NICE National Institute for Health and Care Excellence

NICE guidance

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

HealthTech guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces HTE3.

1 Recommendations

1.1 Four guided self-help digital cognitive behavioural therapy (CBT) technologies can be used as an initial treatment option for children and young people (aged 5 to 18) with mild to moderate symptoms of anxiety or low mood, while evidence is being generated. These technologies can be used once they have Digital Technology Assessment Criteria (DTAC) approval from NHS England. The technologies are:

- 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).

Potential benefits of early access

- **Access:** Guided self-help digital cognitive behavioural therapy (CBT) technologies provide another treatment option for children and young people including those who may not be able to access current treatment or are on a waiting list and so not currently having treatment.
- **Clinical benefit:** Early evidence suggests that digital CBT technologies may improve symptoms of anxiety for children and young people with mild to moderate symptoms of anxiety or low mood.
- **Resources:** Earlier treatment could reduce the demand on other treatment options such as face-to-face CBT and potentially prevent progression to more severe symptoms which could be more costly to treat.
- **Equality:** Because these technologies can be used remotely, they may be preferred by some children and young people compared with face-to-face interactions with adults. This may benefit some neurodivergent children and young people.

Managing the risk of early access

- **Clinical assessment:** An initial assessment with a healthcare professional is needed before using these technologies to make sure they are suitable. This can take place in a range of settings including school mental health support teams, single point of access teams, voluntary sector teams and children and young people's mental health services.
- **Clinical support:** Children and young people will have regular support from a healthcare professional and safeguarding and risk management processes must be in place. This means that if the treatment is not working and symptoms are getting worse, it will be identified quickly, lowering the risks.
- **Individual choice:** These technologies can be used as an initial treatment option. Children and young people may choose to wait for other treatment options including face-to-face CBT. They may also have further treatment such as face-to-face CBT after using these technologies.

- **Care pathway:** This guidance has assessed the use of the technologies as an initial treatment option to address an unmet need and increase access to effective mental health treatments. Their use elsewhere in the care pathway should be based on individual clinical assessment.
- **Costs:** Early results from the economic modelling show that the technologies could be cost effective. This guidance will be reviewed within 4 years and the recommendations may change. Take this into account when negotiating the length of contracts and licence costs.

1.2 Further evidence should be generated on:

- symptom severity
- impairment measures
- health-related quality of life
- level of user engagement
- rates and reasons for stopping treatment.

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

2 The technology

Technologies

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 regular support and guidance from a healthcare professional. Five guided self-help digital CBT technologies were assessed as an initial treatment option for children and young people with mild to moderate symptoms of anxiety or low mood, while evidence is generated. The technologies are:

- Lumi Nova (BfB labs) is for children aged 7 to 12 with symptoms of anxiety. It combines evidence-based therapeutic and psychoeducational content within an intergalactic role-playing game.
- Online Social anxiety Cognitive therapy for Adolescents (OSCA) is for young people aged 14 to 18 with social anxiety. All users receive a core set of modules to work through at the beginning of the programme, which are then individualised for each user.
- Online Support and Intervention for child anxiety (OSI) is for children aged 5 to 12 with symptoms of anxiety. It is an internet based, parent-led intervention that has 3 components: a parent's website, a clinical case management website and an optional game app for children.
- Space from anxiety for teens, space from low mood for teens, space from low mood and anxiety for teens (Silvercloud) is for young people aged 15 to 18 with symptoms of anxiety, low mood or both. It is internet based and has 7 core modules structured around the principles of CBT.
- ThinkNinja CBT Bytesize (Healios) is for children and young people aged 11 and older with anxiety or low mood, and related problems. It is an app that contains psychoeducational and CBT-based content. The coaches and CBT therapists who provide support to users are employed by Healios. This technology is awaiting CE mark approval so cannot be used yet.

Children and young people who use these technologies may have further treatment such as face-to-face CBT.

Care pathway

2.2 Symptoms of anxiety or low mood may be identified by the child or young person themselves, their parents or carers, GPs, community care staff, social workers or school staff. Children and young people can be assessed and treated in a range of settings, including school mental health support teams, single point of access (SPA) teams, voluntary sector teams and children and young people's mental health services (CYPMHS). Some children and young people with mild to moderate symptoms of anxiety or low mood may be seen by CYPMHS, especially if they have other conditions. If they are not seen by CYPMHS they will be supported by mental health support teams or other services, including those provided by the voluntary, community and small enterprise sector. 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, psychiatrists, support workers, social workers, health visitors, school nurses and education mental health practitioners.

Comparator

2.3 The comparator is standard care which may include education, advice, support and signposting without access to healthcare professionals.

3 Committee discussion

Unmet need

3.1 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 who are referred for treatment with a mental health professional may be offered education, advice, support and signposting while waiting for treatment. Early research suggests that the COVID-19 pandemic has had a substantial effect on the mental health of children and young people and has intensified the issues related to accessing effective mental health treatments.

3.2 There is a need to improve access to effective mental health treatments, especially given the increase in mental health conditions seen during the pandemic. The patient experts noted that it can be 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 in their experience there were no options available to them while waiting for treatment. The clinical experts agreed that many children and young people are not getting access to 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

3.3 Further evidence will 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. The companies advised that they have risk management and safeguarding systems in place. Also, all these technologies are supported by healthcare professionals 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 cognitive behavioural therapy (CBT) technologies are a way to increase access to treatment with support from a healthcare professional. The committee concluded that these technologies can be used as an initial option if used with appropriate safeguarding and risk management processes in place while evidence is generated.

Clinical-effectiveness overview

3.4 The evidence shows that digital CBT technologies have a potential benefit 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 was a randomised controlled trial design and 1 was a 2-arm non-randomised design. The external assessment group (EAG) noted that there is weak evidence to suggest an improvement in anxiety symptom severity for these technologies. The 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 that showed an improvement in symptoms of anxiety compared with treatment as usual, but none of them were considered to have a stronger evidence base than the others. See the assessment report for further details.

Equality considerations

3.5 Some 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 may look at digital technologies differently and it is important that the technologies meet their needs. Some patient experts liked the online interaction in place of face-to-face interaction because they can be used without having to meet in person. The committee concluded that some neurodivergent

children and young people may benefit from this more remote method of delivering therapy.

3.6 Children and young people with limited access to equipment, internet connection or the privacy needed to complete the intervention are unlikely to benefit from the guided self-help digital CBT technologies. 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 so other treatment options including face-to-face CBT may be more appropriate.

Costs and resource use

3.7 The duration of the intervention and the licence cost per user may affect costs. The committee noted that the parameter values in the model were based on very limited data sources, so the 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 are the length of treatment and the licence cost per user. It is unknown if the shorter duration of treatment with 4 out of 5 technologies will lead to poorer outcomes, or whether the longer duration of treatment 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 review

3.8 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 use of these technologies by children and young people with low mood only. The clinical experts noted that often children and young people will have symptoms of both 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 use of these technologies by neurodivergent children and young people. The clinical experts noted that the population these technologies are aimed at has a high rate of neurodivergent children and young people, but the evidence implicitly or explicitly excluded them.
- 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-reporting 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 from studies. The clinical experts noted that if children and young people stop using the technologies 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, should be generated to improve the certainty of the results of the model. These should include health-related quality of life, withdrawals from treatment and level of psychological support.

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 groups 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 user engagement
- rates and reasons for stopping treatment.

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

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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Update information

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

Minor changes since publication

December 2025: Health technology evaluation 3 has been migrated to HealthTech guidance 660. The recommendations and accompanying content remain unchanged

October 2023: We updated the equality sections in 1.1 and 3.5 to clarify the population.

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