

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical Technologies Evaluation Programme

Guided self-help digital cognitive behavioural therapy for children and young people with mild to moderate symptoms of anxiety or low mood

Final scope

September 2022

1 Introduction

The topic has been identified by NICE as a pilot for early value assessment (EVA) of medical technologies. The objective of EVA is to identify the most 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 digital cognitive behavioural therapy (CBT) technologies for children and young people with symptoms of anxiety or low mood as potentially suitable for an EVA by the medical technologies evaluation programme (MTEP). The final scope was informed by consultation comments received during the consultation period running from 2 to 10 August 2022 and discussions at the scoping workshop and the assessment subgroup meeting both held on 17 August 2022. A list of abbreviations is provided in appendix B.

2 Description of the technologies

This section describes the properties of the guided self-help digital CBT technologies based on information provided to NICE by manufacturers and experts and information available in the public domain. Guided self-help involves the use of (digital) self-help materials based on CBT to learn techniques to manage symptoms of anxiety and low mood with the support of a mental health practitioner. NICE has not carried out an independent evaluation of this description.

2.1 Purpose of the medical technology

Guided digital CBT may provide an alternative and more accessible treatment option for anxiety and low mood in children and young people. This could be very important development in mental health and improve care by engaging people in treatment in a different way as well as providing greater patient choice. In addition, mental health services are in high demand and access varies widely across the country: the availability of effective mental health treatments is limited, with a shortage of qualified staff, long waiting times and access to treatment depending on the severity of symptoms ([Wright et al, 2019](#)). Early research suggests that the pandemic and subsequent measures have had a significant impact on the mental health of children and young people and subsequently intensified these issues related to accessing effective mental health treatments ([UK parliament website](#)). It is estimated that only 1 in 3 children with a mental health condition get access to NHS care and treatment ([The state of children's mental health services 2019/20, Children's commissioner](#)). In 2019/20, the reported average waits across England ranged from 8 days to 82 days, and only 20% of children referred to services started treatment within 4 weeks ([The state of children's mental health services 2019/20, Children's commissioner](#)) – the ambition set out in the Government's Green Paper on children's mental health.

Given the prevalence of the condition and importance of early treatment, children and young people's mental health services are NHS priorities for care and outcome improvements. Publications including the [NHS Long Term Plan \(2019\)](#) and the [Green Paper for Transforming children and young people's mental health](#) detail the investment and proposed expansion of services in particular in the community and school settings.

Guided self-help digital CBT is a treatment offered for children and young people to help with negative feelings, including mild to moderate symptoms of anxiety or low mood that is delivered via mobile phones, tablets, and computers. It is based on the principles of face-to-face CBT which is a talking therapy that can help a person learn new skills to manage problems by understanding how thoughts can affect how they feel and behave and includes various components including psychoeducation and cognitive restructuring. Digital CBT can be accessed remotely and can be used as a standalone intervention with guidance from a health care professional. It can potentially improve access to mental health services by offering greater flexibility, more choice and self-management through remote online interventions.

Product properties

This scope focuses on guided self-help digital CBT technologies that meet the following criteria:

- Has appropriate regulatory approval or is actively working towards regulatory approval – for example, CE mark and DTAC
- Available to children or young people with symptoms of anxiety or low mood. Interventions can support children and young people directly, or parents or carers to help them support their child.
- Based on the principles of CBT with a guided element built into the intervention including scheduled (weekly) follow up, for example a phone or video call, with mental health practitioners affiliated to the company or the NHS
- Available for use in the NHS

In total, four guided self-help digital CBT technologies designed to treat children and young people with symptoms of anxiety or low mood are included in the scope. Further details are summarised in table 1.

Space from anxiety for teens, Space from low mood for teens, Space from low mood & anxiety for teens (SilverCloud)

Internet-based (computer, tablet or smart phone) intervention for teens aged 15 to 18 years old with symptoms of anxiety, low mood, or both. But it can be used in a younger age group according to CAMHS protocols and clinical judgement. It has 7 core modules structured around the principles of traditional CBT which include: understanding anxiety or low mood, noticing feelings, facing your fears, spotting thoughts, challenging thoughts, managing worry and reflections on learnings. The supported model has online support from psychologists and online cognitive behavioural therapy co-ordinators to assess the needs of the person. After each module, they check in to help the person progress through the CBT content and send motivational messages. It is used in several services in the NHS.

Online support and intervention for child anxiety (OSI)

OSI is an internet based (computer, tablet and smart phone), parent-led and therapist supported psychological intervention for children aged 5 to 12 years old with symptoms of anxiety. It is made up of 3 components, a parent's website, a clinician case management website and an optional game app for children (monster's journey: facing fears). It is made up of 7 core modules that include interactive worksheets, videos and quizzes. Parents or carers have weekly telephone appointments with the therapist to review the work they

have done over the previous week, after which the next weeks weekly module is released.

OSCA (Online Social anxiety Cognitive therapy for Adolescents)

OSCA is an internet programme of cognitive therapy for social anxiety in adolescents aged 14 to 18 years old. All users receive a core set of modules to work through at the beginning of the programme which is then individualised for each user. The therapist will carry out a 15-minute phone call with the user each week and releases modules that will be most helpful to that person, depending on their concerns. They will receive encouragement and support via secure messaging within the online programme and SMS texts. Parents are involved by receiving regular emails on their child's progress. This is explained to children aged 14 to 15 and consented from young people aged 16 to 18 years old.

Lumi Nova (BfB Labs)

Lumi Nova: tales of courage is a CE marked class 1a medical device digital therapeutic intervention in the form of a game available on Android and iOS for children and young people aged between 7 and 12 with symptoms of mild to moderate anxiety. It combines evidence-based therapeutic content (exposure therapy, a form of CBT) and psychoeducational content within an intergalactic role-playing game. Access to Lumi Nova is provided through a secure web-based platform, VitaMind Hub (BfB Labs Ltd), which is a point of access for practitioners that allow them to track and monitor player progress with the game. Practitioners also check in with users and guardians provide support to their child (app user) when needed and can receive SMS notifications when their child uses the app.

3 Target conditions

The target population for this assessment is children and young people with mild to moderate symptoms of anxiety or low mood.

Anxiety disorders is one of the most common types of mental health disorders in children and young people. In 2017, 3.9% of 5- to 10-year-old children were identified as having an anxiety disorder, 7.5% of 11- to 16-year-olds and 13.1% of 17- to 19-year-olds ([NHS Digital's survey on the Mental Health of Children and Young People in England, 2017](#)). Anxiety in children and young people may negatively impact education, social functioning and family life. Anxiety disorders can have a lifelong course of relapse and remission and can persist into adulthood if left untreated. Lifetime prevalence of anxiety disorders

is estimated at 28.8%, with the median age of onset of 11 years ([Kessler et al. 2005](#)).

Depression is also a common mental health problem and can present itself in different symptoms, including low mood. Other symptoms in children include: being irritable, not being interested in things they used to enjoy, feeling tired, having trouble sleeping or sleeping more than usual, not being able to concentrate, being indecisive, not having much confidence, changes in eating habits and weight, talking about feeling guilty or worthless ([NHS website](#)). The prevalence of depression in adolescents is estimated to be between 2 and 4% and is one of the most common mental health problems facing young people ([Wright et al, 2019](#)). Depression in adolescence can have a negative effect on relationships, development trajectory, schooling, and educational attainment and increases the risk of suicide ([Grist et al, 2019](#)).

3.1 Care pathway

Children and young people's mental health services (CYPMHS), sometimes known as Child and adolescent mental health services (CAMHS) are services that support children and young people with their mental health. But care is personalised and varied and provided across a range of settings. The THRIVE framework can be used to determine a care package based on the needs of the child or young person ([Wolpert et al, 2019](#)). The framework integrates a person centred, and needs led approach to delivering mental health services for children, young people and families which conceptualises need in 5 categories: thriving, getting advice and signposting, getting help, getting more help, and getting risk support.

Guided self-help digital CBT may be offered as a first line treatment for children and young people identified as having mild to moderate symptoms of anxiety or low mood, who are considered as 'getting help' or 'getting more help' based on the THRIVE framework, to improve access to treatment. Users may then continue to further support such as face to face CBT.

Symptoms of anxiety or low mood may be identified by the child or young person themselves, their parents or carer, GPs and in community care, social workers or in school. Children and young people can be assessed and treated in a range of settings, including school mental health support teams, single point of access teams (SPA), voluntary sector teams and children and young people's mental health services (CYPMHS). Not all children and young people with mild to moderate symptoms of anxiety or low mood will meet the severity threshold to be seen by CYPMHS and are treated within mental health support teams. Across these settings the professionals will have varying levels of specialist mental health training and expertise to provide targeted

outcome focused help. These professionals might include nurses, therapists, psychologists, child and adolescent psychiatrists, support workers, social workers, health visitors, school nurses, education mental health practitioners.

3.2 Patient issues and preferences

Digital CBT is delivered via mobile phones, tablets, or computers and can thus be accessed remotely. Digital CBT provides more treatment options, flexible access, greater privacy and anonymity, increased convenience and increases capacity and support for face-to-face CBT. It may be particularly appealing to children and young people who are typically regular users of digital technologies such as smartphones and tablets. In 2020, 61% of 5- to 15-year-olds had their own tablet and 55% their own smartphone. The latter increased to 91% in the 12- to 15-year-old age group ([Ofcom report, 2021](#)).

The use of guided self-help digital technologies may create the supportive and motivating therapeutic relationship that reduces the rates of attrition that is a concern for unguided technologies. There may also be concerns around data security and quality control.

4 Comparator

Guided self-help digital CBT technologies could be a first line and alternative treatment for children and young people demonstrating mild to moderate symptoms of anxiety or low mood. The comparator is standard care which may include education, advice, support and signposting.

5 Scope of the assessment

Table 2 Scope of the assessment

Populations	Children and young people with mild to moderate symptoms of anxiety or low mood that are significantly interfering with their ability to function in their daily lives <ul style="list-style-type: none"> • Children aged 5 to 11 • Young people aged 12 to 18
Interventions (proposed technologies)	Guided self-help digital cognitive behavioural therapy technologies supported by healthcare professionals aimed at children and young people with mild to moderate symptoms of anxiety or low mood as a first line treatment: <ul style="list-style-type: none"> • Space from anxiety for teens, Space from low mood for teens, Space from anxiety and low mood for teens • Online support and intervention for anxiety (OSI)

	<ul style="list-style-type: none"> • OSCA (Online Social anxiety Cognitive therapy for Adolescents) • Lumi Nova <p>and standard care that may include education, advice, support and signposting</p>
Comparator	Standard care that may include education, advice, support and signposting
Healthcare setting	Mental health support teams, including those based in schools and primary care
Outcomes	<p>Intermediate measures for consideration may include:</p> <ul style="list-style-type: none"> • Intervention-related adverse events • Rates of and reasons for attrition • Treatment satisfaction and engagement
	<p>Clinical outcomes for consideration may include:</p> <ul style="list-style-type: none"> • Measures of symptom severity (self-, parental- or practitioner reported) • Social, behavioural, and functional outcomes (self, parental or practitioner reported) • Suicidal thoughts and behaviour • Global functioning • Rates of remission
	<p>Patient-reported outcomes for consideration may include:</p> <ul style="list-style-type: none"> • Health-related quality of life, including well-being • Patient experience
	<p>Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration may include:</p> <ul style="list-style-type: none"> • Costs of the technologies including licensing fees • Cost of other resource use (e.g., associated with managing anxiety, adverse events or complications): <ul style="list-style-type: none"> ○ GP, mental health support team or CYPMHS appointments ○ Health care professional training, grade and time for providing regular support and guidance for the users of the dCBT technologies
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.

6 Other issues for consideration

Characteristics of digital technologies

- The digital CBT technologies included in the scope are heterogeneous in terms of delivery mode (computer, app) and access (referred or self-referrals), intended population and condition (anxiety vs low mood), practitioner or parental support, data collected and regulatory status.

7 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.

A number of potential equality issues have been identified. There are multiple equality considerations for this class of technologies which are addressed in more detail in [NICE's guideline on depression in children and young people: identification and management](#). Key aspects include:

- Children and young people from certain socio-economic backgrounds and those with disabilities are disproportionately affected by higher risk of mental health issues.
- Patient-facing digital health technologies may be unsuitable for people with cognitive impairment, problems with manual dexterity or learning disabilities. Carer or advocate assistance may be required to navigate the program and consideration of this should be made by the company as well as the referring practitioner when considering appropriate intervention for the child or young person. Further considerations can be found in NICE Guidance on mental health problems in people with learning disabilities ([NG54, 2016](#)).
- Patient facing digital health technologies should ensure their program is accessible for screen readers (people with visual impairments) and those with hearing impairments.
- Children and young people with English as a second language may have difficulties navigating digital technologies provided in English.
- The way that children and young people with symptoms of anxiety or depression and their families view mental health problems may be affected by their ethnic, religion and cultural background.

- Specific groups may particularly benefit from improved access to CBT online, for example:
 - Adolescents may have increased engagement with this format of intervention.
 - Those living in rural areas might have problems with travelling to face-to-face appointments if public transport is sporadic and unreliable, and their parents are unable to drive them there.
 - Children and young people from lower socioeconomic groups may lack the financial support required to ensure that they attend face to face sessions. These families may also be less likely to seek help in the first place and or be less able to navigate the healthcare system.
 - Children and young people with more chaotic home lives may lack the family support required to ensure that they attend face to face sessions. These families may also be less likely to seek help in the first place and or be less able to navigate the healthcare system.
 - Children and young people from abusive homes may be prevented from seeking help and or attending face to face therapy sessions by controlling parents or carers.
 - Looked after children and young people may lack support needed to engage with mental health services.

However, accessibility would not be improved for those who are unable to engage with a digital service due to a lack of equipment, unavailability of internet connection, lack of experience with computers or lack the privacy needed to complete the intervention.

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

8 Potential implementation issues

A potential barrier to implementation has been identified:

- Children and young people need to be assessed and the appropriateness of guided self-help digital CBT interventions needs to be determined

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Appendix A Abbreviations

EVA	Early value assessment
CBT	Cognitive behavioural therapy
MTEP	Medical technologies evaluation Programme
CYMHS	Children and young persons mental health services
OSI	Online Support and Intervention
OSCA	Online social anxiety therapy for adolescents
CAMHS	Children and adolescent mental health services