NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Evidence generation plan

Digital self-help for eating disorders

July 2025

1 Purpose of this document

NICE's early value assessment Digital self-help for eating disorders recommends that Overcoming Bulimia Online (Five Areas Ltd) can be used in the NHS while more evidence is generated. The other technologies that were assessed can only be used in research and are not covered in this plan.

This plan outlines the evidence gaps and what real-world data needs to be collected for a NICE review of the technology again in the future. It is not a study protocol but suggests an approach to generating the information needed to address the evidence gaps. Evidence generated through other study approaches will also be considered. For assessing comparative treatment effects, well-conducted randomised controlled trials are the preferred source of evidence if these are able to address the research gap.

The company is responsible for ensuring that data collection and analysis takes place.

Guidance on commissioning and procurement of the technology will be provided by the NHS.

NICE will withdraw the guidance if the company does not meet the conditions in section 4 on monitoring.

After the end of the evidence generation period (2 years), the company 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 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 the evidence base by also addressing as many other evidence gaps (see section 2.2) as possible. This will help the committee to make a recommendation by ensuring it has a better understanding of the patient or healthcare system benefits of the technology.

2.1 Essential evidence for future committee decision making

Comparative evidence about remission, relapse and mortality with the technology used as a self-help intervention

To evaluate the efficacy of this technology, it is essential to have comparative data on remission, relapse and mortality outcomes when used as a self-help intervention. Current evidence does not adequately show how the technology works compared with standard NHS care, making it difficult to determine its clinical value in a real-world setting. Understanding the impact on these outcomes is key to assessing whether the technology can help improve long-term wellbeing and quality of life.

Long-term effectiveness and outcomes

There is currently no evidence showing outcomes beyond 3 to 6 months. To fully understand the effectiveness of the technology, it is important to assess the sustainability of any impact that it has on clinical outcomes. To evaluate this, it is essential to collect comparative and longitudinal data on key outcomes such as remission, relapse and health-related quality of life. Other outcomes, like days missed from school or work, use of support services and any changes in NHS resource use should also be captured to reflect patient and system level impacts. The technology is intended to be used while people are waiting for support or treatment. But, understanding how it affects service use once accessed is important, because the technology may reduce the need for more intensive support later.

Reasons for high attrition and barriers to engagement

The available evidence showed that many people did not complete their treatment on the digital intervention. This leads to uncertainty about the effectiveness of the interventions. Further data collection is needed to better understand how many people are likely to stop the digital treatment prematurely and why, including potential barriers to engagement.

Resource and care pathway impact

There was not enough evidence to understand the resource costs and whether the digital technology would change the care pathway in the NHS. Further information about the costs of the technology and the healthcare professional resource necessary to support it are needed to drive economic modelling. Information on the technology's potential to reduce healthcare professional visits or its possible impact on waiting times or other service outcomes would also inform a future model.

2.2 Evidence that further supports committee decision making

Generalisability and population diversity

To assess the impact of this technology on people's health, it is important to understand the efficacy of the technology across age groups, different ethnicities, genders and socio-economic backgrounds. Ideally, when the effectiveness of the technology is studied, the population in question reflects the population who would access care in the NHS.

Equity and accessibility concerns

There is currently no research into how accessible this digital technology is for people with limited digital literacy, limited access to devices or who may struggle to use digital self-help tools. Understanding these barriers is necessary to determine how the technology could be applied in the NHS. It is also important to identify which patient groups are not being offered the technology because of its inaccessibility. This could include people with learning disabilities or without access to private mobile devices.

3 Approach to evidence generation

3.1 Evidence gaps and ongoing studies

Table 1 summarises the evidence gaps and ongoing studies that might address them. Information about evidence status is derived from the external assessment group's report; evidence not meeting the scope and inclusion criteria is not included. The table shows the evidence available to the committee when the guidance was published.

Table 1 Evidence gaps and ongoing studies

Evidence gap	Overcoming Bulimia Online
Comparative evidence about remission, relapse and mortality with the technology used as a self-help intervention	Limited evidence
Long-term effectiveness and outcomes	Limited evidence
Reasons for high attrition and barriers to engagement	Limited evidence
Equity and accessibility concerns	No evidence
Resource and care pathway impact	No evidence
Generalisability and population diversity	Limited evidence
Acceptability and user experience in routine NHS settings	Limited evidence

3.2 Data sources

Most of the data, particularly that relating to comparative evidence and attrition, is likely best collected through primary data collection using the technology itself. There are data sources that may collect some of the necessary outcome information, but they may require linkage to the primary data collection.

There are several existing data collections with different strengths and weaknesses that could potentially support evidence generation. 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. Potential data sources include:

- MHRA's Clinical Practice Research Datalink (CPRD)
- NHS England's Hospital Episode Statistics (HES).

Some data, such as starting therapy and engagement metrics, may be generated through the digital technology itself. This data can be integrated with other data collected with routinely collected datasets where appropriate.

The CPRD and HES data sets are well-established and reliable sources of NHS data. But, neither data set will be modified to add new data fields specific to the technology. So, the digital intervention could be adapted to collect key data items of interest for the evaluation.

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 broad coverage.

3.3 Evidence collection plan

NICE suggests a mixed methods approach to address the identified evidence gaps; a prospective comparative cohort study combined with a qualitative survey. The qualitative component should explore user experience, engagement and barriers to access in more depth.

Data could be collected through a combination of:

- primary data collection (for example, outcome measures and surveys)
- data generated through the technology itself (for example, engagement metrics and session completion)
- routinely collected real-world data sources (for example, CPRD and HES).

Data collection should follow a predefined protocol. Quality assurance processes should be put in place to ensure the integrity and consistency of data collection. See

NICE's real-world evidence framework, which provides guidance on the planning, conduct and reporting of real-world evidence studies. It also provides best practice principles for robustly designed real-world evidence when assessing comparative treatment effects.

Prospective real-world comparative cohort study

In this type of study, data should be collected from healthcare services where the digital technology is offered and compared with services where it is not. People in both groups should be followed from the point at which they would typically be offered the technology.

The comparison group should include people from similar services with comparable patient populations and standard care pathways but without access to the digital technology. Ideally, the study should be conducted across multiple centres to reflect the diversity of the NHS service provision.

Non-random assignment to interventions introduces a risk of confounding bias. So, appropriate methods such as matching or adjustment (for example, propensity score methods) should be used to minimise selection bias and balance confounding factors between groups. High-quality data on patient characteristics will be essential to support these methods. The identification of key confounders should be informed by expert input during protocol development.

Qualitative survey

Feedback should be collected through a survey or structured interviews with people who have used the technology. The robustness of the findings will depend on:

- Broad and inclusive distribution across eligible users
- the sample of respondents being representative of the population of potential users.

3.4 Data to be collected

Real-world prospective comparative cohort study

The following information should be collected:

- remission status at the end of treatment, 3, 6 and 12 months
- relapse rate at 3, 6 and 12 months (reappearance of symptoms after remission)
- abstinence from binge or purge episodes
- mortality
- patient reported outcomes (for example, Global Eating Disorder Examination questionnaire, Hospital Anxiety and Depression Scale and Clinical Impairment Assessment questionnaire)
- health-related quality of life (for example, EQ-5D-5L at baseline, 3, 6 and 12 months)
- uptake of follow-on treatment after digital intervention

impact on reduction for more intensive care

- time to dropout or last session completed
- engagement metrics (for example, time spent per session or number of logins)
- session completion rate
- reported barriers (for example, technical issues, lack of support, lack of perceived benefit)
- patient characteristics and demographics (for example, age, gender, ethnicity, sexual orientation, socioeconomic status, disability or cognitive impairment, education level, diagnosis and symptoms severity)
- usage data stratified by demographic variables (for example, session completion rates by age, ethnicity, disability status or severity of symptoms)
- intervention cost per user (licence, support, maintenance)
- staff time associated with implementation or support
- number of:
  - binge-eating episodes at baseline, end of treatment, 3, 6 and 12 months
  - days missed from school or work
  - GP visits

- specialist consultations (for example, psychiatrists or eating disorders services)
- emergency department visits
- crisis services use
- community mental health teams use
- inpatient admissions
- missed or cancelled appointments.

Qualitative survey study

Outcomes to be collected from people who have an eating disorder and healthcare staff:

- patient-reported barriers to accessing or using the digital intervention (through questionnaires or interviews)
- healthcare-professional-reported reasons for not offering the intervention to certain people
- feedback from excluded people or people who declined to take part
- transparency for inclusion and exclusion criteria
- user feedback via semistructured interviews or open-ended surveys
- feedback from NHS staff (for example, GPs, psychologists, eating disorder specialists).

Information about the technologies

Information should be collected about:

- how the technologies were developed
- how people are referred to the technology and at what point in their clinical pathway
- any updates to the technologies

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. See NICE's real-world evidence framework, which provides guidance on the planning, conduct, and reporting of real-world evidence studies.

3.5 Evidence generation period

This will be 2 years to allow for setting up, implementing the test, data collection, analysis and reporting.

3.6 Following best practice in study methodology

Following best practice when conducting studies is paramount to ensuring the reliability and validity of the research findings. Following rigorous guidelines and established standards is crucial for generating credible evidence that can improve care. The NICE real-world evidence framework details some key considerations.

In the context of evidence generation, it is key to consider as part of the informed consent process that patients (and their carers, as appropriate) understand that data will be collected to address the evidence gaps in section 2. Where applicable this should take account of NICEs guidance about shared decision making.

4 Monitoring

The company must contact NICE:

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

The company should tell NICE as soon as possible of anything that may affect ongoing evidence generation, including:

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

If data collection is expected to end later than planned, the company 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.

5 Minimum evidence standards

The minimum evidence standards were informed by a combination of sources, including company submission, the external assessment group's report and committee discussions. These 3 different sources provided an overview of the clinical and economic evidence available to examine the use of the technology in the NHS. But, important limitations remain across different areas such as comparative effectiveness, long-term outcomes, better understanding of the reasons behind the reported attrition levels and cost effectiveness. The evidence base evaluated did not meet all the preferred standards for robust and generalisable data. So, NICE recommends further evidence generation through a suggested prospective comparative cohort study and qualitative research to address key uncertainties and support future decision-making on routine NHS use.

6 Implementation considerations

Companies should work with providers and NHS teams to begin evidence generation. Planning for a period for the setup of the technology is advised. The following considerations around implementing the evidence generation process have been identified through working with system partners:

- Companies should provide training for staff in using the technology, when support is needed. The training and implementation period should be before the data collection period and be sufficient to account for potential learning effects.
- Evidence generation should be overseen by a steering group including researchers, commissioners, practitioners, and people with lived experience.
- The evidence generation process is most likely to succeed with dedicated research staff to reduce the burden on NHS staff.
- Sites should be carefully selected to, when appropriate, maximise data collection and ensure services representative of those in the NHS are included.
- Careful planning of the approach to information governance is vital. The company should ensure that appropriate structures and policies are in place to ensure that the data is handled in a confidential and secure manner and to appropriate ethical and quality standards.

The following barriers for implementing the evidence generation process have been identified through working with system partners:

- the availability of research funds for data collection, analysis and reporting, as well as NHS funding to cover the costs of implementing the technologies in clinical practice
- lack of expertise and staff to collect data
- burden on clinical staff, such as the need to have training before implementation, data collection and follow up
- variable levels of technological literacy affecting uptake and use of the technologies
- support for languages other than English in the technologies affecting their uptake and use.

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