/11/22	Medline (ALL)	40	
29/11/22	EMBASE	18	
29/11/22	PsycInfo	10	53 records after manual deduplication

EAG Search strategies

Ovid MEDLINE(R) ALL <1946 to November 22, 2022>

1	Anxiety/	102027
2	anxiety disorders/	39925
3	(anxiet* or anxious).tw.	252620
4	"generali?ed anxiety disorder*".tw.	9697
5	GAD.tw.	11873
6	"social anxiety disorder*".tw.	3217
7	phobia*.tw.	9537
8	"panic disorder*".tw.	10038
9	"post?traumatic stress disorder*".tw.	22077
10	PTSD.tw.	30465
11	"body dysmorphic disorder*".tw.	1302
12	"obsessive compulsive disorder*".tw.	15322
13	exp Phobic Disorders/	12249
14	Panic Disorder/	7237
15	Stress Disorders, Post-Traumatic/	39852
16	Body Dysmorphic Disorders/	1226
17	Obsessive-Compulsive Disorder/	16142
18	or/1-17	355241
19	Depression/	145419

20 (depression or depressive or depressed).tw. 509140

21 or/19-20 535264

22 18 or 21 742823

23 "beating the blues".af. 40

24 "365 health solutions".af. 0

25 cerina.af. 157

26 (NoSuffering or "no suffering").af. 20

27 iCT-PTSD.af.3

28 (internet adj2 "cognitive therapy for post traumatic stress disorder").tw. 0

29 iCT-SAD.af. 3

30 (internet adj2 "cognitive therapy for social anxiety disorder").tw. 4

31 OxCADAT.af. 3

32 "iona mind".af. 0

33 Minddistrict.af. 26

34 "mind district".af. 0

35 ("Get.ON" adj2 ("Mood Enhancer" or panic or depression)).af. 10

36 "Koa Health".af. 9

37 (Perspectives adj3 Koa).tw. 3

38 Resony.af. 0

39 "RCube health".af. 0

40 (SilverCloud or "silver cloud").af. 56

41 (space adj2 (anxiety or GAD or "health anxiety" or OCD or panic or phobia)).tw. 40

42 (space adj2 depression).tw. 31

43 Wysa.af. 13

44 Spring.af. and ("cognitive behavio* therap*" or cbt or dcbt or ccbt or icbt or "digital therapeutic*" or "digital cbt" or "online cbt" or "comput* cbt" or "internet cbt").tw. 120

45 Deprexis.af. 50

46 ("Ethypharm digital" or "gaia group").af. 14

47 23 or 24 or 32 or 33 or 34 or 35 or 36 or 37 or 40 or 43 154

48 22 and 47 114

49 25 or 26 or 27 or 28 or 29 or 30 or 31 or 38 or 39 or 41 or 44 347

50 18 and 49 94

51 42 or 45 or 46 93

52 21 and 51 83

53 48 or 50 or 52 276

54 exp animals/ not humans.sh. 5069381

55 53 not 54 262

56 limit 55 to english language 247

Embase <1974 to 2022 November 22>

1 Anxiety/ 259704

2 anxiety disorder/ 89008

3 (anxiet* or anxious).tw. 355537

4 "generali?ed anxiety disorder*".tw. 13031

5 GAD.tw. 17664

6 "social anxiety disorder*".tw. 3983

7 phobia*.tw. 12794

8 "panic disorder*".tw. 13048

9 "post?traumatic stress disorder*".tw. 25731

10 PTSD.tw. 39557

11 "body dysmorphic disorder*".tw. 1677

12 "obsessive compulsive disorder*".tw. 20892

13 exp phobia/ 35341

14 panic/ 25681

15 posttraumatic stress disorder/ 74592

16 body dysmorphic disorder/ 3448

17 obsessive compulsive disorder/ 28550

18 generalized anxiety disorder/ 14076

19 social anxiety/ 729

20 or/1-19 555175

21 depression/ 446162

22 (depression or depressive or depressed).tw. 682442

23 or/21-22 816413

24 20 or 23 1114339

25 "beating the blues".af. 51

26 "365 health solutions".af. 0

27 cerina.af. 193

28 (NoSuffering or "no suffering").af. 27

29 iCT-PTSD.af.2

30 (internet adj2 "cognitive therapy for post traumatic stress disorder").tw. 0

31 iCT-SAD.af. 2

32 (internet adj2 "cognitive therapy for social anxiety disorder").tw. 4

33 OxCADAT.af. 1

34 "iona mind".af. 0

35 Minddistrict.af. 8

36 "mind district".af. 0

37 ("Get.ON" adj2 ("Mood Enhancer" or panic or depression)).af. 10

38 "Koa Health".af. 10

39 (Perspectives adj3 Koa).tw. 2

40 Resony.af. 0

41 "RCube health".af. 0

42 (SilverCloud or "silver cloud").af. 70

43 (space adj2 (anxiety or GAD or "health anxiety" or OCD or panic or phobia)).tw. 51

44 (space adj2 depression).tw. 30

45 Wysa.af. 3

46 Spring.af. and ("cognitive behavio* therap*" or cbt or dcbt or ccbt or icbt or "digital therapeutic*" or "digital cbt" or "online cbt" or "comput* cbt" or "internet cbt").tw. 213

47 Deprexis.af. 60

48 ("Ethypharm digital" or "gaia group").af. 29

49 25 or 26 or 34 or 35 or 36 or 37 or 38 or 39 or 42 or 45 154

50 24 and 49 121

51 27 or 28 or 29 or 30 or 31 or 32 or 33 or 40 or 41 or 43 or 46 491

52 20 and 51 164

53 44 or 47 or 48 111

54 23 and 53 95

55 50 or 52 or 54 371

56 limit 55 to english language 362

APA PsycInfo <1806 to November Week 2 2022>

1	Anxiety/	72807
2	anxiety disorders/	20407
3	(anxiet* or anxious).tw.	240939
4	"generali?ed anxiety disorder*".tw.	9047
5	GAD.tw.	5555
6	"social anxiety disorder*".tw.	3921
7	phobia*.tw.	14047
8	"panic disorder*".tw.	11626
9	"post?traumatic stress disorder*".tw.	33157
10	PTSD.tw.	39717
11	"body dysmorphic disorder*".tw.	1543
12	"obsessive compulsive disorder*".tw.	18225
13	exp phobias/	14015
14	Panic Disorder/	7921
15	posttraumatic stress disorder/	38061
16	body dysmorphic disorder/	1313
17	obsessive compulsive disorder/	15535
18	generalized anxiety disorder/	3451
19	health anxiety/	633
20	social anxiety/	5730

21 or/1-20 309597

22 depression/ 26720

23 (depression or depressive or depressed).tw. 343507

24 or/22-23 344120

25 21 or 24 539329

26 "beating the blues".af. 76

27 "365 health solutions".af. 1

28 cerina.af. 33

29 (NoSuffering or "no suffering").af. 18

30 iCT-PTSD.af. 0

31 (internet adj2 "cognitive therapy for post traumatic stress disorder").tw. 0

32 iCT-SAD.af. 1

33 (internet adj2 "cognitive therapy for social anxiety disorder").tw. 3

34 OxCADAT.af. 7

35 "iona mind".af. 0

36 Minddistrict.af. 4

37 "mind district".af. 0

38 ("Get.ON" adj2 ("Mood Enhancer" or panic or depression)).af. 20

39 "Koa Health".af. 2

40 (Perspectives adj3 Koa).tw. 1

41 Resony.af. 1

42 "RCube health".af. 0

43 (SilverCloud or "silver cloud").af. 23

44 (space adj2 (anxiety or GAD or "health anxiety" or OCD or panic or phobia)).tw. 54

45 (space adj2 depression).tw. 18

46 Wysa.af. 23

47 Spring.af. and ("cognitive behavio* therap*" or cbt or dcbt or ccbt or icbt or "digital therapeutic*" or "digital cbt" or "online cbt" or "comput* cbt" or "internet cbt").tw. 335

48 Deprexis.af. 254

49 ("Ethypharm digital" or "gaia group").af. 8

50 26 or 27 or 35 or 36 or 37 or 38 or 39 or 40 or 43 or 46 150

51 25 and 50 98

52 28 or 29 or 30 or 31 or 32 or 33 or 34 or 41 or 42 or 44 or 47 451

53 21 and 52 143

54 45 or 48 or 49 274

55 24 and 54 206

56 51 or 53 or 55 434

57 limit 56 to english language 398

Cochrane Library

#1 MeSH descriptor: [Anxiety] explode all trees 9306

#2 MeSH descriptor: [Anxiety Disorders] explode all trees 7991

#3 (anxiet* or anxious) 68087

#4 "generalised anxiety disorder*" OR "generalized anxiety disorder*" 3553

#5 GAD 2999

#6 "social anxiety disorder*" 1100

#7 phobia* 2962

#8 "panic disorder*" 2450

#9 "posttraumatic stress disorder*" OR "post traumatic stress disorder*". 5971

#10 PTSD 5518

#11 "body dysmorphic disorder*" 161

#12 "obsessive compulsive disorder*" 2939

#13 MeSH descriptor: [Phobic Disorders] explode all trees 1477

#14 MeSH descriptor: [Panic Disorder] explode all trees 989

#15 MeSH descriptor: [Stress Disorders, Post-Traumatic] explode all trees 3190

#16 MeSH descriptor: [Body Dysmorphic Disorders] explode all trees 81

#17 MeSH descriptor: [Obsessive-Compulsive Disorder] explode all trees 1159

#18 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 77725

#19 MeSH descriptor: [Depression] explode all trees 14311

#20 (depression or depressive or depressed)102081

#21 #19 or #20 102081

#22 #18 or #21 141056

#23 "beating the blues" 47

#24 "365 health solutions" 0

#25 cerina 5

#26 (NoSuffering or "no suffering") 141

#27 iCT-PTSD 0

#28 (internet NEAR/2 "cognitive therapy for post traumatic stress disorder") 0

#29 iCT-SAD 0

#30 (internet NEAR/2 "cognitive therapy for social anxiety disorder") 5

#31 OxCADAT 1

#32 "iona mind" 0

#33 Minddistrict 4

#34 "mind district" 0

#35 ("Get.ON" NEAR/2 ("Mood Enhancer" or panic or depression)) 29

#36 "Koa Health" 2

#37 (Perspectives NEAR/3 Koa) 0

#38 Resony 0

#39 "RCube health" 0

#40 (SilverCloud or "silver cloud") 12

#41 wysa 3

#42 Spring AND ("cognitive behavio* therap*" or cbt or dcbt or ccbt or icbt or "digital therapeutic*" or "digital cbt" or "online cbt" or "comput* cbt" or "internet cbt")33

#43 deprexis 58

#44 ("Ethypharm digital" or "gaia group") 4

#45 (space NEAR/2 (depression or anxiety or GAD or "health anxiety" or OCD or panic or phobia)) 18

#46 #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45 322

#47 #22 and #46 241

[152 in CENTRAL 89 in CDSR]

CRD

1 MeSH DESCRIPTOR anxiety EXPLODE ALL TREES 314

2 MeSH DESCRIPTOR Anxiety Disorders EXPLODE ALL TREES 380

3 ((anxiet* or anxious)) 1762

4 ("generalised anxiety disorder*") OR ("generalized anxiety disorder*") 95

5 (GAD) 32

6 ("social anxiety disorder*") 31

7 (phobia*) 95

8 ("panic disorder*") 121

9 ("posttraumatic stress disorder*") OR ("post traumatic stress disorder*") 182

10 (PTSD) 106

11 ("body dysmorphic disorder*") 6

12 ("obsessive compulsive disorder*") 119

13 MeSH DESCRIPTOR Phobic Disorders EXPLODE ALL TREES 47

14 MeSH DESCRIPTOR Panic Disorder EXPLODE ALL TREES 55

15 MeSH DESCRIPTOR Stress Disorders, Post-Traumatic EXPLODE ALL TREES 139

16 MeSH DESCRIPTOR Body Dysmorphic Disorders EXPLODE 1 0

17 MeSH DESCRIPTOR Obsessive-Compulsive Disorder EXPLODE 1 57

18 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 2001

19 MeSH DESCRIPTOR Depression EXPLODE 1 639

20 ((depression or depressive or depressed)) 3049

21 #19 OR #20 3049

22 #18 OR #21 3937

23 ("beating the blues")7

24 ("365 health solutions") 0

25 (cerina) 0

26 (NoSuffering) OR ("no suffering") 0

27 (iCT-PTSD) 0

28 ((internet NEAR2 "cognitive therapy for post traumatic stress disorder")) 0

29 (iCT-SAD) 0

30 ((internet NEAR2 "cognitive therapy for social anxiety disorder")) 0

31 (OxCADAT) 0

32 ("iona mind") 0

33 (Minddistrict) 0

34 ("mind district") 0

35 (("Get.ON" adj2 ("Mood Enhancer" or panic or depression))) 0

36 ("Koa Health") 0

37 ((Perspectives NEAR3 Koa)) 0

38 (resony) 0

39 ("RCube health") 0

40 (silver cloud) OR ("silver cloud") 0

41 ((space NEAR2 (anxiety or GAD or "health anxiety" or OCD or panic or phobia))) 0

42 ((space NEAR2 depression)) 0

43 (wysa)0

44 (spring) AND (("cognitive behavio* therap*" or cbt or dcbt or ccbt or icbt or "digital therapeutic*" or "digital cbt" or "online cbt" or "comput* cbt" or "internet cbt")) 1

45 (deprexis) 0

46 ("Ethypharm digital") OR ("gaia group"):TI 0

47 MeSH DESCRIPTOR Cognitive Behavioral Therapy EXPLODE ALL TREES 28

48 #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 36

49 #22 AND #48 20

INHATA

48 #47 AND #18 13

47 #46 OR #45 OR #44 OR #43 OR #42 OR #41 OR #40 OR #39 OR #38 OR #37 OR #36 OR #35 OR #34 OR #33 OR #32 OR #31 OR #30 OR #29 OR #28 OR #27 OR #26 OR #25 OR #24 OR #23 106

46 "Ethypharm digital" or "gaia group" 0

45 Deprexis 0

44 (Spring) AND ("cognitive behavio* therap*" or cbt or dcbt or ccbt or icbt or "digital therapeutic*" or "digital cbt" or "online cbt" or "comput* cbt" or "internet cbt")0

43 Wysa 0

42 (space) AND (depression) 0

41 (space) AND (anxiety or GAD or "health anxiety" or OCD or panic or phobia) 2

40 SilverCloud or "silver cloud" 0

39 "RCube health" 0

38 Resony 0

37 (Koa) AND (Perspectives) 1

36 "Koa Health" 0

35 (Get.ON) AND ("Mood Enhancer" or panic or depression) 8

34 "mind district" 0

33 Minddistrict 0

32 "iona mind" 0

31 OxCADAT 0

30 iCT-SAD 0

29 (internet) AND (cognitive therapy for social anxiety disorder) 0

28 (internet) AND (cognitive therapy for post traumatic stress disorder) 1

27 iCT-PTSD 0

26 NoSuffering or "no suffering" 91

25 Cerina0

24 "365 health solutions" 0

23 "beating the blues" 3

22 #21 OR #18 576

21 #20 OR #19 418

20 depression or depressive or depressed 402

19 "Depression"[mh] 136

18 #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1 286

17 "Phobia, Social"[mh] 1

16 "Obsessive-Compulsive Disorder"[mh] 8

15 "Panic Disorder"[mh] 5

14 "Stress Disorders, Post-Traumatic"[mh] 36

13 "Body Dysmorphic Disorders"[mh] 0

12 "obsessive compulsive disorder*" 12

11 "body dysmorphic disorder*" 1

10 PTSD 27

9 "post?traumatic stress disorder*" 27

8 "panic disorder*" 4

7 phobia* 11

6 "social anxiety disorder*" 2

5 GAD 4

4 "generali?ed anxiety disorder*" 0

3 anxiet* or anxious 223

2 "Anxiety Disorders"[mh] 42

1 "Anxiety"[mh]72

ScHARRHUD

((“cognitive behaviour therapy” or “cognitive behavior therapy” or CBT) and (internet or digital))

CEA Registry

((“cognitive behaviour therapy” or “cognitive behavior therapy” or CBT) and (internet or digital))

PubMed

#28 Search: #4 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 313

#27 Search: (spring AND ("cognitive behavio* therap*" or cbt or dcbt or ccbt or icbt or "digital therapeutic*" or "digital cbt" or "online cbt" or "comput* cbt" or "internet cbt")) AND anxiety 35

#26 Search: "gaia group" 15

#25 Search: "ethypharm digital" 2

#24 Search: deprexis 52

#23 Search: wysa 13

#22 Search: "silver cloud" 3

#21 Search: silvercloud 67

#20 Search: "RCube health" 0

#19 Search: "RCube health" - Schema: all 0

#18 Search: resony 0

#17 Search: resony - Schema: all 0

#16 Search: (perspectives[Title/Abstract] AND koa[Title/Abstract]) 10

#15 Search: "koa health" 15

#14 Search: minddistrict 53

#13 Search: "iona mind" 2

#12 Search: OxCADAT 3

#11 Search: iCT-SAD 3

#10 Search: iCT-PTSD 2

#9 Search: nosuffering 0

#8 Search: nosuffering - Schema: all 0

#7 Search: cerina AND anxiety 2

#6 Search: "365 health solutions" and (anxiety or depression) 9

#4 Search: "beating the blues" and (anxiety or depression) 36

Epistemonikos

(title:((title:("beating the blues" OR "365 health solutions" OR cerina OR nosuffering OR "no suffering" OR iCT-PTSD OR iCT-SAD OR OxCADAT OR deprexis OR "Ethypharm digital" OR "gaia group" OR minddistrict OR "mind district" OR "space from depression" OR "space from anxiety" OR silvercloud OR "silver cloud") OR abstract:("beating the blues" OR "365 health solutions" OR cerina OR nosuffering OR "no suffering" OR iCT-PTSD OR iCT-SAD OR OxCADAT OR deprexis OR "Ethypharm digital" OR "gaia group" OR minddistrict OR "mind district" OR "space from depression" OR "space from

anxiety" OR silvercloud OR "silver cloud"))) OR abstract:((title:("beating the blues" OR "365 health solutions" OR cerina OR nosuffering OR "no suffering" OR iCT-PTSD OR iCT-SAD OR OxCADAT OR deprexis OR "Ethypharm digital" OR "gaia group" OR minddistrict OR "mind district" OR "space from depression" OR "space from anxiety" OR silvercloud OR "silver cloud") OR abstract:("beating the blues" OR "365 health solutions" OR cerina OR nosuffering OR "no suffering" OR iCT-PTSD OR iCT-SAD OR OxCADAT OR deprexis OR "Ethypharm digital" OR "gaia group" OR minddistrict OR "mind district" OR "space from depression" OR "space from anxiety" OR silvercloud OR "silver cloud")))) OR (title:(wysa OR "iona mind" OR "Get.ON" OR "koa health" OR "koa perspectives" OR resony OR "RCube health") OR abstract:(wysa OR "iona mind" OR "Get.ON" OR "koa health" OR "koa perspectives" OR resony OR "RCube health")) OR (title:(space AND (anxiety OR GAD OR "health anxiety" OR OCD OR panic OR phobia OR depression)) OR abstract:(space AND (anxiety OR GAD OR "health anxiety" OR OCD OR panic OR phobia OR depression))) OR (title:((internet OR spring) AND ("cognitive behaviour therapy" OR cbt OR dcbt OR ccbt OR icbt OR "digital therapeutic*" OR "digital cbt" OR "online cbt" OR "comput* cbt" OR wellmind OR "online mindfulness" OR "mindfulness course" OR "mindfulness based cognitive therapy" OR MBCT)) OR abstract:((internet OR spring) AND ("cognitive behaviour therapy" OR cbt OR dcbt OR ccbt OR icbt OR "digital therapeutic*" OR "digital cbt" OR "online cbt" OR "comput* cbt" OR wellmind OR "online mindfulness" OR "mindfulness course" OR "mindfulness based cognitive therapy" OR MBCT))) AND (title:(anxiety OR phobia OR panic OR "post tramatic stress disorder" OR PTSD OR "body dysmorphic disorder" OR "obsessive compulsive disorder") OR abstract:(anxiety OR phobia OR panic OR "post tramatic stress disorder" OR PTSD OR "body dysmorphic disorder" OR "obsessive compulsive disorder")) AND (title:(depression OR depressed OR depressive) OR abstract:(depression OR depressed OR depressive))

ClinicalTrials.gov

Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies

Search string	Results
beating the blues | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Anxiety	0
BtB | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Anxiety	0
365 health solutions | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Anxiety	0
beating the blues | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Depression	0
BtB | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Depression	0
365 health solutions | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Depression	0
cerina | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Anxiety	0
cerina | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Obsessive-Compulsive Disorder	0
nosuffering | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Anxiety	0
NoSuffering | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Obsessive-Compulsive Disorder	0

iona mind | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Anxiety	0
iona mind | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Depression	0
minddistrict | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Anxiety	0
minddistrict | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Obsessive-Compulsive Disorder	0
minddistrict | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Panic Disorder	0
minddistrict | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies	1
minddistrict | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Depression	0
silvercloud | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Anxiety	4
silvercloud | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Depression	4
silvercloud | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies	0 additional relevant
Space from depression | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Depression	2
wysa | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Anxiety	3

wysa | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies	0 additional
wysa | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Depression	3
koa | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Depression	2
koa | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Anxiety	2
koa health| Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies |	5
Deprexis| Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies |	1
Ethypharm| Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Depression	0
Gaia| Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Depression	2
resony | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | anxiety	0
RCube Health | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | anxiety	0
iCT-PTSD | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | anxiety	0
iCT-PTSD | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Post Traumatic Stress Disorder	0

iCT-SAD | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | anxiety	0
Oxcadat | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | anxiety	0
spring | Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | Anxiety	0 relevant (12 total)

Completed, Suspended, Terminated, Withdrawn, Unknown status

Search string	Results
beating the blues | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Anxiety	3
BtB | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Anxiety	0 additional
365 health solutions | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Anxiety	0
beating the blues | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | depression	0
BtB | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | depression	0
365 health solutions | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | depression	0
cerina | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | anxiety	0
cerina | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Obsessive-Compulsive Disorder	0

nosuffering | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | anxiety	0
nosuffering | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Obsessive-Compulsive Disorder	0
iona mind | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Anxiety	0 relevant
iona mind Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Depression	0 relevant
minddistrict | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Anxiety	0
minddistrict | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Obsessive-Compulsive Disorder	0
minddistrict | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Panic Disorder	0
minddistrict | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Depression	0
silvercloud | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Anxiety	6
silvercloud | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Depression	2 additional relevant
Space from depression | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Depression	2 additional relevant (48 total)

wysa | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Anxiety	2
wysa | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Depression	0 additional
koa | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Depression	0
koa | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Anxiety	0
Deprexis| Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Depression	11
Ethypharm| Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Depression	0
Gaia| Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Depression	0 additional relevant (4 total)
resony | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | anxiety	0
RCube Health | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | anxiety	0
iCT-PTSD | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | anxiety	0
iCT-PTSD | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Post Traumatic Stress Disorder	0
iCT-SAD | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | anxiety	0

Oxcadat | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | anxiety	0 relevant (1 total)
spring | Completed, Suspended, Terminated, Withdrawn, Unknown status Studies | Anxiety	0 relevant (22)
	26

ICTRP

"beating the blues" 18

365 health solutions 0

cerina 0

nosuffering or "no suffering" 0

iona 0

minddistrict or "mind district" 3

"Silver cloud" or silvercloud 17

"Space from depression" 6

Wysa 5

"koa health" or "koa mindset" or "koa perspectives" 2

Deprexis 17

Ethypharm AND depression 0

Gaia AND depression 3

Resony 0

"RCube Health" 0

iCT-PTSD 2

iCT-SAD 2

Oxcadat 0 relevant (1 total)

Economics searches

Ovid MEDLINE(R) ALL <1946 to November 28, 2022>

1 (computer or computerized or computerised or digital or online or internet$ or app or apps).ti,ab. 726287

2 (cognitive adj2 behavio$ adj3 (therap$ or intervention$ or treatment$ or psychotherap$ or programme$1 or program$1 or method$1 or approach$1)).ti,ab. 27053

3 1 and 2 3678

4 (dCBT or cCBT).ti,ab. 268

5 ((gaming or gamified or game format or video game$) and (CBT or cCBT or dCBT or cognitive behavi$)).ti,ab. 116

6 3 or 4 or 5 3793

7 Anxiety/ or Anxiety Disorders/ 133283

8 exp Depressive Disorder/ or Depression/ 249790

9 (anxiet$ or anxious or low mood or depress$).ti,ab. 662705

10 7 or 8 or 9 725340

11 6 and 10 2267

12 economics/ 27477

13 exp "costs and cost analysis"/ 261369

14 economics, dental/ 1920

15 exp "economics, hospital"/ 25651

16 economics, medical/ 9231

17 economics, nursing/ 4013

18 economics, pharmaceutical/ 3089

19 (economic$ or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic$).ti,ab. 990508

20 (expenditure$ not energy).ti,ab. 35481

21 (value adj1 money).ti,ab. 40

22 budget$.ti,ab. 34192

23 or/12-22 1152950

24 ((energy or oxygen) adj cost).ti,ab. 4644

25 (metabolic adj cost).ti,ab. 1655

26 ((energy or oxygen) adj expenditure).ti,ab. 28278

27 24 or 25 or 26 33534

28 23 not 27 1145212

29 letter.pt. 1200171

30 editorial.pt. 627878

31 historical article.pt. 368891

32 29 or 30 or 31 2175992

33 28 not 32 1105779

34 11 and 33 413

35 limit 34 to english language 408

36 limit 35 to yr="2022 - 2023" 40

Embase <1974 to 2022 November 28>

1 (computer or computerized or computerised or digital or online or internet$ or app or apps).ti,ab. 931565

2 (cognitive adj2 behavio$ adj3 (therap$ or intervention$ or treatment$ or psychotherap$ or programme$1 or program$1 or method$1 or approach$1)).ti,ab. 37848

3 1 and 2 4602

4 (dCBT or cCBT).ti,ab. 434

5 ((gaming or gamified or game format or video game$) and (CBT or cCBT or dCBT or cognitive behavi$)).ti,ab. 176

6 3 or 4 or 5 4853

7 anxiety/ or anxiety disorder/ 339946

8 depression/ 446921

9 (anxiet$ or anxious or low mood or depress$).ti,ab. 885019

10 7 or 8 or 9 1059530

11 6 and 10 2751

12 health-economics/ 34895

13 exp economic-evaluation/ 341870

14 exp health-care-cost/ 327275

15 exp pharmacoeconomics/ 223818

16 (expenditure$ not energy).ti,ab. 47921

17 (value adj2 money).ti,ab. 2838

18 budget$.ti,ab. 44957

19 or/12-18 775606

20 letter.pt. 1248380

21 editorial.pt. 744742

22 note.pt. 916306

23 20 or 21 or 22 2909428

24 19 not 23 656155

25 (metabolic adj cost).ti,ab. 1775

26 ((energy or oxygen) adj cost).ti,ab. 4899

27 ((energy or oxygen) adj expenditure).ti,ab. 35822

28 25 or 26 or 27 41313

29 24 not 28 655598

30 exp animal/ 29411432

31 exp animal-experiment/ 2928971

32 nonhuman/ 7111933

33 (rat or rats or mouse or mice or hamster or hamsters or animal or animals or dog or dogs or cat or cats or bovine or sheep).ti,ab,sh. 6273170

34 30 or 31 or 32 or 33 31572692

35 exp human/ 24374590

36 exp human-experiment/ 604085

37 35 or 36 24376819

38 34 not (34 and 37) 7196992

39 29 not 38 636636

40 11 and 39 264

41 limit 40 to (english language and yr="2022 -Current") 18

APA PsycInfo <1806 to November Week 3 2022>

1 (computer or computerized or computerised or digital or online or internet$ or app or apps).ti,ab. 252712

2 (cognitive adj2 behavio$ adj3 (therap$ or intervention$ or treatment$ or psychotherap$ or programme$1 or program$1 or method$1 or approach$1)).ti,ab. 37356

3 1 and 2 2924

4 (dCBT or cCBT).ti,ab. 206

5 ((gaming or gamified or game format or video game$) and (CBT or cCBT or dCBT or cognitive behavi$)).ti,ab. 129

6 3 or 4 or 5 3028

7 exp Anxiety/ or exp Anxiety Disorders/ 134889

8 exp "Depression (Emotion)"/ or exp Major Depression/177416

9 (anxiet$ or anxious or low mood or depress$).ti,ab. 473455

10 7 or 8 or 9 506849

11 6 and 10 1836

12 "costs and cost analysis"/ 18662

13 "Cost Containment"/699

14 (economic adj2 evaluation$).ti,ab.2085

15 (economic adj2 analy$).ti,ab. 1702

16 (economic adj2 (study or studies)).ti,ab. 926

17 (cost adj2 evaluation$).ti,ab. 394

18 (cost adj2 analy$).ti,ab. 4251

19 (cost adj2 (study or studies)).ti,ab. 996

20 (cost adj2 (effectiv$ or benefit$ or utili$ or minimi$ or consequence$ or comparison$ or identificat$)).ti,ab. 22429

21 (economic$ or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic$).ti,ab. 243492

22 or/12-21 245661

23 (task adj2 cost$).ti,ab,id. 769

24 (switch$ adj2 cost$).ti,ab,id. 1533

25 (metabolic adj cost).ti,ab,id. 112

26 ((energy or oxygen) adj cost).ti,ab,id. 309

27 ((energy or oxygen) adj expenditure).ti,ab,id. 2998

28 or/23-27 5405

29 (animal or animals or rat or rats or mouse or mice or hamster or hamsters or dog or dogs or cat or cats or bovine or sheep or ovine or pig or pigs).ab,ti,id,de. 378653

30 editorial.dt. 44328

31 letter.dt. 25566

32	dissertation abstract.pt.	541765
33	30 or 31 or 32	611659
34	22 not (28 or 29 or 33)	201241
35	11 and 34	263
36	limit 35 to (english language and yr="2022 -Current")	10

Appendix B: Excluded Studies

Where a technology had evidence available, the decision to include a study was based on criteria such as outcomes, comparators, sample size and setting. Studies were excluded if the outcomes were not relevant to the scope regardless of whether there was any alternative evidence. For technologies where the outcomes were relevant, inclusion was based on meeting one of the following criteria

- Comparator relevant to the scope
- Sample size <100
- Conducted in UK / IAPT service

Study	Technology	Reason for Exclusion
Beatty 2022	Wysa	The aim and outcomes of the study were not relevant to the scope.
Eilert 2022	SilverCloud	Outcomes were not considered to be within the scope of this review (use of CBT skills following completion of treatment)
Eilert 2022	SilverCloud	Outcomes were not considered to be within the scope of this review (follow-up on use of CBT skills following completion of treatment)
Enrique 2021	SilverCloud	Outcomes were not considered to be within the scope of this review (beliefs in rumination and emotion regulation and their impact on CBT use)
Lawler 2021	SilverCloud	N=15 Results for depression and anxiety cannot be separated
McMurchie 2013	Beating the Blues	Primary indication for use of technology is depression. Depression with co-morbid anxiety is included but EAG considered this not to be relevant to the anxiety

		topic.
Pittaway 2010	Beating the Blues	Outcomes were not considered to be within the scope of this review. N=50 across 3 groups,
Thew 2022	iCT-SAD	N=44, compared with waitlist control and not a UK based study

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Early Value Assessment

MT589 Digitally Enabled Therapies for Adults with Anxiety Disorder

External Assessment Group Addendum

Produced by: Cedar

Date: 27/02/2023

Correspondence to: Cedar, Cardiff Medicentre, Heath Park, Cardiff CF14 4UJ

Contains confidential information: Yes

The EAG has prepared this addendum in response to requests from NICE following the MTAC meeting for the topic.

Key issues addressed in this addendum

NICE Query	**EAG Response**
Companies raised concerns that some evidence may have been missing for their technology.	The EAG has reviewed the company submissions to ensure no relevant evidence has been excluded inadvertently from the main report. • Evidence from 3 additional studies has been reviewed and summarised in the addendum. • Available details for one additional ongoing study are summarised in section 2. • For other studies where there was a question over eligibility of inclusion, but which the EAG consider should be excluded, they have been added to section 3 of the addendum.
Adverse events were a key discussion point for the committee	The EAG reviewed all included studies for adverse event data and included a table in the addendum

1. Additional Clinical Evidence

An additional 3 studies have been included in this addendum (table 1). A rating of Green indicates an element that meets the scope fully, amber meets the scope partially and red indicates does not meet the scope.

The additional studies cover generalised anxiety (1 study) and PTSD (2 studies) and report on a range of outcomes including clinical outcomes, acceptability and uptake. Results from the additional studies are reported in table 2 for generalised anxiety and table 3 for post-traumatic stress disorder.

Results for generalised anxiety ([redacted]) relate to SilverCloud and are in line with findings from other studies reporting [redacted]For PTSD both studies relate the use of Spring. One study (Lewis 2017) reports improvements across a range of measures for people using Spring with significant differences reported for those using Spring compared with people in the delayed treatment group. It should be noted that by week 22, when all patients in the delayed treatment group had crossed over and completed treatment, the differences between the groups was no longer significant.

One study (Simon 2021) explored the views of 10 NHS commissioners and managers in relation to the acceptability and implementation of internet-based therapies. Three key themes were identified including increasing acceptance of internet-based therapies, potential for offering a solution to capacity issues which create barriers to the provision of face to face therapy and the need for a national coordinate approach with appropriate training and supervision to facilitate roll-out. Although based on Spring which is used in for PTSD, the findings from this study may be generalisable across all technologies.

Table 1: Additional Studies

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Spring				
Study: Lewis 2017 **Location:** UK	**Design:** exploratory single blind randomised trial **Aim:** to establish efficacy of guided internet-based self-help for PTSD in comparison to a delayed treatment control group. **Comparator:** Delayed Treatment (Waitlist until week 14 then crossover to treatment arm) **Therapist Involvement:** 1-hour face to face session at beginning with fortnightly 30min face to face or telephone sessions. Therapist guide also contacted participants by phone / e-mail between appointments **Amber**	**Participants:** N=42 adults who continued to meet diagnostic criteria for DSM-5 PTSD of mild to moderate severity after a 2-week period of symptom monitoring **Setting:** Traumatic Stress service, expanded to include mental health services at a primary care level **Green**	**Primary Outcome** CAPS-5 (30 item structured interview that corresponds to the DSM-5 criteria for PTSD) **Secondary Outcome** • PTSD checklist for DSM-5 • Beck Depression Inventory (BDI • Beck Anxiety Inventory (BAI) • Alcohol Use Disorders Identification Test (AUDIT) • Social Support Questionnaire (SSQ) • Sheehan Disability Scale (SDS) **Green**	Small number of participants and comparator not relevant to scope.
Study: Simon 2021	**Design:** Qualitative Interview Study	**Participants:** N= 10 individuals in NHS roles likely to fund, commission, signpost-to, or	Interview findings around issues such as capacity, acceptability and usability	Not clinical outcomes, limited evidence on the views of NHS

Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
Location: UK	**Aim:** explore in-depth the views on Internet-based psychological therapies and their implementation from the perspective of NHS commissioners and managers. **Comparator:** N/A **Green**	implement an i-CBT intervention for NHS patients **Setting:** NHS **Green**	**Green**	professionals likely to use / recommend digital therapies.
SilverCloud				
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table 2: Results for generalised anxiety

Study	Technology	Anxiety measures	WSAS	Recovery and remission	Acceptability and usage
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table 3: Results for PTSD

Study	Technology	PTSD specific measures: Change in CAPS-5, PCL-5 and PSS-I	Acceptability and usage	Therapist time
Lewis 2017	Spring	Clinician assessed traumatic stress symptoms: • Immediately after treatment (week 10) significantly lower levels of compared with delayed treatment group (Group mean difference of 18.60 points) • Similar differences at week 14 (group mean difference of 17.16) • At week 22 differences were not significant CAPS scores and PTSD checklist scores showed the greatest improvement from baseline to week 10 in the treatment group and from week 14 to week 22 in the delayed	19% of participants dropped out prematurely with reasons for dropping out including: • Perceived lack of time • Finding the program difficult • Feeling symptoms had improved sufficiently	Mean amount of therapist input was 147.53 mins per participant including a mean 3.09 face to face meetings, 2.09 telephone calls and 1.00 e-mails.

Study	Technology	PTSD specific measures: Change in CAPS-5, PCL-5 and PSS-I	Acceptability and usage	Therapist time
		treatment group. No significant difference observed between the groups at week 22. Similar patterns were observed across measures of depression, anxiety and functional impairment– no statistically significant differences once both groups received treatment		
Simon 2021	Spring		Three main themes identified: • Internet based therapies offer a solution to barriers to face to face therapies that result from capacity issues in the service • Acceptance of internet-based therapies is growing as they are accessible and empowering treatment options however reservations include potential threat to therapeutic relationship and risk they may exclude some individuals • Successful roll out of internet-based interventions should include a national approach to implementation with clear understanding of implementation requirements. Barriers to successful roll-out include set	

Study	Technology	PTSD specific measures: Change in CAPS-5, PCL-5 and PSS-I	Acceptability and usage	Therapist time
			up costs and delays due to NHS inflexibility.	

2. Ongoing Studies

One company (Cerina) provided a protocol for a trial using the technology for OCD which may provide evidence in the future. The feasibility trial aims to investigate the feasibility of the Cerina app (including participants` views on the quality and usability of the User Interface Design) and the clinical aspects of the Cerina application as well as testing the preliminary effects of the intervention in reducing OCD symptoms over time. There are no details for timelines and currently the study is not mentioned on the company website.

3. Adverse Events and Safety

The committee considered adverse events and safety of the technologies to be one of the most important factors. While the EAG identified no safety concerns with any of the technologies, the committee were concerned that safety in the context of this topic might include broader and relate specifically to factors such as mental health and well-being.

The EAG has revisited the included studies and reported on any potential adverse events and / or safety concerns for completeness (table 4). One study (Richards 2020) reported rates of deterioration as adverse events, however other studies have reported deterioration as a clinical outcome.

Table 4: Safety Adverse Events

Study	Adverse Event data collected	Adverse Events reported	Considered to be study / treatment related
Bisson 2022	Possible adverse events considered to be a deterioration in mental health assessed by outcome measures and suicidal ideation.	Risk assessment framework triggered 105 times, once due to report of self-harm and remaining for suicidal ideation. Six serious adverse events reported	No
Duffy 2020	No details – significant SAEs were handled by the clinical team and escalated appropriately	None reported	

Study	Adverse Event data collected	Adverse Events reported	Considered to be study / treatment related
Richards 2020	Rates of deterioration at post-treatment (increase in PHQ-9 ≥ 6 and/or GAD-7 ≥ 4) and an increase in the number of diagnoses at 3-months were considered as adverse events	5.2% (n=10) in the intervention arm and 12.2% (n=11) in the waitlist arm deteriorated. No severe adverse events reported 25.7% (n=55) in the intervention arm received further mental health treatment during follow-up	
Wilhelm 2020	Monitored by investigator at each clinical assessment	None reported	
Wilhelm 2022	A standardised adverse event form which consisted of 4 yes / no questions	30 out of 80 participants reported a total of 42 adverse events during the 12-week randomized controlled phase of the trial. • 45.2% were mild (new event that did not interfere with activities of daily living) • 47.6% were moderate (new event that posed some interference or required intervention to prevent interference) • 7.1% were severe (new event that posed interference and required intervention). Two adverse events (one in each group) resulted in an investigator-initiated study withdrawal; No serious adverse events occurred in this trial.	Adverse events were found to be definitely unrelated (69.1%) or unlikely to be related (30.9%)

4. Excluded Studies

Study	Technology	Reason for Exclusion
Beatty 2022	Wysa	The aim and outcomes of the study were not relevant to the scope.
Cheng 2022a	Wysa	Population is not within scope. People with chronic pain and symptoms of anxiety / depression.

Cheng 2002b	Wysa	Population is not within scope. Orthopaedic patients with symptoms of anxiety and depression.
Ingelsias 2022	Wysa	Not within scope. People using an adapted 'Return to Work' version of Wysa. The version of the technology is not commercially available.
Inkster 2022	Wysa	Population not within scope – people with self-reported maternal event while using Wysa.
Eilert 2022	SilverCloud	Outcomes were not considered to be within the scope of this review (use of CBT skills following completion of treatment)
Eilert 2022	SilverCloud	Outcomes were not considered to be within the scope of this review (follow-up on use of CBT skills following completion of treatment)
Enrique 2021	SilverCloud	Outcomes were not considered to be within the scope of this review (beliefs in rumination and emotion regulation and their impact on CBT use)
Lawler 2021	SilverCloud	N=15 Results for depression and anxiety cannot be separated
Grime 2004	Beating the Blues	Narrative Review
Van Den Berg 2004	Beating the Blues	Narrative Review
Hunt 2006	Beating the Blues	Depression is the primary descriptor
Learmonth & Rai 2007	Beating the Blues	Narrative Review
Mitchell & Dunn 2007	Beating the Blues	Narrative Review
Learmonth 2008	Beating the Blues	Depression appears to be the primary descriptor and results not reported separately for depression or anxiety
Rollman 2018	Beating the Blues	Not relevant to scope – study looks at including an internet support group as part of care is effective.
McMurchie 2013	Beating the Blues	Primary indication for use of technology is depression. Depression with co-morbid anxiety is included but EAG

		considered this not to be relevant to the anxiety topic.
Proudfoot 2004	Beating the Blues	Assessment made using GHQ
Pittaway 2010	Beating the Blues	Outcomes were not considered to be within the scope of this review. N=50 across 3 groups,
Thew 2022	iCT-SAD	N=44, compared with waitlist control and not a UK based study
Goessl 2017	Resony	Outcomes not relevant to scope – physical changes in factors such as heart rate variability, autonomic reactivity
Levine 2016	Resony	Outcomes not relevant to scope – physical changes in factors such as heart rate variability, autonomic reactivity
Shinba 2017	Resony	Outcomes not relevant to scope – physical changes in factors such as heart rate variability, autonomic reactivity
Chalmers 2014	Resony	Outcomes not relevant to scope – physical changes in factors such as heart rate variability, autonomic reactivity
Chang 2013	Resony	Outcomes not relevant to scope – physical changes in factors such as heart rate variability, autonomic reactivity
Fisher & Newman 2013	Resony	Outcomes not relevant to scope – physical changes in factors such as heart rate variability, autonomic reactivity
Chang 2013	Resony	Outcomes not relevant to scope – physical changes in factors such as heart rate variability, autonomic reactivity
Pittig 2013	Resony	Outcomes not relevant to scope – physical changes in factors such as heart rate variability, autonomic reactivity
Verma 2011	Resony	Outcomes not relevant to scope – physical changes in factors such as heart rate variability, autonomic reactivity
Conrad & Roth 2007	Resony	Outcomes not relevant to scope – physical changes in factors such as heart rate variability, autonomic reactivity

Francis & Pennebaker	Resony	Outcomes not relevant to scope – writing therapy
Lieberman	Resony	Outcomes not relevant to scope – writing therapy
Lewis 2013	Spring	Not relevant to scope – app / programme development study

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Health technology evaluation

Assessment report overview

Digitally enabled therapies for adults with anxiety disorders

This assessment report overview has been prepared by the Medical Technologies Evaluation Programme team to highlight the significant findings of the external assessment group (EAG) report. It includes **brief** descriptions of the key features of the evidence base and the cost analysis, any additional analysis carried out, and additional information, uncertainties and key issues the committee may wish to discuss. It should be read along with the company submission of evidence and with the external assessment report. The overview forms part of the information received by the medical technologies advisory committee when it develops its recommendations on the technology.

Key issues for consideration by the committee are described in section 9, following the brief summaries of the clinical and cost evidence.

This report contains information that has been supplied in confidence and will be redacted before publication. This information is underlined and highlighted in either [redacted] (for academic in confidence information) or in [redacted] (for commercial in confidence information). Any depersonalised data in the submission document is underlined and highlighted in [redacted].

This overview also contains:

- Appendix A: Sources of evidence
- Appendix B: Additional analyses carried out by EAG

1 The technology

Digitally enabled therapies deliver a substantial portion of therapy through the technology but are designed to be used with practitioner or therapist support. They can be delivered online or through apps on mobile phones, tablets and computers. Technology use is based on practitioner or therapist review along with regular interactions with the patient about their progress. This helps people deepen their understanding of the intervention materials, supports them in setting goals and provides advice on real world assignments.

This assessment focuses on the use of digitally enabled therapies in NHS Talking Therapies (previously known as IAPT). In total, 11 digitally enabled therapies for adults with anxiety disorders are included in this assessment. Details of these are provided in the scope and EAG report.

- Beating the Blues (365 Health Solutions) for mild to moderate depression or anxiety including generalised anxiety disorder (GAD)
- Cerina (NoSuffering) for GAD
- iCT-PTSD (OxCADAT) for post-traumatic stress disorder (PTSD)
- iCT-SAD (OxCADAT) for social anxiety disorder (SAD)
- Iona Mind (Iona Mind) for GAD or depression
- Minddistrict (Minddistrict) for GAD, health anxiety, social anxiety, obsessive compulsory disorder (OCD), panic disorder and phobias
- Perspectives BDD (Koa Health) for body dysmorphic disorder (BDD)
- Resony (RCube Health) for worry and anxiety and to manage GAD
- SilverCloud for anxiety, GAD, health anxiety, social anxiety, OCD, panic and phobias
- Spring (Cardiff University) for PTSD
- Wysa (Wysa) for mild to moderate anxiety of depression.

Technologies included in this EVA are expected to complete the NHS Talking Therapies 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 NHS Talking Therapies.

2 Proposed use of the technology

2.1 Disease or condition

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 involve excessive fear, worry and anxiety that is severe enough to cause significant distress or impairment in functioning and daily living. They can have a lifelong course of relapse and remission and commonly occur with other conditions such as depression or substance misuse. Anxiety disorders treated in NHS talking therapies services include:

- Body dysmorphic disorder (BDD)
- Generalised anxiety disorder (GAD)
- Health anxiety
- Obsessive-compulsive disorder (OCD)
- Panic disorder
- Post-traumatic stress disorder (PTSD)
- Social anxiety disorder
- Specific phobias

Details of these anxiety disorders are provided in the scope.

2.2 Patient group

Adults with anxiety disorders receiving low intensity and high intensity psychological interventions at step 2 and step 3 of the care pathway, respectively within NHS talking therapies services.

2.3 Unmet need and current management

Waiting times for NHS psychological therapy vary from 4 days to over 80 days in different parts of England (House of Commons library 2021). There were

1.81 million referrals to NHS talking therapies services between April 2021 to March 2022, but only 37% completed a course of treatment (NHS Digital 2022). This may be for many reasons including NHS talking therapies not being suitable for a person's level of risk or impairment. Digitally enabled therapies can be used to provide an alternative and more accessible treatment option.

NHS talking therapies services provide evidence-based psychological therapies in the NHS to people with anxiety disorders and depression using a stepped care approach (National Collaborating Centre for Mental Health 2021). This means offering the least intrusive, most effective intervention first. People may be offered more intensive treatments if they have marked functional impairment or do not improve after low intensity treatments. This is based on patient-clinician decision making that considers the patient's needs and preferences.

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

There are NICE guidelines on specific anxiety disorders (Table 1) except for health anxiety and specific phobias. The NHS (2020) suggests that people with health anxiety use self-help and see a GP if symptoms do not improve or worries significantly impact daily living. It also 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).

Table 1: NICE guidelines on adults with anxiety disorders

Condition (Guideline)	Recommendation
BDD (CG31)	High intensity interventions • Mild functional impairment: individual or group CBT including exposure and response prevention (ERP) • Moderate impairment: either a selective serotonin reuptake inhibitor (SSRI) or more intensive individual CBT with ERP • Severe impairment: both an SSRI and CBT with ERP
GAD (CG113)	Low intensity interventions • Individual guided or unguided self-help based on principles of CBT or psychoeducational groups High intensity interventions • CBT or applied relaxation • Drug treatment for some people who prefer it to therapy
OCD (CG31)	Low intensity interventions • Mild impairment or patient preference: brief individual CBT including ERP using structured self-help materials or by telephone, or group CBT with ERP High intensity interventions • Moderate impairment or did not benefit from low intensity treatment: SSRI or more intensive CBT with ERP • Severe impairment: both an SSRI and CBT with ERP
Panic disorder with or without agoraphobia (CG113)	Low intensity interventions • Mild to moderate panic disorder: guided or unguided self-help High intensity interventions • Moderate to severe panic disorder with or without agoraphobia: CBT or an antidepressant
PTSD (NG116)	High intensity interventions • 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
Social anxiety disorder (CG159)	High intensity interventions • 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 • People who decline either may be offered drug treatment or short-term psychodynamic psychotherapy where appropriate.

2.4 Proposed management with new technology

In NHS talking therapies services, digitally enabled therapies may 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.

3 The decision problem

Details of the decision problem are described in the scope and the EAG provided comments in Table 1 in the EAG report. No changes were made to the decision problem during this assessment.

4 The evidence

4.1 Summary of evidence of clinical benefit

The EAG included 19 published studies in the assessment (Table 2). Further detail of these studies can be found in table 3. Unpublished data, further study protocols and trial registry entries are discussed under ongoing research (section 5). The rationale for the selection of these studies can be found in section 4.1 and 4.2 of the EAG report.

Table 2: Published studies included in the assessment

Technology	Publication and study design
Beating the Blues	6 publications: • 1 secondary analysis of a three-arm RCT (Jonassaint 2020) • 5 single-arm studies (Cavanagh 2006, Cavanagh 2009, Cavanagh 2011, Learmonth 2008) of which 1 is from a secondary analysis of a RCT (Jonassaint 2017)
Cerina	No relevant published evidence found
iCT-PTSD	1 publication: • 1 before-and-after study (Wild 2016)
iCT-SAD	2 publications: • 1 RCT (Clark 2022) • 1 pilot cohort study (Stott 2013)
Iona Mind	No relevant evidence found
Minddistrict	No relevant evidence found
Perspectives BDD	2 publications: • 1 RCT (Wilhelm 2022) • 1 single-arm feasibility study (Wilhelm 2020)
Resony	No relevant published evidence found
SilverCloud	7 publications: • 1 RCT (Richards 2020) • 1 secondary analysis of a pragmatic RCT (Palacios 2022b) • 1 comparative observational cohort study (Palacios 2022a) • 4 single arm studies (Duffy 2020), of which 2 were prospective cohort studies (Chien 2020, Jardine 2020), and 1 a feasibility study (Palacios 2018)
Spring	1 publication: • 1 randomised controlled non-inferiority trial (Bisson 2022)
Wysa	No relevant evidence found

The results of the published studies are presented for each of the disorders. See section 5.2 of the EAG report for further detail.

Body dysmorphic disorder (Perspectives, Koa Health)

The evidence consists of 1 RCT and 1 single-arm feasibility study. The RCT suggests that Perspectives is more effective than waitlist control in terms of reducing BDD symptom severity ($p<0.001$), BABS ($p<0.001$), depressive symptoms ($p=0.002$), functional impairment ($p<0.001$) and quality of life ($p=0.001$). It also showed that 52% were in full or partial remission (Wilhem, 2022). A reduction in BDD symptom severity and BABS was supported by the feasibility study (Wilhem, 2020).

Generalised anxiety disorder (Beating the Blues, Cerina, Iona Mind, Minddistrict, Resony, Silvercloud, Wysa)

There are 13 included studies that focused on generalised anxiety reporting for either Beating the Blues or SilverCloud.

The evidence for Beating the Blues consists of 1 secondary analysis of a three-arm RCT and 5 single arm studies. The evidence indicates that Beating the Blues results in improvement in anxiety symptoms, reporting reduced levels of anxiety, as measured by the GAD-7, BAI and PROMIS-Anxiety, over the treatment sessions. Two studies including the secondary analysis of the three-arm RCT looked at differences between African Americans and white participants in relation to anxiety measures and acceptability/usage of the guided technologies (Jonassaint 2017; Jonassaint 2020). African Americans showed a greater benefit from the Beating the Blues app in anxiety measures compared to usual care than white participants. They also found that African Americans were less likely to start session 1 of the CCBT program compared to white participants and that white participants completed more sessions of BtB than African Americans in their study.

The evidence for Silvercloud consists of 1 RCT, 1 secondary analysis (non-comparative) of a pragmatic RCT, 1 comparative observational cohort study, and 4 single arm studies. The comparative studies showed a significant improvement in anxiety symptoms, functional impairment and reliable improvement. This was supported by the single arm studies which also suggested a reduction in anxiety symptoms.

There is no published evidence for Cerina, Iona Mind, Minddistrict, Resony and Wysa.

Post-traumatic stress disorder (iCT-PTSD, Spring)

The evidence for iCT-PTSD consists of 1 before-and-after study with 10 participants suggesting a significant improvement in disorder specific and anxiety outcome measures compared with baseline.

The evidence for Spring consists of 1 RCT. It showed that Spring was non-inferior to face-to-face CBT-TF in reducing PTSD symptoms and secondary outcomes such as anxiety symptoms and functional impairment at the primary endpoint at 16 weeks after randomisation. Clinically substantial improvements were maintained at 52 weeks after randomisation, when most results were inconclusive but in favour of face-to-face CBT-TF.

Social anxiety disorder (iCT-SAD, Minddistrict and Silvercloud)

The evidence for iCT-SAD consists of 1 RCT and 1 pilot cohort study. The RCT reported no difference between the iCT-SAD and CT-SAD for social anxiety disorder composite, anxiety symptoms or functional impairment indicating that digital therapy can achieve outcomes at least as good as face-to-face therapy. Total therapist time for iCT-SAD was 6.45h compared with the 15.8h needed for CT-SAD for the same reduction in social anxiety. When compared with conventional face-to-face therapy (CT-SAD), iCT-SAD was associated with 2.45 times the amount of symptom change per hour of therapist time. The pilot study showed improvements in anxiety symptoms compared with baseline.

There is no published evidence for Minddistrict and Silvercloud.

There is no evidence for the following disorders:

- Health anxiety (Minddistrict, Silvercloud)
- Obsessive compulsory disorder (Minddistrict, Iona Mind)
- Panic disorders with or without agoraphobia (Minddistrict, Silvercloud)
- Specific phobias (Minddistrict, Silvercloud)

A search of the MAUDE database and MHRA did not identify any adverse events or safety concerns relating to any of the included technologies. Two included studies listed safety as an outcome (Richards 2020 and Wilhelm 2020). Neither of these reported any adverse events. One specialist committee member noted that digital therapies would not be suitable for

moderate or high-risk clients as digital therapy review involves much less detailed safety review compared with one – to – one guided self-help. The EAG made the following overarching comments regarding the limitations and generalisability of the evidence base:

- **Population** – the populations reported specifically in the GAD studies had no clear DSM-V or ICD-10 diagnosis of GAD, but were presented as having high levels of anxiety symptoms using the GAD-7 or depression symptoms on the PHQ-9. This does not constitute a diagnosis of either disorder and is a major limitation of the included GAD studies as they cannot be wholly generalised to the NHS talking therapies pathway. Also, these studies grouped people with symptoms of anxiety, depression or both together, without splitting the results by disorder or symptom group. It is therefore unknown whether participants showing a reduction in GAD-7 score had symptoms of anxiety symptoms, depression, or both. This also limits the generalisability to the NHS talking therapies pathway.

- **Comparator** – there is a general lack of comparator groups in the included evidence. Those that did have a comparator group generally used 'waitlist' for the control group which is not within scope and therefore limits the applicability of this evidence.

- **Setting** – several studies relating to specific conditions such as PTSD, SAD and BDD were done in an NHS talking therapies setting. However, for GAD, the study settings were mixed. Some studies were done in an NHS talking therapies setting, whereas others were done in a non-NHS or non-UK setting. Those studies not done in an NHS talking therapies setting have limited generalisability compared to the studies done in an NHS talking therapies setting.

- **Outcomes** – specifically for BDD, validated measures were used to assess BDD in study but these are not aligned with the NHS talking therapies measures.

- **Generalisability** – the individual technologies have different information, use different methods to interact and apply to different conditions. The EAG considered it therefore not appropriate to consider evidence from one technology to be indicative of any clinical effectiveness with a different technology or to use existing data for one condition to infer generalisability to another condition.
- **Therapist time** - There is a lack of therapist or a guided element within the included research and, while for many studies it is indicated that there is a therapist guided element the details are not clearly reported and therapist time is only reported as an outcome in a small number of studies. If this is different from what is delivered for NHS talking therapies than the results may be less generalisable.

In summary, the EAG concluded that the clinical evidence suggests that guided digitally enabled technologies can reduce anxiety symptoms (as measured by general and condition specific measures) across a range of anxiety disorders and that reductions can persist up to 12 months post treatment. Limited comparative evidence indicates the reduction in anxiety symptoms was larger using the guided therapies, compared to waiting list or usual care. However, 1 study reporting results for SAD and iCT-SAD (Clark, 2022) reported no difference compared with face-to-face CBT indicating that digital therapy can achieve outcomes at least as good as face-to-face therapy. The evidence also suggests that the technologies are easy to use as they have high levels of usage and low levels of drop out across conditions and tend to have comparable if not increased rates of remission and recovery following use. There is no evidence that the technologies lead to any adverse events nor is there evidence of any safety concerns with any of the technologies. There is a lack of relevant evidence for health anxiety, obsessive compulsive disorder, panic disorder and specific phobias. Therefore, the EAG was unable to draw any clinical or economic conclusions in these areas.

The EAG concluded that digitally enabled technologies show promise, but additional evidence is needed for recovery, remission and relapse rates, over longer periods, for a specific population and using appropriate comparators.

Table 3: Details of published studies included in the assessment report, grouped by target disorder

Study name, design & location	Participants & setting	Intervention & comparator	Outcome measures	Key results
Body dysmorphic disorder (BDD, number of studies=2)				
Perspectives BDD (=2)				
Wilhelm 2022 RCT Location: US	80 people with BDD **Setting**: Not reported **Green**	**Intervention**: Perspectives BDD (n=40) **Comparator**: Waitlist (n=40) **Amber**	**Primary Outcome** • Intent to treat analysis of difference in BDD-YBOCS scores between treatment and waitlist groups **Secondary Outcomes** • BABS, QIDS-SR, SDS, Q-LES-Q • Dropout • Engagement • Satisfaction **Amber**	**BDD-YBOCS** At 12 weeks, BDD symptom severity was significantly lower in the intervention group compared with the control group (p<000.1). At 12 weeks, significant improvements were found for the intervention compared with the control group for **BABS** (p<0.001), **depressive symptoms** (p=0.002), **functional impairment** (p<0.001) and **quality of life** (p=0.001) **Response rates at end of treatment** • Intervention: 68% • Control: 14% **Full or partial remission** • Intervention: 52% (16/31) • Control: 8% (3/37) **Drop out rate** • Intervention: 23% (9/40) • Control: 8% (3/40) • P=0.11 **App usage** • Intervention: 130.2min, mean 30.4 days **Satisfaction**

				86% were very (14/28) or mostly (25/28) satisfied. 89% would recommend Perspectives
Wilhelm 2020 Single-arm feasibility study Location: US	10 adults with at least moderately severe BDD **Setting**: outpatient setting **Green**	**Intervention**: Perspectives BDD **Comparator**: None **Amber**	Diagnostic assessment using SCID-5 and MINI and feasibility, acceptability and satisfaction (CSQ-8) **Primary treatment outcome** • BDD-YBOCS **Secondary outcomes** • BABS score • PHQ-9 • SDS • Q-LES-Q-S • Safety **Amber**	**BDD-YBOCS** scores decreased across treatment (mean 45.27%) **BABS scores** decreased across treatment (mean 67.08%) **Remission & recovery** • 90% of participants were treatment responders (≥30% reduction on BDD-YBOCS). Treatment response remained 90% at follow up. • Reliable change index was 5.08 posttreatment and 5.69 at follow up, indicating a reliable improvement **App usage** Participants spent a mean of 398 minutes over 12 weeks using the service
Generalised anxiety disorder (GAD, number of studies=13)				
Beating the Blues (=6)				
Cavanagh 2011 Single-arm study Location: UK	351 people completed baseline assessment (n=295 started BTB program) **Setting** NHS mental health services **Green**	**Intervention** Beating the Blues **Comparator** None **Amber**	Change in the following measures: • PHQ-9 • GAD-7 • Clinical Outcomes in Routine Evaluation-Outcome Measure (CORE-OM) • WASA Numbers reaching	**GAD-7** over the course of at least 2 treatment sessions mean GAD-7 scores reduced from 12.6 at baseline to 7.6 (p<0.001). **WSAS** over the course of at least 2 treatment sessions mean WASA scores reduced from 24 at baseline to 19.2 (p<0.001). **CORE-OM** over the course of at least 2 treatment sessions mean CORE-OM scores reduced from 19.6 at baseline to 14.5 (p<0.001). **Recovery and remission**

			caseness criteria (depression caseness criteria PHQ-9 ≥ 10; anxiety caseness criteria GAD-7 ≥ 8) **Green**	• At baseline, 226 (85.3%) of those who completed at least two sessions of CCBT (n=265) met caseness criteria for one of (n = 58, 21.9%) or both anxiety and depression (n = 168, 63.4%) • Following treatment of at least 2 sessions, 142 (53.6%) no longer met caseness for either depression or anxiety, 41 (15.5%) continued to meet caseness for one, and 82 (30.9%) for both. • Therefore 50.0% cases moved to recovery status
Cavanagh 2009 Single-arm study Location: UK	219 people with anxiety and/or depression **Setting** NHS mental health services **Amber**	**Intervention** Beating the Blues **Comparator** None **Amber**	Change in the following measures: • The Attitudes to CCBT Questionnaire (A-CCBT) • Opinions about Psychological Problems Questionnaire (OPP) • The Patient Feedback Questionnaire for CCBT (PFQ-CCBT) **Amber**	**EAG comment:** questionnaires/ measures used in the study do not align with the NHS talking therapies measures. Mean pre-treatment total for the **A-CCBT** was 6.3 with all questions rated significantly higher than the midpoint score of 4 ($p<0.001$). Mean scores of **CBT credibility** were 1.8 which is significantly higher than the midpoint of 0 ($p<0.001$). Mean scores from the **PFQ-CCBT** showed the usefulness of the program's introductory video were above the midpoint of 2.5 (Mean=3.3, $p<0.001$). Mean scores of the interactive, multimedia program features were above the midpoint of 3 (mean = 4.0, $p<0.001$). Eighty-nine per cent of patients providing feedback rated the program overall as very (35%) or quite (54%) helpful, and averaged ratings of its usefulness were above the midpoint of 2.5 (mean =3.2, $p <0.001$)
Cavanagh 2006 Single-arm study Location: UK	219 people with anxiety and/or depression **Setting** NHS mental health services **Amber**	**Intervention** Beating the Blues **Comparator** None **Amber**	Change in the following measures: • CORE-OM • WASA • Self-reported anxiety and depression scores **Amber**	104 participants (47%) completed all 8 sessions of BtB and post-treatment measures – referred to as 'Research completers' **Self-reported anxiety score** • Research completers: score reduced from 5.47 at baseline to 3.64 post-treatment ($p<0.001$) • Intention to treat analysis: score reduced from 5.23 at baseline to 4.00 post-treatment ($p<0.001$) **WSAS**

				• Research completers: mean score reduced from 23.14 at baseline to 18.51 post-treatment (p<0.001) • Intention to treat analysis: mean score reduced from 22.39 at baseline to 20.05 post-treatment (p<0.001) **CORE-OM** • Research completers: mean score reduced from 1.88 at baseline to 1.27 post-treatment (p<0.001) • Intention to treat analysis: mean score reduced from 1.81 at baseline to 1.53 post-treatment (p<0.001)
Jonassaint 2020 Secondary analysis of a three-arm RCT Location: USA	704 people with anxiety and/or depression **Setting** Primary care (mental health) **Amber**	**Intervention** Beating the Blues (n=301) **Comparators** • Beating the Blues plus internet support group (n=302) • Usual care (n=101) **Amber**	Change in • PROMIS-Anxiety score • PROMIS depression Differences in PROMIS-Anxiety change between people from White ethnic background and people from African American ethnic background **Amber**	**PROMIS-Anxiety score** • African Americans in the cCBT group showed significantly greater decreases in PROMIS-Anxiety scores compared to those in the UC group (difference of 10.46 vs 4.81, p<0.01). • No significant difference between cCBT and UC was seen in the white participants' group for PROMIS-Anxiety score (difference of 8.77 vs 7.37). • Compared to the white group, African Americans reported a greater benefit of the cCBT programme on PROMIS-Anxiety score only (p=0.05) • For white participants, the number of BtB sessions completed was associated with 6-month improvements PROMIS-Anxiety(p=0.01 - <0.01). For African Americans, more sessions showed a greater benefit on the PROMIS-Anxiety score only (p = 0.014) **App engagement** White participants completed more BtB sessions on average than African Americans (5.5 vs 4.7, p = 0.03).
Jonassaint 2017 Secondary analysis of randomised	590 people with moderate symptoms of anxiety and/or depression	**Intervention** Beating the Blues **Comparator** None	Changes in: • GAD-7 • PHQ-9 Engagement in the app	**GAD-7** African Americans showed a similar level of decline in anxiety (estimated 8-session change: −5.3 vs. −5.6; P=0.80) over the course of the eight BtB sessions compared to white people. Pharmacotherapy use at baseline was not a predictor of decline in GAD-7 scores over time (P=0.6713).

controlled trial (single arm study) Location: USA	**Setting** Primary care **Amber**	**Amber**	**Green**	**App engagement** • African Americans were less likely than white people to start session 1 of the CCBT programme (75% vs. 87%, P=0.01) • African Americans completed slightly fewer sessions at 6 months (mean 4.7 vs. 5.5; P=0.03)
Learmonth 2008 Single-arm study Location: UK	555 adults with anxiety and/or depression symptoms (394 completed full follow-up; 'Research completers') **Setting** NHS talking therapies services **Amber**	**Intervention** Beating the Blues **Comparator** None **Amber**	Reliable and clinically significant changes in: • Beck Depression Inventory II (BDI-II) • Beck Anxiety Inventory (BAI) **Amber**	**BAI** • Research completers: a statistically significant mean BAI score difference was found between pre and post BtB treatment (difference = -5.9, p<0.001). • Intention to treat analysis: a statistically significant mean BAI score difference was found between pre and post BtB treatment (difference = -4.9, p<0.001) **Recovery and remission** • Of the 195 completers recording clinical caseness on the BAI measure, 44 (23%) showed reliable and clinically significant improvement, with 46 (19%) in the intention to treat population (n=238) • Of the 394 who completed the program, 85 were referred on for further treatment. Of the 161 who did not complete the programme, 153 were referred for further treatment
SilverCloud (=7)				
Chien 2020 Prospective cohort study Location: UK	54,604 adults assigned to Space from depression and anxiety treatment programme **Setting** NHS mental health services	**Intervention** Space from depression and anxiety **Comparator** None **Amber**	Changes in the following measures: • PHQ-9 • GAD-7 Log data from interactions with programme to inform engagement patterns over time.	**GAD-7** mean scores reduced from 11.85 at baseline to 4.01 at 14 weeks. 5 different classes of engagement were suggested: • Class 1 – low engagers • Class 2 – late engagers • Class 3 – high engagers with rapid disengagement • Class 4 – high engagers with moderate decrease • Class 5 – high engagers Estimated engagement class specific mean GAD-7 change over 14 weeks:

	Green		**Green**	• Baseline/Class 1 = -4.72 • Class 2 = -4.18 • Class 3 = -6.36 • Class 4 = -4.98 • Class 5 = -5.56
Duffy 2020 Single-arm study Location: UK	124 people on a waiting list for face-to-face therapy for anxiety or depression **Setting** NHS talking therapies services **Green**	**Intervention** Space from Depression, Space from Anxiety or Space from Depression & Anxiety **Comparator** None **Amber**	Changes in the following measures from baseline, treatment exit and service exit: • GAD-7 • WSAS • PHQ-9 Reliable change, recovery, and reliable recovery **Green**	**GAD-7** post-hoc analysis of the linear mixed model • Baseline scores were reduced by on average 3.2 points at iCBT exit point (p<0.001) • iCBT exit to service exit (completers) showed a reduction of 3.985 (p<0.001) • iCBT exit to service exit (dropouts) increase of 0.164 (n.s.) **WSAS** post-hoc analysis of the linear mixed model • Baseline to iCBT exit: reduction of 2.426 (p<0.001) • iCBT exit to service exit (completers): reduction of 4.103 (p<0.001) • iCBT exit to service exit (dropouts): increase of 0.168 (n.s) **Recovery and remission** • N=100 participants had full data at all time points. 58 showed reliable improvement from baseline to iCBT exit • Ninety-nine participants were above clinical caseness threshold at baseline; 22 had achieved recovery by iCBT exit and 20 had achieved reliable recovery; 33 were in recovery at point of service exit all of which reliably recovered
Jardine 2020 Prospective cohort study Location: UK	361 people **Setting** NHS talking therapies services **Green**	**Intervention**: Space from Depression, Space from Anxiety or Space from Depression & Anxiety **Comparator**	Patient expectations of their: • online treatment • experience of the intervention • context of their use of the intervention • their perception of the aesthetics employed	**Experience vs expectation theme** • 71 (39%) participants reported that it was more helpful than they expected it to be • 11 (6%) of clients felt that their experience of online treatment was generally harder than they expected **Experience of online treatment theme** • Only 66 (36%) participants reported developing self-management skills (compared to the 75% who expected it)

		None **Amber**	Assessed at baseline (pre-treatment), 4 weeks and 8 weeks. **Green**	• 93 (51%) participants stated that their overall experience of using the platform was a positive, enjoyable or pleasant one. • For more than a third of clients in this sample, the flexibility and autonomy of online treatment were significant positive factors in their experience. • 31 (17%) participants reported challenges with online treatment, such as the treatment lacked adequate support and guidance, the platform was difficult to use or the content was repetitive. • 16 (9%) participants felt the flexibility of the platform hindered their engagement with it as the lack of deadlines and structure meant it was easy to put off or forget about. Study identified managing expectations, polarised preferences, momentary help-seeking and long-term support as important aspects of the experience to consider in future design
Palacios 2022a Naturalistic, observational cohort study Location: UK	21,215 people in NHS talking therapies step 2 for anxiety and/or depression **Setting** NHS talking therapies services **Amber**	**Intervention** Space from anxiety and Space from depression (n=6,862) **Comparators** • Guided self-help bibliotherapy (n=12,896) • Psychoeducational group (n=1,457) **Green**	Changes over time in: • GAD-7 • WSAS • PHQ-9 Rates of reliable recovery **Green**	**GAD-7** all differences between pre and post were significant at p<0.001: • iCBT = 12.4 to 6.2 • GSH = 13.4 to 7.9 • PGT = 11.4 to 7.6 **WSAS** all differences between pre and post were significant at p<0.001: • iCBT = 15.6 to 9.9 • GSH = 17.7 to 11.9 • PGT = 16.8 to 12.3 **Remission and recovery** Overall reliable improvement rate was higher in the iCBT group (67%) compared to GSH (59%) and PGT (41%, p<0.001).
Palacios 2022b Secondary analysis from pragmatic RCT	241 people with symptoms of anxiety and/or depression **Setting**	**Intervention** Space from anxiety and Space from depression	Follow up at 3-, 6- and 9-months posttreatment: • PHQ-9 • GAD-7	**GAD-7 scores** decreased over the course of treatment then increased slightly over 9 months follow-up: • Baseline = 11.5 • End of treatment = 3.2 • 3 months follow-up = 4.5

Location: UK	NHS talking therapies services **Amber**	**Comparator** None **Amber**	Durability of treatment effects Predictors of relapse at end of treatment **Green**	• months = 4.2 • 9 months = 4.5 **Remission and recovery** • Of the 89 participants included in analysis, 70.8% remained in remission whereas 28.2% had relapsed at the 9-month follow-up. • Of those who relapsed, 53.8% experienced a relapse of depression and anxiety, 7.7% depression only and 38.4% anxiety only. • Younger age, having a long-term condition, and residual symptoms of anxiety at end-of treatment were all significant predictors of relapse at end of treatment.
Palacios 2018 Single-arm feasibility study Location: US	102 university students referred from counselling or mental health services or the international office **Setting** US university mental health services **Amber**	**Intervention** Space from Depression, Space from Anxiety, or Space from Stress **Comparator** None **Amber**	Change at 8 weeks and 3 months in • GAD-7 • RCI • PHQ-9 Satisfaction with treatment **Amber**	**GAD-7** mean scores reduced for those in the Space from Anxiety program from 10.9 at baseline to 7.5 at 8 weeks and 6.7 at 3 months. **Remission and recovery** • On the GAD-7, for those with 8-week follow-up data, 17/53 (32%) decreased their scores by more than the RCI (4+), classed as reliable change; 30/53 (57%) had no reliable change and 6/53 (11%) had reliable deterioration (increase of 4 of more). • At 3 months, 26/50 (52%) had reliable change, 22/50 (44%) had no reliable change, and 2/50 (4%) had reliable deterioration
Richards 2020 RCT Location: UK	361 people with anxiety disorder (n=192) or depressive disorder (n=169) **Setting** NHS talking therapies services	**Intervention** Space from Depression, Space from Anxiety and Space from Depression and Anxiety (n=241) **Comparator** Waitlist (n=120)	Change over 12 months in: • GAD-7 • PHQ-9 • MINI diagnosis • WSAS App usage Safety	**GAD-7** paired comparisons showed in those who received Silvercloud, GAD-7 scores were reduced from baseline to 8-weeks more than in those who did not: • Silvercloud = 12.7 to 8.2 • Waitlist = 12.5 to 10.8 8-week models suggested significant interaction effects of time-by-intervention-arm for GAD-7 ($p<0.0001$).

	Amber	Green	Green	**Recovery and remission** • At 8-week follow-up 46.4% (90/194) of the intervention arm relative to 16.7% (15/90) control-arm participants recovered, with 63.4% (123/194) intervention-arm relative to 34.4% (31/90) control-arm participants showing reliable improvement. • Reliable recovery in the intervention-arm was 40.7% (79/194), and 13.3% (12/90) in the control arm. All between-group differences were significant (p < 0.01).
Health anxiety (number of studies=0)				
No relevant published evidence found.				
Obsessive compulsive disorder (OCD, number of studies=0)				
No relevant published evidence found.				
Panic disorder with or without agoraphobia (number of studies=0)				
No relevant published evidence found.				
Post-traumatic stress disorder (PTSD, number of studies=2)				
i-CT-PTSD (=1)				
Wild 2016 Before-and-after study Location: UK	10 people with DSM-IV diagnosis of PTSD Setting: NHS talking therapies services Amber	Intervention: iCT-PTSD Comparator: None Green	Changes in: • PTSD checklist for DSM-V (PCL-5) • PTSD symptom scale interview (PSS-I) • Post-traumatic cognition inventory (PTCI) • GAD-7 • PHQ-9 • WSAS • Rates of recovery as measured using the	**PCL-5** mean scores decreased from 47.90 to 15.80 post treatment (p<0.001) **PSS-I** mean scores decreased from 31.7 to 12.44 post treatment (p<0.001) **GAD-7** mean scores decreased from 11.6 to 4.4 post treatment (p<0.01) **WSAS** mean scores decreased from 20.8 to 10.58 post treatment (p<0.05) **Rates of recovery and remission** • 9 (90%) participants showed reliable change on the PCL-5, achieving a mean drop of 32.10 points

			Impact of events scale – revised (IES-R) • Rates of remission as defined by a loss of diagnosis on the PSS-I **Green**	• 8 (80%) participants showed a drop of 20 points or more on the PCL-5, meeting criteria for clinically significant change • At the end of the treatment, 8 (80%) participants were assessed as not having PTSD by an independent assessor on the PSS-I. The same eight patients met NHS talking therapies recovery criteria. **App usage** participants spent a mean of 21.7 hrs over a mean period of 9.6 weeks on the app.
Spring (=1)				
Bisson 2022 RCT Location: UK	196 adults with primary diagnosis of mild to moderate PTSD from one event Setting: NHS mental health services **Green**	Intervention: Spring (n=97) Comparator: face-to-face CBT (n=99) **Green**	Primary outcome: • Clinician Administered PTSD Scale for DSM-5 (CAPS-5) at 16 weeks post randomisation Secondary outcomes: • CAPS-5 at 52 weeks • Generalised Anxiety Disorder (GAD-7) • Work and Social Adjustment (WASA) Scale • The Patient Health Questionnaire Depression (PHQ-9) • EuroQol (EQ-5D-5L) **Green**	**CAPS-5** **Intervention**: decreased from a mean score of 34.6 at baseline to 13.1 at 16 weeks and 12.9 at 52 weeks **Comparator**: decreased from a mean score of 35.6 at baseline to 13.0 at 16 weeks and 10.9 at 52 weeks **GAD-7** **Intervention:** decreased from a mean of 13.9 at baseline to 5.6 at 16 weeks and 5.3 at 52 weeks **Comparator:** decreased from a mean of 13.4 at baseline to 5.3 at 16 weeks and 3.8 at 52 weeks **WSAS** **Intervention:** decreased from a mean of 21.1 at baseline to 8.9 at 16 weeks to 8 at 52 weeks **Comparator:** decreased from a mean of 20.9 at baseline to 10.4 at 16 weeks to 6.5 at 52 weeks **Drop out rates** 10 (10.3%) participants dropped out of guided internet based CBT-TF compared with four (4%) in the face-to-face CBT-TF
Social anxiety disorder (number of studies=2)				

iCT-SAD (=2)				
Clark 2022 RCT Location: UK	102 people with social anxiety disorder **Setting** NHS talking therapies services **Green**	**Intervention** iCT-SAD (n=34) **Comparators** • Cognitive therapy for social anxiety disorder (n=34) • Waitlist (n=34) **Amber**	**Primary outcome** The social anxiety disorder composite including ADIS, SPIN, LSAS, SPS, SIAS and FNE **Secondary outcomes** • GAD-7 • PHQ-9 • WSAS **Recovery rates** as defined by NHS talking therapies. **Green**	There were no significant differences found between iCT-SAD and CT-SAD for the primary outcome, process composition, GAD-7 or WSAS. **LSAS** Post treatment, iCT-SAD patients had dropped 45.5 points on the LSAS after an average of 6.45 h contact with their therapist. In CT, 15.8 h of therapist contact were required to achieve the same drop on the LSAS. iCT-SAD is therefore associated with 2.45 times more symptom change per hour of therapist contact time. **Recovery and remission** • 84% of iCT participants lost their SAD diagnosis at 12 months follow-up compared with 87% in the CT group • 67% met me the NHS talking therapies recovery criteria in the iCT group compared to 75% in the CT group **Drop out rates** • 2% (1/50) of patients for iCT-SAD • 0 patients for CT-SAD
Stott 2013 Pilot cohort study Location: UK	11 people with DSM-IV diagnosis of social anxiety disorder **Setting** NHS talking therapies services **Amber**	**Intervention** iCT-SAD **Green**	Improvement in: • Liebowitz social anxiety scale (LSAS) • Social Cognitions Questionnaire (SCQ) • Social Behaviour Questionnaire (SBQ) • Social Attitudes Questionnaire (SAQ) • GAD-7 • PHQ-9	**LSAS** scores reduced significantly from 80 to 39.8 ($p<0.001$) over the course of the treatment (mean 13.7 weeks). **GAD-7** scores reduced significantly from 9.3 to 4.3 ($p<0.01$) over the course of the treatment. **Recovery and remission** Nine patients (82%) were classified as treatment responders (improvement of 31% on the LSAS) and 7 (64%) were in remission. No patients dropped out during treatment.

			Patient drop-out Rates of response and remission Therapist time **Green**	**Therapist time** mean iCT-SAD therapist time spent supporting the patient was 3.87 hours compared to mean face to face therapist time of 19.14 hours
Specific phobias (number of studies=0)				
No relevant published evidence found.				
Abbreviations used: **A-CCBT**, Attitudes to CCBT Questionnaire; **ADIS**, Anxiety Disorders Interview Scale; **BABS**, Brown Assessment of Beliefs Scale; **BAI**, Beck Anxiety Inventory; **BDD-YBOCS**, Yale–Brown Obsessive Compulsive Scale, Modified for BDD; **BDI-II**, Beck Depression Inventory II; **CAPS-5**, Clinician Administered PTSD Scale for DSM-5; **CORE-OM**, Clinical Outcomes in Routine Evaluation-Outcome Measure; **EQ-5D-5L**, EuroQol; **GAD-7**, Generalised Anxiety Disorder, **FNE**, Fear of Negative Evaluation; **IES-R**, Impact of Events Scale – Revised; **LSAS**, Liebowitz Social Anxiety Scale; **M.I.N.I.,** Mini-International Neuropsychiatric Interview; **OPP**, Opinions about Psychological Problems Questionnaire; **PCL-5**, PTSD checklist for **DSM-V**; **PFQ-CCBT**, Patient Feedback Questionnaire for CCBT; **PHQ-9**, Patient Health Questionnaire Depression; **PSS-I**, PTSD Symptom Scale Interview; **QIDS-SR**, Quick Inventory of Depressive Symptomatology – Self Report; **Q-LES-Q-S**, Quality of Life, Enjoyment, and Satisfaction Questionnaire—Short Form; **RCI**, Reliable Change Index; **SAQ**, Social Attitudes Questionnaire; **SBQ**, **SIAS**, Social Interaction Anxiety Scale; Social Behaviour Questionnaire; **SPIN**, Social Phobia Inventory; **SPS**, Social Phobia Scale; **SF-12**, Short form health survey; **WASA**, Work and Social Adjustment Scale				

4.2 Summary of economic evidence

The EAG did a rapid review to identify key economic evaluations that used a modelling approach for anxiety in adults. It identified 8 published economic modelling studies on interventions for anxiety disorders not limited to digital interventions. The EAG also considered the economic modelling used in NICE clinical guidelines on anxiety disorders and depression in adults.

The economic models varied by model type and structure as outlined in section 9.1 of the EAG report. The EAG considered a combined decision tree and Markov model most representative. In this approach, a decision tree is used for short term modelling of the pathway through alternative treatment options. This is linked with a longer-term Markov model to consider movement between different severities of anxiety over several years.

The EAG literature search also identified 4 studies reporting within trial economic analyses on technologies included in the scope (Bisson 2022, McCrone 2004, [redacted], Richards 2020). Findings suggested SilverCloud (Richards 2020) and Beating the Blues (McCrone et al. 2004) are cost-effective treatment options for GAD and non-specified anxiety disorders when compared with waiting list or usual care. Bisson et al. (2022) found that Spring was not cost effective when compared with face-to-face CBT but may still add value in reducing therapist time and increasing access to care. Results showed the intervention to be cost saving, but with a slightly lower improvement in QALY values for the intervention.

4.2.1 Conceptual modelling

The EAG considered that the most relevant models would ideally include the following:

- The long-term nature of anxiety disorders
- The possibility that recovery may be followed by relapse or recurrence
- The impact that previous or adjunct treatment may have on efficacy
- Other healthcare and personal social service costs incurred, including those outside the NHS talking therapies pathway

- Alignment with NHS talking therapies pathways and definitions, where used for decision making in NHS talking therapies services.

It developed a conceptual hybrid model for anxiety disorders that combines a decision tree with a fixed duration leading into a Markov model with a longer time horizon (see Figure 2, section 9.3 of the EAG report). The decision tree could be used to model 1 or 2 subsequent treatments in the stepped care pathway, after which the Markov model would consider the longer-term impact of future relapses or changes in health state.

4.2.2 Simplified economic model for preliminary results

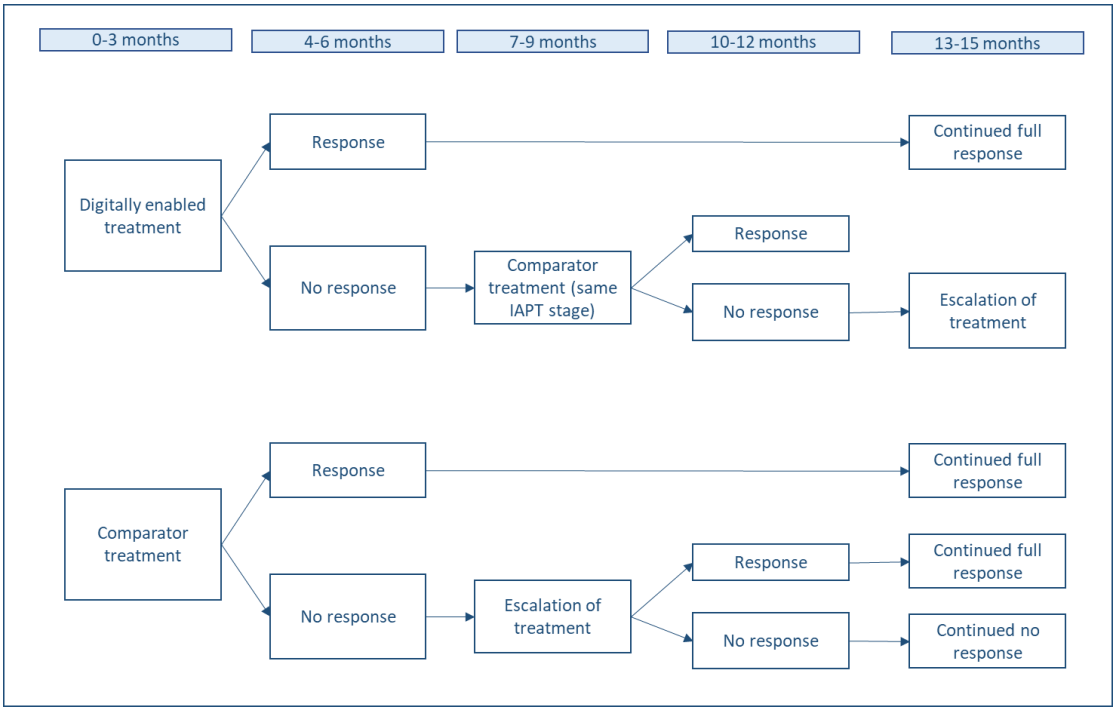
The EAG noted that there is not enough evidence to populate the proposed conceptual model for this assessment. It therefore developed a simplified model to assess the potential cost-effectiveness of using the digitally enabled therapies in NHS talking therapies services for treating adults with anxiety disorders.

The simplified model uses a decision tree with a 15-month time horizon and an NHS and personal social services perspective. The EAG caution that several assumptions have been made to populate the model and it should be seen as an initial exploration of the economic impact of the technologies. Assumptions and limitations of the simplified model are outlined in Table 15 of the EAG report.

The model compares digitally enabled therapy with the alternative standard care treatment option for that step in the NHS talking therapies pathway (Figure 1). It assumes that people using digitally enabled therapies either respond to treatment and need no further intervention in the time horizon, or do not respond and are offered the comparator treatment at the same step. If they do not respond to this, treatment is escalated to the next recommended treatment.

The model is split into 3-month periods of intervention followed by 3 months of assessment or waiting list with no intervention. Utility values remain static during the intervention period but then increase if there is a response.

Figure 1: EAG simple decision tree model



4.2.3 Model inputs

Clinical parameters

The key clinical parameter in the model is the recovery rate which is defined as the proportion of people who move from caseness to non-caseness. People are described as 'caseness' if at least 1 indicator meets the clinical threshold on the condition specific tools (for example on GAD-7). Recovery rate for the intervention was reported or calculated from the studies for technologies with evidence. The EAG noted that most studies use mean cohort score or mean change per person at 2 time points to calculate recovery. This is a limitation for economic modelling because there is no information on the distribution within the trial population to calculate progression to other treatments or utilities.

Only 1 of the economic analysis papers had an appropriate comparator in line with the scope (Bisson 2022). The NHS talking therapies database is a source of real-world evidence and was used to estimate the recovery rates for the comparators. Weighted recovery rate of NHS talking therapy interventions were calculated for GAD, PTSD, social anxiety disorder and other anxiety disorders because this is how NHS talking therapies data was presented. See table 16 in section 9.3 of the EAG report for further details on the recovery rates.

Limitations from using the NHS talking therapies database for this purpose were noted by the EAG:

- The digitally enabled interventions are modelled using trial data, which may experience higher response rates than those reported in real-world data. This may increase the resultant cost-effectiveness.

- The NHS talking therapies data used for the EAG base case analysis breaks down recovery results by therapy type. This data considers only instances within an overall episode of care where there were at least two sessions coded as the same therapy type. This means that the initial assessment is not captured, and this may have a therapeutic effect prior to the start of the first recorded therapy session. It is likely that intervention trial data will include this initial assessment at the start of the trial, and this may result in higher clinical effectiveness being shown for the trial data than within the NHS talking therapies secondary analysis.

- NHS talking therapies data needs 2 data points to be able to report recovery, so people with only 1 data point are not included. It does not use an intention-to-treat approach and the net effect of this is unknown.

Group and individual CBT are grouped together within the NHS talking therapies database. These may show different effectiveness, have different cost implications and may be delivered within different NHS talking therapies stages. See section 9.3 of the EAG report for further detail.

4.2.4 Costs and resource use

The resource use assumptions for each of the conditions are described in table 4 and the unit costs in table 5. There are differences in therapist time and suggested level of support from healthcare professionals. The license costs listed are based on the costs provided by the companies, using pricing based on an assumption of 1,000 licenses for those that have a volume-based pricing structure. Some technologies are not currently provided commercially; therefore, costs were estimated. See table 17 in section 9.3 in the EAG report for more detail.

Table 4. Resource use

	Resource items	Notes
Digitally enabled therapies at step 2	2.5 hours of PWP time	IAPT guidance is 5-7 weekly or fortnightly face-to-face or telephone sessions, each 20-30min. Assumption: 6 x 25 minutes.
Comparator therapies at step 2	2.2 to 2.3 hours of PWP time	Calculated as a weighted mean of different available therapies. Individual guided self-help: 2.5 hours per person Psychoeducational groups: 1 PWP per 12 participants, 6 weekly sessions, each 2 hours. Assumption: 1 hour of PWP time per person
Digitally enabled therapies at step 3	4 to 6.45 hours of high intensity therapist time	PTSD: 4 hours per person BDD: 4 hours per person SAD: 6.45 hours per person GAD: weighted mean of provided stage 2 interventions
Comparator therapies at step 3	10 to 14 hours of high intensity therapist time	PTSD: 10 hours per person BDD: 10 hours per person SAD: 13.5 hours per person GAD: 14 hours per person

Table 5. Unit costs

Item	Value	Distribution	Source / Notes
Per user licence: Beating the blues	[redacted]	[redacted]	Company
Per user licence: Cerina	[redacted]	[redacted]	Company
Per user licence: iCT-PTSD	[redacted]	[redacted]	Company
Per user licence: iCT-SAD	[redacted]	[redacted]	Company
Per user licence: Iona Mind			Not commercialised in UK
Per user licence: MindDistrict	[redacted]	[redacted]	Company
Per user licence: Perspectives	[redacted]	[redacted]	Company
Per user licence: Resony	[redacted]	[redacted]	Company
Per user licence: Silvercloud	£49.90	U(40, 50)	Company
Per user licence: Spring	£40.00	U(40, 50)	Assumption
Per user licence: Wysa	[redacted]	[redacted]	Company
Psychological wellbeing practitioner (per hour)	£38		PSSRU (2021) Mean of band 4 (£35) and band 5 (£41), community based scientific and professional staff, not including qualifications.
High intensity therapist (per hour)	£119		PSSRU (2021) Mean of band 6 (£54) and band 6 (£65), community based scientific and professional staff, not including qualifications.

Abbreviations: N, Normal distribution; U, Uniform distribution.

4.2.5 Health state utilities

The EAG used utility data from Gega's (2022) NIHR HTA report derived from Revicki et al. (2008, 2012). Utilities ranged from 0.720 for no anxiety, 0.640 for mild, 0.600 for moderate and 0.530 for severe anxiety. The EAG calculated the utility of response to treatment for anxiety disorders as 0.680 and no response as 0.620. The utilities for social anxiety disorder and PTSD were different. The utility of response to treatment for PTSD and social anxiety disorder was 0.620, with no response having a utility value of 0.565. See table 18 in section 9.3 of the EAG report for further detail.

4.2.6 Approach to analysis

The EAG conducted a cost utility analysis reporting net benefit at willingness to pay threshold of £20,000 per QALY gained, confidence intervals were calculated using probabilistic sensitivity analysis using 10,000 simulations.

4.2.7 Results

The exploratory base case results are presented separately for each anxiety disorder (table 6 to table 10), based on the assumption that 1,000 licenses are purchased, over a 15-month period and using NHS talking therapies database reported recovery to illustrate alternative treatment option outcomes. The EAG notes that across all the interventions the model finds that they are slightly less costly at 15 months than the modelled NHS talking therapies equivalent, with some at stage 3 (PTSD, SAD) having a slightly larger cost saving. The model found similar QALY gains for the interventions and the comparator, with only small differences across the different interventions and technologies.

Table 6. Base case results – Generalised anxiety disorder

	NHS talking therapies current pathway	Beating the blues	MindDistrict	Silvercloud
Cost	£494	[redacted]	[redacted]	£410
QALYs	0.81	0.81	0.82	0.81
Mean NB @ £20,000/ QALY	£15,771	[redacted]	[redacted]	£15,811

95%CI	12707, 18615	12828, 18724	13357, 19546	12641, 18714

Table 7. Base case results – Body dysmorphic disorder

	NHS talking therapies current pathway	Koa Health
Cost	£1,009	[redacted]
QALYs	0.74	0.74
Mean NB @ £20,000/ QALY	£13,783	[redacted]
95%CI	10,639, 16661	10,930, 16,978

Table 8. Base case results – other anxiety descriptors

	NHS talking therapies current pathway	MindDistrict	Silvercloud
Cost	£587	[redacted]	£459
QALYs	0.81	0.82	0.81
Mean NB @ £20,000/ QALY	£15,538	[redacted]	£15,725
95%CI	12459, 18455	13306, 19573	12540, 18625

Table 9. Base case results – post traumatic stress disorder

	NHS talking therapies current pathway	iCT-PTSD	Spring
Cost	£1,289	[redacted]	£496
QALYs	0.72	0.74	0.75
Mean NB @ £20,000/ QALY	£13,044	[redacted]	£14,542
95%CI	9807, 16214	11167, 17097	11362, 17444

Table 10. Base case results – Social anxiety disorder

	NHS talking therapies	iCT-SAD	MindDistrict	Silvercloud

	current pathway			
Cost	£1,433	[redacted]	[redacted]	£1,168
QALYs	0.73	0.75	0.75	0.74
Mean NB @ £20,000/ QALY	£13,233	[redacted]	[redacted]	£13,578
95%CI	10060, 16141	10938, 17006	11549, 17824	10520, 16519

For Cerina, Iona Mind, Resony and Wysa, insufficient evidence on efficacy was available. Therefore, the EAG concluded that cost-effectiveness could not be modelled, and no results were presented for these technologies.

The key driver of the simplified model is the clinical effectiveness of the technologies, meaning that all the limitations noted for the clinical evidence also impact on the model.

Other limitations of the model noted include:

- Beating the Blues, MindDistrict and SilverCloud efficacy data is based on a mixed population with depression, mixed anxiety and depression and other anxiety descriptors. Therefore, the model may not be representative of outcomes for the stated anxiety descriptors.
- The initial interventions in the care pathway for BDD are group or individual CBT, and the appropriate costs to apply for both the NHS talking therapies comparator and the guided element of the intervention are unclear.

Assumptions have been stated in the model input tables. Although there is uncertainty in the exact costs, the general direction of the results is likely to be robust.

One way sensitivity analyses

The one way sensitivity analysis showed that the recovery rate is a key driver of the model.

5 Ongoing research

The EAG reported unpublished data and several ongoing studies which are presented below. Full details are available in table 12, section 8.2 of the external assessment report.

Ongoing research for Silvercloud

One ongoing study for Silvercloud (space from anxiety, space from depression, and space from stress). This study has been withdrawn for logistical reasons.

Ongoing research for Perspectives (Koa Health)

One ongoing randomised crossover assignment study for Perspectives for people with BDD. The study ended in January 2022 and the EAG states that information from the company suggests that this study has been completed with results reported in Wilhem (2022).

Ongoing research for iCT-PTSD

Two ongoing studies for iCT-PTSD, 1 RCT (ISRCTN16806208) and 1 interventional multi-centre implementation study (ISRCTN12462559). These studies have no results in the public domain.

The unpublished randomised controlled trial [redacted]. Comparative results are considered to be outside of the current scope as [redacted] and not included in the scope.

[redacted]

Ongoing research for iCT-SAD

One ongoing interventional multicentre non-randomised implementation study for iCT-SAD (ISRCTN72832736). This study has no results in the public domain.

The limited real-world results were from [redacted]

Ongoing research for Cerina

The EAG did not identify any ongoing studies for Cerina. However, the company provided a short unpublished report and results from this unpublished pilot study providing limited information [redacted]

Ongoing research for Resony

The EAG did not identify any ongoing studies for Resony. However, the company provided a real-world evidence report which was stated as having limited applicability to the assessment. It also submitted results from 1 unpublished study after the final report was completed which included 86 participants. The aim of the study was to assess safety, clinical outcomes and engagement and treatment satisfaction. [redacted]

[redacted]

6 Evidence gap analysis

The EAG presented a summary of the evidence gaps, relating to the comparator, clinical and intermediate outcomes from the scope, and those related to the decision modelling for the conditions and technologies where there was some evidence available. These can be found in table 11 to table 14.

There is no relevant published clinical evidence for 5 technologies (Cerina, Iona Mind, Mind District, Resony and Wysa) and 4 conditions (health anxiety, obsessive compulsive disorder, panic disorder and specific phobias), which is a key evidence gap.

Where evidence was identified the main evidence gap is related to a valid comparator in the NHS talking therapies pathway.

Table 11. Post-traumatic stress disorder evidence gap analysis

	iCT-PTSD	**Spring**
Clinical studies		
Comparator NHS talking therapies pathway	No studies *Red*	Yes – One RCT *Green*
Clinical outcome: Symptom severity	Yes – One non-comparative study and data from 1 unpublished study *Amber*	*Yes – One RCT* *Green*
Clinical outcome: Remission and recovery	Yes – One non-comparative study and data from 1 unpublished study *Amber*	Partially reported *Amber*
Intermediate outcome: Acceptability and usage	Yes – One non-comparative study *Amber*	No studies Red
Intermediate outcome: Therapist time	Yes – One non-comparative study *Amber*	No studies Red

Intermediate outcome: Adverse events	No studies Red	No *Red*
Economic outcome: utilities	Yes Green	Yes – One RCT Green
Economic within trial analysis	One economic analysis of an RCT, comparator is another digital therapy that would not be provided on the NHS talking therapies pathway. Amber	One economic analysis of a non-inferiority RCT, with face to face therapy as the comparator. Green
Real world evidence		
	Yes – real world evidence Amber	None identified

Table 12. Social anxiety disorder evidence gap analysis

	iCT-SAD	**MindDistrict**	**Silvercloud**
Clinical studies			
Comparator NHS talking therapies pathway	No studies *Red*	No studies *Red*	No studies *Red*
Clinical outcome: Symptom severity	Yes – One non-comparative study and one RCT Green	No studies *Red*	No studies *Red*
Clinical outcome: Remission and recovery	Yes – One non-comparative study and one RCT *Green*	No studies *Red*	No studies *Red*
Intermediate outcome: Acceptability and usage	Yes – One non-comparative study *Amber*	No studies *Red*	No studies *Red*
Intermediate outcome: Therapist time	Yes – One non-comparative study and one RCT *Green*	No studies *Red*	No studies *Red*
Intermediate outcome: Adverse events	Yes – One RCT *Green*	No studies *Red*	No studies *Red*
Economic outcome: utilities	No *Red*	No studies *Red*	No studies *Red*
Economic within trial analysis	No *Red*	No studies *Red*	No studies *Red*
Real world evidence			
	Yes – real world evidence. *Red*	None identified	None identified

Table 13. Body dysmorphic disorder evidence gap analysis

	Perspectives, Koa Health
Clinical studies	
Comparator NHS talking therapies pathway	No studies *Red*
Clinical outcome: Symptom severity	Yes – One non-comparative study and one RCT Green
Clinical outcome: Remission and recovery	Yes – One non-comparative study and one RCT *Green*
Intermediate outcome: Acceptability and usage	Yes – One non-comparative study and RCT *Green*
Intermediate outcome: Therapist time	Yes – One RCT *Amber*
Intermediate outcome: Adverse events	Yes – one non-comparative study *Amber*
Economic outcome: utilities	Quality of life scores are reported (Quality of Life, Enjoyment, and Satisfaction Questionnaire—Short Form (Q-LES-Q-S) *Amber*
Economic within trial analysis	No Red
Real world evidence	
	None identified Red

Table 14: Generalised anxiety disorder evidence gap analysis

	Beating the Blues	**Cerina**	**Iona Mind**	**Mind District**	**Resony**	**Silver Cloud**	**Wysa**
Clinical Studies							
Comparator: NHS talking therapies pathway	No *Red*	No *Red*	No *Red*	No *Red*	No *Red*	Yes – one study comparing self-guided help with group therapy *Green*	No *Red*
Clinical outcome: Symptom severity	Yes – 5 studies All included studies reported a baseline anxiety score however this was not specifically reported as a symptom severity outcome and the tools	No *Red*	No *Red*	No *Red*	No *Red*	Yes – 6 studies All included studies reported a baseline anxiety score as measured using GAD 7 *Green*	No *Red*

	used in each study varied *Amber*						
Clinical outcome: Remission and recovery	Yes – 5 studies All included studies reported the change from baseline anxiety score in some format. Studies reported changes at different timepoints to indicate change (improvement) over time however this was not specifically reported as remission/recovery *Amber*	No *Red*	No *Red*	No *Red*	No *Red*	Yes – 6 studies All included studies reported the change from baseline anxiety score as measured using GAD 7 Studies reported changes at different follow-up timepoints to indicate change (improvement) over time however this was not specifically reported as remission/recovery	No *Red*
Intermediate outcome: Acceptability and usage	Yes – 2 studies One randomised trial reporting the acceptability of using the technology in two user groups One non-comparative study reporting patient feedback on usefulness/helpfulness of technology *Green*	No *Red*	No *Red*	No *Red*	No *Red*	Yes – 2 studies One non-comparative study reporting engagement rates One comparative study (comparing to waitlist control) reporting participants expectations of technology including experience versus expectation *Green*	No *Red*
Intermediate outcome: Therapist time	No *Red*	No *Red*	No *Red*	No *Red*	No *Red*	No *Red*	No *Red*
Intermediate outcome: Adverse events	No *Red*	No *Red*	No *Red*	No *Red*	No *Red*	Yes – one study included adverse events as an outcome. *Green*	No *Red*
Economic outcome: Utilities	Yes *Green*	No *Red*	No *Red*	No *Red*	No *Red*	Yes *Green*	No *Red*

Economic within trial analysis	Yes, but not relevant comparator *Amber*	No *Red*	No *Red*	No *Red*	No *Red*	Yes, but not relevant comparator *Amber*	No *Red*
Real World Evidence No real-world evidence identified *Red*							

Summary and conclusions of evidence gap analysis

The EAG identified several evidence gaps. The evidence gaps considered most relevant to the early value assessment are presented below.

Technologies

- Technologies that currently have no relevant published evidence including Cerina, Iona Mind, Mind District, Resony and Wysa. No ongoing studies have been identified to address this evidence gap. However, for Cerina and Resony the companies have provided unpublished data which may address some of the evidence gaps for these technologies.

Population

- There is currently no published relevant evidence for the effectiveness of technologies on health anxiety, obsessive compulsive disorder, panic disorder and specific phobias. No ongoing studies have been identified to address this evidence gap.
- Evidence on the effectiveness of technologies on GAD should make it clear whether participants have a defined DSM-V or ICD-10 diagnosis of GAD or are experiencing high levels of anxiety as assessed (usually self-assessed) by the GAD-7 questionnaire. No ongoing studies have been identified to address this evidence gap.

Comparator

- Evidence comparing the digitally enabled CBT technologies to a valid comparator within the NHS talking therapies pathway. More studies need to be conducted within the UK and preferably within

an NHS talking therapies setting so that results generated can be readily generalised to the NHS talking therapies pathway.

Outcomes

- NHS talking therapies recommends certain tools or outcome measures for specific anxiety conditions. However, some studies used outcomes measures that are not routinely collected in NHS talking therapies, for example for BDD. No ongoing studies have been identified to address this evidence gap.

Decision modelling

- The evidence gaps for the economics are mostly related to the limited clinical evidence, quality of life outcomes and utilities. No ongoing studies have been identified to address this evidence gap.

7 Equalities considerations

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

8 Implementation

The NICE adoption team identified potential factors that could encourage implementation of digitally enabled therapies for adults with anxiety disorders:

- May increase treatment options and can allow people to take ownership of their own care.
- Could reduce waiting times and allow more people to access treatment because of greater practitioner capacity.
- May be a successful treatment option and lead to improved outcomes.
- Greater accessibility and flexibility for those with long-term conditions, busy schedules and those where being open about mental health conditions may be particularly challenging.

Potential adoption barriers include:

- Time necessary for therapists to attend 1- or 2-day training sessions is needed to gain a good understanding of the digital content, including on what is available within each programme and to tailor content for specific users.

- Cost may be a barrier, especially if there is not a strong evidence base showing that use leads to good outcomes and savings elsewhere, for example in therapist capacity.
- Digitally enabled therapies may not be an option for everyone because of access to a smartphone or computer, or technology literacy levels.

9 Issues for consideration by the committee

9.1 Unmet need

- Between April 2021 to March 2022, there were 1.81 million referrals to NHS talking therapies services. 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. This may be for many reasons including NHS talking therapies not being suitable for a person's level of risk or impairment. Digitally enabled therapies can be used to provide an alternative and more accessible treatment option by offering greater flexibility, more choice and self-management through remote interventions.

9.2 Population

- Specifically for GAD, there is heterogeneity in the populations reported in the evidence. Participants had no clear DSM-V or ICD-10 diagnosis of GAD but were presented as having high level of anxiety symptoms using the GAD-7 or depression symptoms on the PHQ-9. In addition, people with symptoms of anxiety, depression or both were grouped together. The clinical experts noted that these populations have high comorbidity. The committee may want to consider the generalisability to the NHS talking therapies pathway.
- There is currently no published relevant evidence for the effectiveness of technologies on health anxiety, obsessive compulsive disorder, panic disorder and specific phobias.

9.3 Clinical evidence

- The clinical evidence consists of 19 published studies. Most of the evidence is for GAD (13 studies). The clinical evidence suggests that guided digital technologies can reduce anxiety symptoms (as measured by general and condition specific measures) across a range of anxiety disorders and that reductions can persist up to 12 months post treatment. Limited comparative evidence (5 studies) indicates the reduction in anxiety symptoms was larger in those using the guided therapies, compared to waiting list or usual care. One study for SAD indicated that digital therapy could achieve outcomes at least as good as face-to-face therapy and iCT-SAD was associated with 2.45 times the amount of symptom change per hour of therapist time.
- At present there is no peer-reviewed evidence published for 5 out of 11 technologies, including Cerina, Iona Mind, MindDistrict, Resony and Wysa.

9.4 Economic evidence

- The economic model may not accurately reflect the care pathway and disease progression because data was not available to populate the conceptual model considered most representative. A simplified model was populated instead.
- The preliminary results of the simple decision analysis showed a trend towards digitally enabled therapies being equally effective compared with other NHS talking therapies treatments, at a lower total cost. Based on the analysis the biggest issue affecting the robustness of the results is the clinical evidence used to calculate the recovery rates.

9.5 Key gap analysis conclusions

- There is no published relevant evidence for 5 of the 11 technologies, and for 4 of the 8 conditions.
- The EAG identified several ongoing studies for some technologies that aligned in part with the decision problem such as population and intervention. Some companies also provided unpublished data.

However, the ongoing or planned studies and unpublished data only partly address the research gaps.

- For the model and economic outcomes, the main evidence gaps are:
    - Robust clinical evidence
    - Quality of life outcomes and utilities

10 Authors

Lirije Hyseni and Dionne Bowie, technical leads

Lizzy Latimer, technical adviser

NICE Medical Technologies Evaluation Programme

February 2023

11 Appendix A: Sources of evidence considered in the preparation of the overview

Details of assessment report:

- Chong HY, Knight L, Dale M, et al. Digitally Enabled Therapies for Adults with Anxiety Disorder. February 2023.

For a list of the organisations that accepted the invitation to participate in this assessment as stakeholders and the Expert Adviser Specialist Committee members, see the published project documents. They were invited to attend the scoping workshop and to comment on the external assessment report.

11.1.1 Manufacturers and developers of technologies included in the final scope:

- 365 Health Solutions
- NoSuffering
- OxCADAT
- Iona Mind
- Minddistrict

- Koa Health
- RCube Health
- SilverCloud
- Cardiff University
- Wysa

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12 Appendix B: Additional analyses carried out by the EAG

The EAG made changes to the assessment report after the factual inaccuracies check. Please see the addendum for the External Assessment Report that outlines these changes.

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 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

Populations	Adults 18 and over with anxiety disorders who have been referred to IAPT services. Specifically, adults with: • Body dysmorphic disorder • Generalised anxiety disorder • Health anxiety • Obsessive compulsive disorder • Panic disorder with or without agoraphobia • Post-traumatic stress disorder • Social anxiety disorder • Specific phobias
Interventions (proposed technologies)	Digitally enabled therapies for adults with anxiety disorders that are delivered with practitioner or therapist support. Namely: • Beating the Blues • Cerina • iCT-PTSD for post-traumatic stress disorder • iCT-SAD for social anxiety disorder • Iona Mind • Minddistrict • Perspectives • Resony • SilverCloud • Spring • Wysa
Comparator	Standard care low intensity and high intensity psychological interventions currently delivered in IAPT services.
Healthcare setting	Improving access to psychological therapies (IAPT) services
Outcomes	Intermediate measures for consideration may include:

	• Patient choice and preferences • Treatment satisfaction and engagement • Intervention adherence and completion • Referral to treatment time • Assessment to treatment time • Intervention-related adverse events • Inaccessibility to intervention (digital inequalities) •
	Clinical outcomes for consideration may include: • Change in anxiety symptoms • Change in other psychological symptoms • Global functioning and work and social adjustment Service level clinical outcomes: • Rates of reliable recovery • Rates of reliable improvement • Rates of reliable deterioration • Rates of relapse including relapse rate and time from remission to relapse
	Patient-reported outcomes for consideration may include: • Health-related quality of life • Patient experience
	Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration may include: • Costs of the technologies • Cost of other resource use (e.g., associated with managing anxiety, adverse events, or complications): o GP or IAPT appointments o Medication o Healthcare professional grade and time
Time horizon	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.

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 heterogenous 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 phycological therapies
MTEP	Medical technologies evaluation programme
OCD	Obsessive-compulsive disorder

Adoption report: MT588 Early Value Assessment: Digitally enabled therapies for adults with Depression and MT589 Early Value Assessment: Digitally enabled therapies for adults with anxiety disorders

Summary

Adoption levers identified by contributors

- May increase treatments options.
- Could lead to an increase in practitioner capacity.
- May be a successful treatment option and lead to improved outcomes.
- Greater accessibility for those with long term conditions, busy work/life schedules and those where being open about mental health conditions may be particularly challenging.

Adoption barriers identified by contributors

- Training: time required to attend 1–2-day training sessions and then to gain a thorough understanding of the digital content.
- Cost may be a barrier. Particularly if there isn't a strong evidence base showing that use leads to good outcomes and savings elsewhere e.g., therapist capacity.
- Equity of access- This type of therapy may not be an option for all due to access to technology (e.g., smartphone or computer) and or technology literacy level.

1 Introduction

This adoption report has been developed to support both MT588 Early Value Assessment: Digitally enabled therapies for adults with Depression and MT589 Early Value Assessment: Digitally enabled therapies for adults with anxiety disorders. Although some technologies are being considered for either depression or anxiety disorders only, others are for both. We found that there was significant overlap between the adoption barriers and levers to using digitally enabled therapies for

adults experiencing depression and/or anxiety disorders. We highlight within the report if a barrier is specific to one condition or technology only.

Following the scoping workshop, the adoption team has collated information from healthcare professionals working within NHS organisations with experience of using some of the digitally enabled therapies considered within the scoping documents. All contributors apart from 1 had experience of using one of the therapies either as part of their service or a pilot. The contributors table in section 2 shows the split of contributors across the different technologies. It has been developed for the medical technologies advisory committee (MTAC). This report provides context from current practice and an insight into the potential levers and barriers to adoption and includes adoption considerations for the routine NHS use of the technologies. It does not represent the opinion of NICE or MTAC.

2 Contributors

Details of contributing individuals are listed in the below table.

Job title	Organisation	Current use	Technology	Anxiety/ Depression/ Both	Therapy stage
GP partner and Clinical Director of Primary Care Warwickshire	Grange Medical Centre and GP Federation in North Warwickshire	Free access as part of a pilot involving 7 GP practices	Deprexis	Depression	Prior to IAPT access
Lead Psychological Wellbeing Practitioner	Telford and Wrekin IAPT	Part of current service provision	Silvercloud	Both	Step 2
Primary Care Therapist	Cwm Taf Morgannwg University Health Board	Part of current service provision	Spring	Anxiety-PTSD	
Primary Care Therapist	Oxford Health NHS Foundation Trust	As part of research trial within IAPT service	iCT-PTSD	Anxiety- SAD	
Step 3 Lead / Cognitive Behavioural Therapist	Telford and Wrekin IAPT	No	Silvercloud	Both	Step 3
Senior Cognitive Behavioural Psychotherapist	Hywel Dda University Health Board	Part of current service provision	Spring	Anxiety-PTSD	
Primary Care Therapist	Cwm Taf Morgannwg University Health Board	Part of current service provision	Spring	Anxiety-PTSD	
Clinical lead of IAPT service & clinician	Hertfordshire Partnerships University NHS Foundation Trust	As part of research trial within IAPT service	iCT-PTSD	Anxiety-PTSD	Step 3
Head of commissioning, mental health and learning disabilities & Therapist	Isle of Wight CCG	Part of current service provision	Silvercloud (previously) & Minddistrict	Both	Step 2

Clinical Services Director	Trent PTS, provides services for regional IAPT	Part of current service provision	Iona Mind Minddistrict SilverCloud	Both	
Clinical lead of IAPT service & clinician	Hertfordshire Partnerships University NHS Foundation Trust	As part of research trial within IAPT service	iCT-PTSD	Anxiety-PTSD	Step 3
GP (non – user)	Birmingham Medical School	N/A		Both	N/A

3 Use of digitally enabled therapies in practice

All the contributors to this report who are currently using digitally enabled technology are doing so following an initial assessment. This assessment identifies the mental health condition to be treated and assesses if the person is likely to be suitable for guided treatment with digitally enabled therapy. Assessment of risk also happens here in addition to throughout treatment. Risk assessment is embedded within all the technologies the contributors to this report are using.

The contributor currently using Iona Mind, has set up a minimum contact pathway. This involves training their psychological wellbeing practitioners (PWPs) to complete short follow up calls with people using the app and only set up longer virtual or face to face (traditional) appointments for those who are not demonstrating an improvement.

One of the contributors using Spring has set up a separate waiting list for those assessed as appropriate for treatment assisted with this technology. This is much shorter than the waiting list for traditional face to face CBT.

One contributor is currently offering Deprexis as part of a pilot within primary care. They are offering this to people prior to accessing IAPT (following supported decision making, an assessment and completion of PHQ9) due to long waiting lists. This contributor provides follow up phone calls/appointments with people as they work

through and after completion of the 90-day programme. If, following the assessment, people decide they would prefer face-to-face therapy via IAPT, this service initiates Deprexis for them to use while they await their IAPT appointments. Once IAPT has commence, Deprexis is stopped.

Some contributors have simply integrated the use of digital therapy into the IAPT service as is. No one reported that offering this service has required large service or care pathway redesign.

4 Reported benefits

The potential benefits of adopting digitally enabled therapies, as reported to the adoption team by the healthcare professionals using the technologies are:

- May increase treatment options.
- Could reduce waiting times and allow more people to access treatment due to greater practitioner capacity.
- Could allow people to take ownership of their own care.
- Should lead to greater flexibility for users to access therapy at a time that suits their needs/lifestyle.
- May help with confidentiality as the user can pick a time when other people may not overhear or be able to see any content they add to the digital therapy.
- Continued support post guided therapy.
- Use may lead to improved outcomes and successful treatment.
- Digital enabled therapy may include features which are not possible to achieve through standard therapy, e.g., normalisation of symptoms through insight into other people's journeys.

5 Insights from the NHS

Commissioning

One contributor discussed the fact that it is challenging to pull together a business case for a technology that is not yet proven to work and won't work for all. Different

digital therapies are likely to work for different people and so an estimate of how many of each to be purchased is required. This is difficult to forecast.

Some of the companies do not routinely provide reports or feedback to commissioning services on attrition rates which can contribute to this issue.

Selecting a digital therapy needs to be informed by the balance between cost and expected outcomes. One contributor felt that guidance on this would help their decision-making process when the EVA publishes.

One contributor referenced the difficulty experienced when commissioning a new treatment. The multiple levels at which decisions need to be agreed mean that the process is lengthy and cumbersome. This may act as a barrier to the adoption of these therapies other than silvercloud which is already offered in many areas of the country within IAPT services.

Resource impact

Cost was referenced by all contributors as being a potential barrier. Costs of the different products varies. Silvercloud charges a fee for a number of licences. These numbers are high and 2 contributors offering Silvercloud reported that using the amount purchased was not possible resulting in this option being expensive.

One contributor reported that the best price they could get for the various digital therapies offered was similar to the cost of providing traditional face to face therapy. They explained that there would be a capacity saving but only if the digital therapy was effective.

One contributor mentioned that their service was given access to a number of licences for some of the digital therapies detailed in the scope for free by the companies. This was/is so the companies can test their use in NHS services and begin to collect real world data. However- this contributor reported that to be able to continue with and roll out adoption- a cost/benefit assessment would need to be carried out.

Training

Time required to attend 1–2-day training sessions and then to gain a thorough understanding of the digital content may act as a barrier and lead to variation. All contributors reported that training was provided by the company/research trial team for free, and that time was also needed post initial training to work through and fully understand the content. This may lead to a resource impact especially as there is a high turnover of staff within these services. They also highlighted that as the learning is self-directed motivation of therapists would vary and therefore the knowledge and understanding of the digital therapy and how best to use it, could vary across regions and within a service.

As all the digital therapies allow the therapist to pick specific modules/content to direct a user towards, a good understanding of what's available within each program is required.

All also reported that there was a period of supervision required post training and this varied from once per week (until a person has been supported through use of the whole program/app), to weekly for 1 year.

Two contributors reported that the time invested in working through the programme was time well spent as it served to upskill therapists and therefore improve the quality of all interventions offered to people.

Clinician confidence

Two IAPT clinical service leads using iCT-PTSD as part of a research trial reported that the program has been developed by a highly respected team and has therefore created a trusted brand. They felt that the program mapped onto what would be provided by a face-to-face protocol well and that guided use enhances treatment rather than replicating it or offering a second rate option. These same two contributors also stated that the quality of the programme is such that it served to upskill them in their ability to work with people with PTSD.

One contributor explained that they are an adopter/implementer of digital therapy but are also cautious about their use. There are so many technologies to choose from

and development of them can be easy, so it is important to maintain QA processes and use ones that have demonstrable outcomes.

A clinical service director reported that Practitioners are trained to and enjoy speaking to people to deliver therapy and support them to problem solve. Practitioners may be reluctant to deliver care via a digital platform, though savings in time may incentivise this. This same contributor reported that PWPs have been trained to deliver therapy in a certain way. Changing this and incorporating use of a digital therapy may be difficult.

Practitioner/clinician capacity

One contributor reported that the delivery of guided therapy takes longer to begin with due to limited experience with the app. This gets better with time but is still a consideration for adoption as there is a high turnover of practitioners in IAPT.

Another contributor reported that whilst they found the ability to message clients and receive messages, between sessions, a positive factor, they thought that some clinicians might find this hard to manage / accommodate.

All contributors reported that once practitioners were familiar with using the technologies, capacity was released as less time was needed to deliver the guided element.

Data collection

There is a need to track outcomes whilst using these technologies. One contributor reported that their service uses an EMIS bundle system which tracks outcomes for free.

Two contributors explained the importance of data needing to cover the whole pathway as well as including information on rates and rational for drop out. These same two contributors reported that they don't currently collect data on re-referrals- i.e., numbers of people going through IAPT and needing help again in the future. This should be included, especially when using digital therapy to see if there is a difference.

As mentioned earlier in the report, some contributors reported that they rely on the company to provide them with access and outcome data. This means that companies are responsible for the data they provide. One contributor talked about the lack of transparency in this data and the limitations of real-world evidence data.

The contributor using Deprexis, explained that the company does not provide feedback on access and attrition rates. As this contributor follows up people referred for Deprexis access, they get the data this way, however this needs to be embedded in electronic patient record systems if wide scale adoption is recommended.

Two contributors using iCT-PTSD reported that outcomes using the program were good and recovery rates high. These same two contributors explained that data collection is embedded within the programme and that it is linked to the service electronic patient record system. This means that outcome data can be processed and analysed in the same way as the rest of the initiatives on offer.

Sustainability

One contributor expressed a concern about the sustainability of some of the companies behind the newer digital therapies supported by a small company team.

One contributor commented that using digitally enabled therapy may be more environmentally friendly as it limits the need for both the therapist and person to travel.

Patient choice

One contributor expressed a concern that offering guided digital therapy may limit patient choice. If a person is assessed as being more suitable for traditional CBT therapy, they should not be offered digitally guided therapy first to see if it works. People should have a discussion with their therapist and make a choice on what they think will be the best therapy type for them.

Patient experience

Iona Mind was referenced by the contributor offering this within their service as being more light touch and therefore easier for people to engage with than others. Some of

the digital therapies used by this service required people to read lots of material and complete lots of activities in between sessions.

Both contributors using iCT-PTSD reported that patient feedback has been positive. They stated that the positive elements of the program include; the ability for a person to log onto the programme at any time and watch/interact with content that is engaging, informative, empathic and motivating. For the therapist the ability to see what the person has viewed and the comments they have left were described as positive features. Additionally, the program has the ability to timetable messages to go to people at points relevant to the targets set which provides further support in between sessions.

One of the contributors using i-CT-PTSD reported that the programme includes features which are not possible to achieve through standard therapy, e.g., normalisation of symptoms through insight into other people's journeys (therapy stories and videos). The ability to see how someone else has experienced similar trauma and symptoms and how they have responded to different aspects of therapy was described as being powerful and effective.

The 3 contributors using Spring spoke about the positive feedback they had received on the continued access following discharge. People can access the programme for 3 years following discharge.

One contributor reported that for some people, their difficulties may be such that it is hard for them to face tackling them independently at home and then dealing with the impact on their lives (or feared impact). This should however be picked up at initial assessment and individuals in this category should not be referred for digitally enabled therapy.

6 Comparators

One contributor referenced using Limbic to support the management of referrals, initial assessment and provision of self-help. They referenced the fact that there is a recently available study which demonstrates that use of this app- leads to an improvement in outcomes.