NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Early value guidance consultation document

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

The National Institute for Health and Care Excellence (NICE) is producing early value guidance on using digital cognitive behavioural therapy technologies. The medical technology advisory committee has considered the evidence and the views of clinical and patient experts. This topic is the first pilot using the new early value assessment approach. The aim of early value guidance is to provide quicker conditional recommendations from NICE on promising medical technologies while uncertainty in their evidence base is being addressed.

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

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

- Has all of the relevant evidence been considered?
- Are the summaries of clinical effectiveness, costs and resource use reasonable interpretations of the evidence?
- Are the recommendations sound, and a suitable basis for early value guidance to the NHS?

Equality issues

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

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

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

Note that this document is not NICE's final guidance on guided self-help digital cognitive behavioural therapy for children and young people with mild to moderate symptoms of anxiety or low mood. The conditional recommendations in section 1 and the accompanying points on evidence generation in section 4 may change after consultation.

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

Key dates:

Closing date for comments: 18 November 2022

1 Recommendations

1.1 Five guided self-help digital cognitive behavioural therapy (CBT) technologies:

- Lumi Nova (BfB labs)
- Online Social anxiety Cognitive therapy for Adolescents (OSCA)

- Online Support and Intervention for child anxiety (OSI)
- Space from anxiety for teens, space from low mood for teens, space from low mood and anxiety for teens (Silvercloud)
- ThinkNinja CBT Bytesize (Healios)

are conditionally recommended as a first-line treatment option (or alongside other treatments) for children (aged up to 12) and young people (aged 12 to 17) with mild to moderate symptoms of anxiety or low mood, while further evidence is generated.

1.2 Key outcomes captured while further evidence is generated should include:

- symptom severity
- impairment measures
- health-related quality of life
- level of engagement including attrition
- reasons and rates of drop out.

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

Why the committee made these recommendations

Guided self-help digital CBT technologies provide a different way to help children and young people manage their symptoms of anxiety or low mood and could allow earlier access to mental health treatment. Children and young people will be able to work through self-help materials on their own but will be guided by support from a mental health professional. Offering guided self-help digital CBT technologies could help engagement with treatment and result in better patient outcomes. Many children and young people are not able to access treatment for mild to moderate symptoms of anxiety or low mood, or could be on a waiting list. There is a high unmet need for earlier access and alternative approaches to treatments in mental health.

There is some evidence to suggest that guided self-help digital CBT technologies may improve symptoms of anxiety but more evidence is needed to be confident that the benefits will be realised from using these technologies.

These 5 technologies can be used as a first-line treatment if used with appropriate safeguarding and risk management processes in place. Once further evidence is generated, this guidance will be reviewed to make a decision on the routine adoption of these technologies.

2 The technology

Technology

2.1 Guided self-help digital cognitive behavioural therapy (CBT) provides self-help materials based on the principles of face-to-face CBT in a digital format with some professional guidance. Five digital CBT technologies are available for children and young people with mild to moderate symptoms of anxiety or low mood:

- Lumi Nova (BfB labs)
- Online Social anxiety Cognitive therapy for Adolescents (OSCA)
- Online Support and Intervention for child anxiety (OSI)
- Space from anxiety for teens, space from low mood for teens, space from low mood and anxiety for teens (Silvercloud)
- ThinkNinja CBT Bytesize (Healios).

Comparator

2.2 The comparator is standard care which may include education, advice, support and signposting.

Clinical need

2.3 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 and long waiting times. Access to treatment can depend on the severity of symptoms. Children and young

people may be offered education, advice, support and signposting without access to healthcare professionals while waiting for treatment. Early research suggests that the COVID-19 pandemic and subsequent measures have had a substantial effect on the mental health of children and young people and subsequently intensified the issues related to accessing effective mental health treatments.

3 Committee discussion

Unmet need

3.1 There is a need to improve access to effective mental health treatments. The patient experts noted that it is difficult to get access to mental health care but that it was important for children and young people to have access to treatment as soon as possible. They also noted that there are no options available to them while waiting. The clinical experts agreed that many children and young people are not getting access to the treatment when they need it. The committee concluded that there is an unmet clinical need and access to effective mental health treatments needs to be improved.

Further evidence

3.2 Further evidence should be generated while the technologies are in use to address the immediate unmet need, with appropriate risk management processes in place. The clinical experts stressed the importance of clinical risk management. When questioned, the companies advised that they have risk management and safeguarding systems in place. Also, all these technologies are supported by mental health practitioners that check in with users on a weekly basis. The clinical experts noted that even though risk management is important, many children and young people do not currently get access to any treatment while they are waiting. These guided self-help digital CBT technologies are a way to increase access to treatment with support from a mental health practitioner. The committee concluded that these 5 technologies can be used as a first-line treatment

if used with appropriate safeguarding and risk management processes in place while evidence is generated.

Clinical-effectiveness overview

3.3 There is very limited evidence on using all 5 digital CBT technologies for children and young people with mild to moderate symptoms of anxiety or low mood. The evidence base consists of 5 published studies, 2 unpublished studies and 2 conference abstracts. Of these, 7 were single arm designs with no direct comparator, 1 randomised controlled trial design and 1 2-arm non-randomised design. The external assessment group (EAG) noted that the sample sizes across the studies were small so presented a risk of false chance findings and underpowered analyses. The committee concluded that the evidence base is very limited for all 5 technologies. One technology had some higher-level evidence, but none of them were considered to have a stronger evidence base than the others.

Equality considerations

3.4 Neurodivergent children and young people may benefit from these guided self-help digital CBT technologies. The patient experts noted that neurodivergent children and young people are more likely to have significant mental health needs. They look at digital technologies differently and it is important that the technologies meet their needs. They liked the online interaction in place of face-to-face interaction because they do not have to socialise. The committee concluded that this subgroup may benefit from this more remote method of delivering therapy.

3.5 Children and young people with accessibility issues are unlikely to benefit from the guided self-help digital CBT technologies. The clinical experts noted that some children and young people are unable to access digital technologies. They may not have the equipment, internet connection or the privacy needed to complete the intervention. They may also lack experience with computers or electronic devices. These digital

technologies are unlikely to improve treatment options for these children and young people. Other treatment options including face-to-face CBT may be more appropriate for these children and young people.

Costs and resource use

3.6 The duration of the intervention and the per user license cost may affect costs. The committee noted that the parameter values in the model were based on very limited data sources, so results are uncertain. Also, the value of information analysis confirmed that further research is needed on the effectiveness of the 5 digital CBT technologies and the health state utilities. Based on the analysis, the key parameters affecting the cost effectiveness is the length of treatment and the per user license cost. It is unknown if the shorter duration with 4 out of 5 technologies will lead to poorer outcomes, or whether the longer duration simply increases costs. The model seemed relatively insensitive to the use of a mental health support worker compared with a clinical psychologist. The committee concluded that more data on these parameters is needed.

Evidence gap overview

3.7 The key evidence gaps relate to the population and key outcomes. The committee concluded that the evidence is very limited, so evidence generation is needed to address these key evidence gaps for all 5 technologies:

- There is no evidence for children and young people with low mood only. The clinical experts noted that often children and young people will have symptoms of anxiety and low mood. Most of the technologies are intended to treat symptoms of anxiety, but the companies confirmed that they can be used for children and young people with symptoms of low mood, if they are primarily presenting with symptoms of anxiety. Silvercloud has 1 technology that is specifically designed for young people with low mood only.

- There is no evidence for neurodivergent children and young people. The clinical experts noted that the target population has high neurodiversity, but the evidence implicitly or explicitly excluded neurodivergent children or young people.
- There is some heterogeneity in reporting symptoms of severity and impairment. Most studies reported symptom severity using the revised child anxiety and depression scale and impairment measures using the child anxiety impact scale and the strength and difficulties questionnaire. The clinical experts confirmed that these are appropriate measures. But, self-report of these measures for young people would be preferable, whereas for children this can be parent-reported.
- There is limited evidence on levels of engagement and reasons and rates of drop out. The clinical experts noted that if children and young people drop out early without any improvement it may make further re-engagement and treatment effectiveness less likely.
- There is no evidence on health-related quality of life. The clinical experts noted the importance of measuring quality of life and stated that different measures may be needed for children and young people. The EAG clarified that the EQ-5D-Y does not have a UK value set, but that the CHU-9D is specifically for children and young people.
- There is limited evidence available for the decision modelling. The EAG noted that evidence on outcomes related to the effectiveness of the digital CBT technologies compared with treatment as usual, health-related quality of life, withdrawals and level of psychological support should be generated to improve the certainty of the results of the model.

4 Evidence generation recommendations

4.1 The committee recommended further evidence generation for children and young people with mild to moderate symptoms of anxiety or low

mood. Specific subgroups that also need further evidence generation include:

- Neurodivergent children and young people
- Children and young people with low mood only.

The key outcomes that were prioritised by the committee for evidence generation include:

- Symptom severity: revised child anxiety and depression scale (parent-reported for children and self-reported for young people)
- Impairment measures: child anxiety impact scale and strength and difficulties questionnaire
- Health-related quality of life: CHU-9D
- Level of engagement including attrition
- Reasons and rates of drop out.

5 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

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

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

NICE project team

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

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