NICE National Institute for Health and Care Excellence

NICE guidance

Digital self-help for eating disorders: 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

1 Recommendations

Can be used with evidence generation

1.1 Overcoming Bulimia Online can be used in the NHS during the evidence generation period as an option to treat the following conditions in adults:

- binge eating disorder
- bulimia nervosa
- other specified feeding or eating disorder (OSFED) with similar features to binge eating disorder or bulimia nervosa
- disordered eating with similar features to binge eating disorder or bulimia nervosa.

It can only be used:

- if the evidence outlined in the evidence generation plan for Overcoming Bulimia Online is being generated
- as long as it has appropriate regulatory approval including NHS England's Digital Technology Assessment Criteria (DTAC) approval.

1.2 Overcoming Bulimia Online should only be used:

- after an initial eating disorder assessment in primary care or further assessment by specialist eating disorder services
- alongside usual waiting list care, such as regular check-ins and routine physical monitoring.

1.3 The company must confirm that agreements are in place to generate the evidence. It should contact NICE annually to confirm that evidence is being generated and analysed as planned. NICE may revise or withdraw the guidance if these conditions are not met.

1.4 At the end of the evidence generation period (2 years), the company should submit the evidence to NICE in a format that can be used for decision making. NICE will review the evidence and assess if the technology can be routinely adopted in the NHS.

More research is needed

1.5 More research is needed on Digital CBTe and Worth Warrior to treat the following conditions before they can be funded by the NHS:

- binge eating disorder
- bulimia nervosa
- OSFED with similar features to binge eating disorder or bulimia nervosa
- disordered eating with similar features to binge eating disorder or bulimia nervosa.

What this means in practice

Can be used with evidence generation

Overcoming Bulimia Online can be used as an option in the NHS during the evidence generation period (2 years) and paid for using core NHS funding. During this time, more evidence will be collected to address any uncertainties. Companies are responsible for organising funding for evidence generation activities.

After this, NICE will review this guidance and the recommendations may change. Take this into account when negotiating the length of contracts and licence costs.

Potential benefits of use in the NHS with evidence generation

- **Access:** Unguided digital self-help is a treatment option that can start as soon as an eating problem is identified. This could be in primary care or straight after an eating disorder is diagnosed in specialist eating disorder services. This is important because early intervention increases the chances that a person makes a full recovery. Digital self-help alongside usual waiting list care also provides a greater level of intervention than usual waiting list care alone.
- **Clinical benefit:** Using digital self-help could improve eating disorder symptoms. Randomised controlled trials show that Overcoming Bulimia Online reduces the frequency and severity of eating disorder symptoms compared with usual waiting list care.
- **Resources:** Earlier treatment could reduce the demand on or the length of more intensive treatments such as guided self-help, and group or individual eating-disorder-focused cognitive behavioural therapy. Results from the short-term economic modelling show that Overcoming Bulimia Online has the potential to be cost saving, even with conservative assumptions about the effects of the technology.
- **Equality:** Some people may particularly benefit from having access to unguided digital self-help, for example:
  - people with less severe eating disorders who may otherwise wait longer for treatment
  - people who live in areas where specialist eating disorder service capacity is

lower.

Managing the risk of use in the NHS with evidence generation

- **Patient outcomes:** When unguided digital self-help is used alongside usual waiting list care, it is not expected to cause harm to people with eating disorders.
- **Contraindications:** Unguided self-help is not intended for people with severe eating disorders or at a high medical risk. Self-help is not suitable for people with any form of anorexia nervosa.
- **Equality:** Some people may find it more difficult to use or engage with digital self-help technologies, for example:
  - neurodivergent people
  - people with learning disabilities
  - people with visual, hearing or cognitive impairments
  - people who have problems with manual dexterity and
  - people who are less familiar with using digital technologies.

More research is needed

There is not enough evidence to support funding Digital CBTe and Worth Warrior in the NHS.

Access to Digital CBTe and Worth Warrior should be through company, research or non-core NHS funding, and clinical or financial risks should be managed appropriately.

What evidence generation and research is needed

More evidence generation and research is needed on:

- remission, relapse and mortality compared with usual waiting list care, with digital self-help used as an unguided intervention
- longer-term remission, relapse and mortality after digital self-help compared with no digital self-help
- how well the technologies work for people who may find it more difficult to use digital self-help technologies
- the proportion of people who do not complete the digital self-help, their characteristics and reasons for stopping
- effects of digital self-help on resource use and the care pathway compared with usual waiting list care.

Why the committee made these recommendations

People with eating disorders can face long waits to access specialist assessment and psychological treatment. Earlier treatment can help to stop their condition becoming more severe. Unguided digital self-help is a treatment option that can start as soon as an eating problem is identified in primary care or diagnosed in specialist eating disorder services.

When used alongside usual waiting list care, there is a low risk of harm with unguided digital self-help compared with usual waiting list care alone.

Clinical trial evidence shows that people with eating disorders who use Overcoming Bulimia Online have fewer binge eating episodes and less severe symptoms than people having usual waiting list care.

Short-term economic evidence suggests that Overcoming Bulimia Online is likely to be cost effective. So it is recommended for use with evidence generation.

Evidence from observational studies suggests that Digital CBTe and Worth Warrior may also reduce eating disorder symptoms. But this is uncertain because the studies did not compare the technologies with anything else. The study on Worth Warrior is also too small to draw firm conclusions on its clinical effectiveness. Because of the uncertainties in the clinical evidence, it is not possible to say whether Digital CBTe and Worth Warrior are likely to be cost effective. So they are only recommended for use in research.

More evidence is needed to show how well these technologies work and why some people stop using them. Evidence is also needed to show how using the technologies might affect resource use and the wider care pathway.

2 Information about the technologies

2.1 This assessment included 3 technologies that can be used to offer NICE-recommended, evidence-based, eating-disorder-focused cognitive behavioural therapy based self-help in a digital format.

2.2 In eating disorder services, guided self-help programmes are currently the first treatments to offer or consider for:

- all people with binge eating disorder type conditions
- adults with bulimia nervosa type conditions.

Guided self-help involves working through a self-help book or online programme about binge eating or bulimia nervosa, and having brief, usually virtual, supportive sessions intended to support adherence.

2.3 The 3 included technologies can be used with guidance but they are also designed to work as unguided self-help. This assessment is of their use as independent, unguided self-help therapies.

Table 1 Features of each technology

Technology (provider), regulatory status	Intended age group	Format	License cost
Digital CBTe (Credo Therapies) Class I UKCA mark	18 years and over	Smart phone app and online	£95.00 per person

Technology (provider), regulatory status	Intended age group	Format	License cost
Overcoming Bulimia Online (Five Areas Ltd) The company has stated that the technology does not need medical device regulatory approval	16 years and over	Online	£19.34 per person (2 to 5 licences) £13.44 per person (6 to 10 licences) £10.75 per person (11 to 25 licences) £9.14 per person (26 to 50 licences) £7.79 per person (51 to 99 licences) £6.72 per person (100 to 499 licences) £5.91 per person (for 500 or more licenses, used in the health economic model)
Worth Warrior (stem4) The company has stated that the technology does not need medical device regulatory approval	12 years and over (under 12 with adult guidance)	Smart phone app	£12,000 per year for a primary care network-level licence in year 1, plus £6,500 per year after that Per-person costs (calculated based on the prevalence of bulimia nervosa and binge eating disorder): £18.99 for year 1 and then £10.28 per year for binge eating disorder £71.43 for year 1 and then £38.69 per year for bulimia nervosa

Carbon Reduction Plans

2.4 For information, Carbon Reduction Plans for UK carbon emissions for each

technology are published here:

- Credo Therapies' Carbon Reduction Plan
- Five Areas Ltd's Carbon Reduction Plan
- stem4's Carbon Reduction Plan.

3 Committee discussion

The diagnostics advisory committee considered evidence on digital self-help for eating disorders from several sources. This included evidence submitted by Credo Therapies, Five Areas Ltd and stem4, a review of clinical and cost evidence by the external assessment group (EAG), and responses from stakeholders. Full details are available in the project documents for this guidance.

The condition

3.1 It is estimated that at least 1.25 million people in the UK have an eating disorder (Beat's data on eating disorder prevalence in the UK). Eating disorders are described as mental health conditions in which controlling food is used to cope with feelings and situations.

Having a binge eating disorder means eating very large quantities of food without feeling in control of it, and includes:

- eating much faster than normal until feeling uncomfortably full
- eating large amounts of food when not physically hungry
- eating alone through embarrassment at the amount being eaten
- feelings of disgust, shame or guilt during or after the binge.

People with bulimia nervosa cycle between bingeing and trying to compensate for the overeating (purging) by:

- vomiting
- taking laxatives or diuretics
- fasting
- exercising excessively.

People can have symptoms that are similar to an eating disorder but do not

exactly fit the typical symptoms for the condition. Then, the condition may be diagnosed as other specified feeding or eating disorder (OSFED). Disordered eating refers to food- and diet-related behaviours that do not meet diagnostic criteria for recognised eating disorders but may still negatively affect physical and mental health.

Current practice

3.2 Signs of eating disorders can be noticed in many settings, such as school, university, work, home or social care. Often the first healthcare contact, who will do an initial assessment, is a GP. After the initial assessment, people with a suspected eating disorder are usually referred to a community-based eating disorder service for further assessment or treatment. While people wait for further assessment or treatment in specialist care, usual waiting list care may include:

- further appointments at the GP practice
- appointments with the eating disorder service while on the waiting list
- signposting to voluntary, community and social enterprise organisations, for example, eating disorder charities
- books or online resources (including the books used in eating-disorder-focused cognitive behavioural therapy based guided self-help)
- local groups or telephone helplines for additional support.

Unmet need

3.3 The incidence of eating problems and eating disorders is increasing. People often wait a long time for psychological treatment to start. More referrals to specialist care mean that the services cannot meet the increasing need for psychological treatment with the healthcare professional capacity available. Earlier treatment could help prevent the condition from becoming more severe. There is a need for a treatment option that could start as soon as possible once eating problems are

identified. This could be in primary care or straight after an eating disorder is diagnosed in specialist eating disorder services.

Innovative aspects

3.4 Using digital self-help does not depend on healthcare professional capacity to provide support for using the therapy. It could also offer people with signs and symptoms of eating disorders faster access to eating disorder therapy.

Clinical effectiveness

Overcoming Bulimia Online

3.5 The EAG identified 3 randomised controlled trials (RCTs), 3 cohort studies and 3 qualitative studies on Overcoming Bulimia Online. The RCTs showed reductions in binge eating episode frequency and eating disorder symptom severity compared with usual waiting list care. The cohort studies also reported improvements in clinical outcomes during the study.

In only 1 of the RCTs on Overcoming Bulimia Online, people in the study used the technology as an unguided intervention. The committee noted that digital self-help may be more effective when it is guided than unguided. So the improvements in outcomes seen in the studies may have been smaller if no support was provided. The committee recalled that people often wait a long time to access guided self-help because it needs healthcare professional capacity. Unguided digital self-help could provide earlier access to psychological treatment. To confirm the effectiveness of Overcoming Bulimia Online, more data on the unguided use of the technology is needed. Despite the limited evidence on unguided therapy, the committee concluded that Overcoming Bulimia Online is likely to be clinically effective.

Digital CBTe and Worth Warrior

3.6 There were 3 cohort studies on Digital CBTe. In 2 of the 3 studies, people used Digital CBTe as an unguided intervention. All 3 studies showed reductions in binge eating episode frequency and eating disorder symptom severity during the study. There was 1 small cohort study on Worth Warrior. People in the study used the technology as an unguided intervention. Clinical outcomes for some people in the study showed improvement.

The studies on Digital CBTe and Worth Warrior did not have comparator groups. The committee noted that this meant that it was possible that people's eating disorder symptoms improved for reasons other than the technologies. The study on Worth Warrior was also very small. So it was difficult to know whether the improvements in the study happened by chance and whether they could happen in a larger group of people. The committee concluded that it is uncertain whether Digital CBTe and Worth Warrior are likely to be clinically effective. To better understand this, comparative data on the technologies is needed.

The committee considered evidence on the printed programme version of Digital CBTe (Overcoming Binge Eating). The digital version took the main aspects of the printed version and put it into a digital format. The changes included reducing the text volume, enhancing interactivity and increasing customisation tailored to individual eating disorder presentations. For example, the module on strict dieting is only available to the user if they select that this is relevant to them. The committee noted that Digital CBTe is not a direct translation of the printed programme. So they concluded that the evidence on the printed programme is not generalisable to the digital version of the programme.

Long-term effects

3.7 None of the studies included a long-term follow up. The clinical experts noted long-term evidence on book-based self-help for context (it was not included in the assessment). It suggests that people who start with self-help are likely to have better outcomes in the long term compared with people who start with therapist-led sessions. This is because they are more actively involved in their own therapy. To better understand the effects of unguided digital self-help,

longer-term data after its initial use, compared with no initial use, is needed.

Completion rates

3.8 In many studies, the proportion of people who did not complete the digital self-help treatment was high. Not much information was available on the people who did not complete the treatment or the reasons why. The Digital CBTe company representatives explained that their studies were done either in community or NHS settings. The attrition (non-completion) rates in these studies were higher than in tightly controlled clinical trials. But the rates are typical and common in real-world evaluations of digital mental health interventions, particularly when self-guided or minimally supported. The committee concluded that, to better understand the potential benefits of the technologies, more information on people who did not complete the digital self-help treatment, and the reasons why, is needed.

Equality considerations

3.9 The committee noted that some people may particularly benefit from having access to unguided digital self-help, for example:

- people with less severe eating disorders who may otherwise wait longer for treatment
- people who live in areas with lower specialist eating disorder service capacity.

In addition, some people may have increased engagement with self-help treatment in an interactive digital format than with a book in a printed or electronic format. But it may be more difficult for some people of low socioeconomic status to use digital self-help technologies if they do not have access to a smart phone, tablet or computer or an internet connection.

Most of the people in the key studies were white women but not all the studies reported information on the participants' ethnicities. Also, not all of

them included whether participants had conditions that may make it more difficult to use or complete digital self-help, such as:

- neurodivergence
- a learning disability
- difficulty reading
- not having English as a first language
- visual, hearing or cognitive impairment
- problems with manual dexterity
- less experience using digital technologies in general.

The patient and carer experts highlighted the importance of inclusive technologies. If digital self-help programmes are designed only with neurotypical women from white ethnic groups in mind, people from other groups may find it harder to engage with the therapy. This could include people experiencing poverty and food insecurity, neurodivergent people, people from minority ethnic groups and trans people. People who fit into more than one of these groups may be even more likely to have difficulties engaging with digital self-help technologies. The committee agreed that future studies should collect information about the characteristics of participants. This should include their ethnicity, and whether they have conditions that may make it more difficult to access and use the technology. Studies should aim to include a diverse group of people and an equality impact assessment.

Cost effectiveness

Short-term model

3.10 The EAG adapted the model from NICE's guideline on eating disorders to estimate short-term resource use and costs for digital self-help technologies in

primary care and specialist eating disorders services. The base-case model assumptions were conservative. This was because of the uncertainties in the evidence base. The model assumed that only people who completed the digital self-help treatment had an increased probability of no longer having eating disorder episodes (remission). Partially completing the treatment had no benefits. The model did not include:

- potential improvements in health-related quality of life
- avoided deaths
- potential reductions in longer-term resource use
- costs associated with comorbidity (such as obesity in binge eating disorder, or other mental health conditions such as depression and anxiety).

The EAG advised that, in a future assessment, a longer-term model is needed to more fully capture the benefits and costs of the technologies.

Clinical inputs to the model

3.11 The key clinical inputs to the short-term model were the probabilities of remission and relapse (eating disorder symptoms returning after the condition being in remission). The probability of remission was taken from the Sánchez-Ortiz et al. (2011) study. This was because this was the only study that reported on remission using the current online format of Overcoming Bulimia Online. There was no evidence on how digital self-help affects relapse. So relapse probability in the base case was based on clinical expert estimates. It was assumed to be the same for people having usual waiting list care and people using Overcoming Bulimia Online. The EAG advised that mortality would be a key clinical input to a longer-term model, but it was not included in the short-term model. None of the studies reported on mortality. The committee concluded that more information on remission, relapse and mortality is needed.

Resource use

3.12 Resource use in the model included healthcare use during a 1-year follow-up period. There was no evidence on the effect of using digital self-help on resource use. So it was based on clinical expert estimates from 2 group interviews. The experts noted that it was very difficult to give definitive estimates. The model assumed that people whose eating disorder was in remission after the initial digital self-help treatment or usual waiting list care did not need further assessment or treatment. The clinical experts also noted that, if digital self-help is helpful for people, it could reduce the need for further treatment, and reduce treatment length or intensity later in the care pathway. If there was evidence for this, it could be captured in a longer-term model. The committee concluded that, to reduce uncertainty in the model, more short- and long-term data is needed on the effects of digital self-help on resource use and the NHS care pathway.

Overcoming Bulimia Online

3.13 The conservative base-case analysis estimated that, compared with usual care in bulimia, using Overcoming Bulimia Online would save £5.52 in primary care and £39.86 in specialist eating disorder services. The EAG analysed several plausible alternative scenarios in which Overcoming Bulimia Online was more effective, or in which higher resource use and costs were avoided. In some of these alternative scenarios the cost savings were considerably higher. The committee concluded that using Overcoming Bulimia Online was likely to be a cost-effective use of NHS resources.

Digital CBTe and Worth Warrior

3.14 Because Digital CBTe and Worth Warrior did not have comparative clinical-effectiveness evidence, the EAG did 2-way sensitivity analyses. These were to show how much more effective a hypothetical digital self-help technology at a given per-person cost would need to be than usual care to be potentially cost saving (using the EAG's conservative base-case assumptions). Based on these analyses, Digital CBTe and Worth Warrior would likely only be cost saving if:

- some of the most conservative assumptions in the model were relaxed and
- the effect sizes seen with Overcoming Bulimia Online were replicated for both technologies.

The committee concluded that it is uncertain whether using Digital CBTe and Worth Warrior is likely to be a cost-effective use of NHS resources.

Acceptability

3.15 User feedback from the studies on Overcoming Bulimia Online and Digital CBTe was mainly positive. The users who completed all or most of the treatment appreciated the technologies' usability, effect on their eating disorder, privacy and flexibility. The preliminary user feedback from the study on Worth Warrior included some positive views on the content and interactivity of the technology. In the NICE survey on views on using digital self-help, most people who had used digital self-help were likely to recommend it to others with eating disorders. Two studies on Digital CBTe also included the views of NHS staff. The staff thought that the technologies could be helpful for people with eating disorders and may reduce the intensity of further treatment or need for further support from the service. The committee concluded that it was likely that the technologies would be acceptable to people with eating disorders and healthcare professionals.

Risk of harm

3.16 The committee discussed whether there was potential for harm if digital self-help is used in the NHS alongside usual waiting list care while further evidence is generated. Most studies did not report on adverse events but the committee noted that:

- digital self-help may not be suitable for some people
- if people do not complete the digital self-help course, they could feel demotivated and their eating disorder symptoms could get worse

- people with severe eating disorders are at risk of crisis.

  The clinical experts noted that self-help-type therapy in general is not suitable for people with severe eating disorders or a high mortality risk. This is because of the potential physical health impact of the eating disorder, or other mental or physical health conditions. The technologies in the assessment are not intended for this population.

  The clinical experts explained that, when unguided digital self-help is used alongside usual waiting list care, such as regular check-ins and routine physical monitoring, it is not expected to cause harm to people with eating disorders. The committee concluded that it was important that the technologies should be used after an initial eating disorder assessment in primary care or further assessment by specialist eating disorder services. It also concluded that the technologies should be used alongside usual waiting list care, such as regular check-ins and routine physical monitoring.

4 Committee members and NICE project team

This topic was considered by specialist committee members appointed for this topic and NICE's diagnostics 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 each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chair

Brian Shine
Chair, diagnostics advisory committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

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