NICE National Institute for Health and Care Excellence

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

Implementation support

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1 Purpose of this document

NICE's assessment of guided self-help digital cognitive behavioural therapies recommends that further evidence is generated on these technologies while they are being used in the NHS.

This plan outlines the evidence gaps for the technologies and what real-world data needs to be collected to support a NICE review of the technologies again in the future. It is not a study protocol.

The technology developers are responsible for ensuring that data collection and analysis takes place. Support for evidence generation will be available through a competitive process facilitated by the Office for Life Sciences, pending business case approval. This will be in the form of funding for evidence generation consortia, bringing analytical partners and implementation sites together with developers for evidence generation.

Guidance on commissioning and procurement of the technology will be provided by NHS England. NHS England is developing a digital health technology policy framework which will further outline commissioning pathways.

NICE will withdraw the guidance if the technology developer does not meet the conditions about monitoring evidence generation in section 5.2 on monitoring.

After the end of the evidence generation period (3 years), the developer should submit the evidence to NICE in a form that can be used for decision making. NICE will review all the evidence and assess whether or not the technology can be routinely adopted in the NHS.

2 Evidence gaps

This section describes the evidence gaps, why they need to be addressed and their relative importance for future committee decision making.

The committee will not be able to make a positive recommendation without the essential evidence gaps (see section 2.1) being addressed. The company can strengthen their evidence base by also addressing as many other evidence gaps (see section 2.2) as possible. Addressing these will help the committee to make a recommendation by better understanding the patient or healthcare system benefits of the technology.

2.1 Evidence that is essential to allow the committee to make a recommendation in future

Effectiveness of the technologies compared with routine care

This is essential to understand the technologies clinical and cost effectiveness. The committee has highlighted that this evidence should use validated clinical outcomes for symptoms of severity and impairment such as the Revised Children's Anxiety and Depression Scale (RCADS) and the Strengths and Difficulties Questionnaire (SDQ).

2.2 Evidence that further supports committee decision making

Evidence for important subgroups of children and young people

Neurodivergent children and young people, and children and young people with low mood only, may interact with the technologies differently or have different outcomes compared with other children and young people. So, the clinical and cost effectiveness of the technologies should be established for these 2 subgroups if the technology developers expect their technology to be used in those groups.

Levels of user engagement and rates for stopping treatment

This will support the NICE committee in assessing the real-world uptake of the technology, its acceptance by children and young people, and other implementation challenges. Ideally, reasons for stopping treatment should also be collected.

Health-related quality of life

This outcome measures children and young people's perspectives on how changes in their health state relate to their quality of life. This information can be incorporated into health economic evaluations, for which quality of life is an important driver. The committee have recommended Child Health Utility (CHU-9D) as a valid tool for measuring this outcome.

3 Ongoing studies

Table 1 summarises the evidence gaps and ongoing studies that might address them for each technology recommended. More information on the studies in this table can be found in the external assessment group (EAG) report (PDF only).

Table 1 Summary of the evidence gaps and ongoing studies

Evidence gap	Silvercloud technologies	Online Social anxiety Cognitive therapy for Adolescents (OSCA)	Online Support and Intervention for child anxiety (OSI)	Lumi Nova
Effectiveness of digital CBT compared with usual treatment (RCADS, SDQ)	Limited current evidence Ongoing studies	Limited current evidence	Limited current evidence Ongoing studies	Limited current evidence Ongoing studies
Evidence for important subgroups of children and young people	Limited current evidence Ongoing study	No evidence	No evidence	Limited evidence Ongoing study
Levels of engagement and drop out	Limited current evidence Ongoing study	Limited current evidence	Limited current evidence Ongoing studies	Limited current evidence Ongoing study
Health-related quality of life measured using CHU-9D	No evidence	No evidence	Limited current evidence Ongoing studies	No evidence

Silvercloud technologies are space from anxiety for teens, space from low mood for teens, space from low mood and anxiety for teens.

Abbreviations: RCADS, Revised Children's Anxiety and Depression Scale; SDQ, Strengths and Difficulties Questionnaire; CHU-9D, Child Health Utility.

4 Approach to evidence generation

This section presents an approach to generating evidence and a description of real-world data that may be able to support evidence generation.

The technologies have varied positions with regards to their ongoing studies and the evidence gaps. All ongoing studies will complete within the evidence generation period. OSI has studies that may address most of the evidence gaps including its comparative effectiveness. Other technologies have studies that could address some of the evidence gaps, but not comparative effectiveness, and will need additional evidence generation.

4.1 Evidence generation plan

To address the evidence gaps a historical control study with propensity score methods is recommended

In a prospective study with propensity score matching, data is collected on a control group before the intervention is implemented among children and young people at the point at which they would have been eligible for the intervention. This is followed by data collection in the intervention group after implementation of the technology. In this approach, propensity score methods are used to balance observed characteristics to create comparable cohorts, reducing bias from confounding.

This approach allows direct comparison between an individual technology and the comparator (routine care) and can produce the evidence necessary for NICE decision making. There are limitations to this approach; head-to-head comparison between the technologies will not be possible and good information on important confounding factors is needed for each individual. It will also be important to control for seasonality. Ideally, the study should be run in multiple services or centres for each technology.

The experimental design will compare the technologies against routine care. As described in the scope, routine care is the current first-line treatment for children and young people with mild to moderate symptoms of anxiety or low mood. This may include education, advice, support and signposting.

Although the early value assessment for these technologies does not describe a particular

setting in which they are to be used, services provided in schools may be a good option for evidence generation. These services are likely to identify children and young people for whom the technologies may be appropriate and follow up after treatment is likely to be more straightforward.

Data collection is best approached using multiple sources, for example:

- some information generated through the technologies themselves (such as engagement and drop out)
- some information generated through linked mental health-GP electronic health records (such as important confounding factors, for example, comorbidities or medications or safety outcomes such as suicide or self-harm)
- other information collected by clinicians or research staff working with the children and young people (symptom measures such as the Revised Children's Anxiety and Depression Scale).

The technologies are well suited to collecting engagement information, but the outcome scales are clinical tools not designed for use in this way and are better administered by trained practitioners.

Data collection should follow a predefined protocol and quality assurance processes should be put in place to ensure the integrity and consistency of data collection. Analysis and reporting of the data should be completed by an independent party. See NICE's real-world evidence framework, which provides guidance on the planning, conduct, and reporting of real-world evidence studies.

4.2 Real-world data collections

The technologies will be able to collect some of the specific outcome measures such as use and level of engagement. But this data would need to be integrated with other data collected. There are several different data collections that could potentially support evidence generation with different strengths and weaknesses. NICE's real-world evidence framework provides detailed guidance on assessing the suitability of a real-world data source to answer a specific research question.

The Mental Health Services Data Set (MHSDS) is a mandated national data collection that could potentially collect the necessary data. But it may not routinely collect all the

outcome measures identified in the early value assessment. Also, there are potential issues with data quality and whether data on all people who are eligible has been submitted. NHS England has suggested that modification of MHSDS may take up to 2 years, so it is unlikely that it could be modified in time to support data collection.

There may be local or regional data collections that do collect the specific outcome measures recommended in the early value assessment. For example, questionnaires administered by Child and Adolescent Mental Health Services or the South London and Maudsley NHS Foundation Trust Biomedical Research Centre Case Register Interactive Search tool. These datasets or others that are similar, may be available through sub-national secure data environments (SDEs). Within an SDE the data may be linked to other useful data such as that from primary care and could provide information on important confounders (for example, comorbidities).

The quality and coverage of real-world data collections are of key importance when used in generating evidence. Active monitoring and follow up through a central coordinating point is an effective and viable approach of ensuring good-quality data with high coverage.

4.3 Data to be collected

The following information has been prioritised for collection, for both control and treatment groups:

- Revised Children's Anxiety and Depression Scale, recorded at baseline and after treatment at 3 months and ideally at 6 months
- ideally, the Strengths and Difficulties Questionnaire should also be recorded at baseline and after treatment at 3 months and ideally at 6 months
- engagement and drop-out information, including reasons for stopping
- incidence of self-harm and suicide
- information about potential confounding factors at baseline (for example, comorbidities and socioeconomic status), evidence developers should seek clinical input to ensure important confounding factors are captured to support robust propensity score methods

- information about a subgroup of children and young people with low mood only
- information about a subgroup of neurodivergent children and young people
- CHU-9D, recorded at baseline and after treatment at 3 months and ideally at 6 months.

4.4 Evidence generation period

It is proposed that the evidence generation period is 3 years, this would leave enough time for ongoing studies to complete, and the time needed to implement evidence generation, collect the necessary information and analyse collected data.

5 Safety and monitoring

5.1 Safety

NICE's patient safety oversight group recommends additional data collection during the evidence generation process on the incidence of suicide and self-harm among users, to monitor the safety of the technologies.

NICE should be notified of any data collected that could indicate a safety concern, and the proposed response.

5.2 Monitoring

The technology developer is required to contact NICE:

- within 6 months of evidence generation plan publication to confirm agreements are in place to generate the evidence specified
- annually to confirm that the data is being collected and analysed as planned.

Technology developers should inform NICE at the earliest opportunity of anything that may affect ongoing evidence generation, including:

- any substantial risk that the evidence will not be collected as planned
- new safety concerns
- the technology significantly changing in a way that affects the evidence generation process.

If data collection is expected to end later than planned, the technology developers should contact NICE to arrange an extension to the evidence generation period. NICE reserves the right to withdraw the guidance if data collection is delayed, or if it is unlikely to resolve the evidence gaps.

6 Implementation considerations

The following considerations around implementing the evidence generation process have been identified through working with system partners.

6.1 General

- Developers should provide training for staff to support use of the technologies
- The evidence generation process is most likely to succeed with dedicated research staff to reduce the burden on NHS staff, and by using suitable real-world data to collect information when possible.
- Evidence generation should be overseen by a steering group including researchers, commissioners, practitioners and representatives with lived experience.
- Contributing services or centres should be chosen to maximise the generalisability of evidence generated, or to improve data collection for important subgroups.
- Careful planning of approaches to information governance is vital.

6.2 Topic-specific

- Head-to-head comparison between the technologies is limited because they may be designed for different groups of children and young people. For example, several developers have indicated that their technology is not designed for use by children and young people with low mood only. This may limit the availability of evidence for this subgroup
- There is variation in the services and settings where the technologies may be used. Treatment processes and outcome performance vary. This may create issues with the generalisability of any evidence generated to the wider NHS, reducing its utility for NICE decision making. Developers should provide clear descriptions of the services and settings in which the study is done, and the characteristics of the included children and young people. Generalisability may be improved by using a range of sites, or sites considered more representative of national norms

- Using school settings for data collection may support follow up, but these settings are narrower in scope than the NICE early value assessment
- There is a wide spectrum of neurodivergent children and young people, and their support and needs vary considerably. Complete evidence across this spectrum will be difficult to generate
- Information collected about engagement and drop out may not necessarily correlate with outcomes. For example, children and young people may choose to drop out early if they feel better. Developers should consider whether it is possible to collect information on any further interactions with health services after drop out
- Using CHU-9D requires a licence, with an associated cost.

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