**Final Protocol April 2025**

# Digital self-help for people with eating disorders: early value assessment

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*This study is funded by the NIHR Evidence Synthesis Programme (project no NIHR175495).*

**Plain English Summary**

Approximately 1.25 million people in the UK suffer from eating disorders. These can affect people of any age and may include eating too much or too little or worrying about your weight or body shape. Common types are anorexia nervosa, binge eating disorder and bulimia. People with binge eating disorder eat large quantities of food until they feel sick. Those with bulimia lose control over how much they eat and then try to stop putting on weight by vomiting or using other extreme measures. People with anorexia keep their weight down by eating very little or exercising too much. Eating disorders can cause serious health problems, poor quality of life and may even be life-threatening. They can also impact the lives of friends, family and carers.

In the UK, one of the main therapies offered to people with eating disorders is a type of psychological therapy called guided cognitive behavioural self-help therapy, where the person works through a printed/electronic book with supplementary virtual/telephone sessions from a healthcare professional. Unfortunately, the number of people with eating disorders in the UK is rising, and the NHS cannot meet the growing need for specialist psychological therapies. Digital cognitive behavioural self-help therapies could help people to have earlier treatment because they can be accessed online or through smartphones and do not need the involvement of a healthcare professional. People may also prefer to use digital therapies in their own space and time without having to make healthcare appointments.

The purpose of this assessment is to gather information on the use of digital self-help technologies for the treatment of disordered eating, binge eating disorder and bulimia among adults, children and young people. We aim to collect information on whether these treatments might be effective or could represent good value for money. We are planning to summarise what is currently known about the costs and benefits of treatments, such as whether they can provide earlier access to treatment and might improve patients' health and quality of life. We will also find out where additional evidence may be required to answer these questions.

# 1. Decision problem

## *1.1 Purpose of the assessment*

The National Institute for Health and Care Excellence (NICE) is evaluating the potential clinical and cost-effectiveness of digital self-help technologies for people with disordered eating and eating disorders such as binge eating disorder (BED) and bulimia nervosa (BN), and identifying evidence gaps to help further evidence generation. This is due to the potential benefit of digitally enabled therapy in addressing the significant unmet needs of the relevant population. 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, mental, or emotional health. BED is characterised by binge eating (eating very large quantities of food without feeling in control of it).[1] People with bulimia cycle between recurrent episodes of binge eating, followed by trying to compensate for overeating to prevent weight gain by vomiting, taking laxatives or diuretics (purging), fasting, or exercising excessively.[2] Table 1 summarises the decision problem to be addressed in this assessment. Further details on each element can be found in the published scope for the assessment.

## *1.2 Aim and Objectives*

This assessment aims to address the following research question:

*Does offering digital self-help programmes as a treatment option for disordered eating, binge eating disorder and bulimia have the potential to be clinically and cost-effective use of NHS resources?*

The main objectives of this assessment are the following:

- To evaluate the potential clinical effectiveness and acceptability of digital CBT-ED self-help therapies for disordered eating, binge eating disorder and bulimia.
- To develop and, where feasible, parameterise an economic model to assess the potential cost-effectiveness of digital CBT-ED self-help therapies for disordered eating, binge eating disorder and bulimia.
- To collate information from the technology providers on how the digital self-help technologies manage safeguarding concerns and mitigate any potential risks of independent use

- To identify gaps in the current evidence base and identify evidence gaps to help further evidence generation.

## 2. Evidence synthesis methods

The eligibility criteria for the review of clinical effectiveness evidence are summarised in Table 1 below. The methods related to the development of the economic model are described in Section 3.

**Table 1 Eligibility criteria for the review of clinical effectiveness evidence**

| | |
|---|---|
| **Population of interest** | • People with disordered eating who do not need a referral to eating disorder services for further assessment and treatment<br>• People with binge eating disorder or other specified feeding or eating disorder (OSFED) with similar symptoms, or adults (people aged 18 or over) with bulimia or OSFED with similar symptoms who are referred to specialist eating disorder services, for whom CBT-ED based self-help is considered suitable as the first line treatment<br><br>Where data permit, the following subgroups may be considered:<br>• Children and young people; adults<br>• People who may find it difficult to use digital self-help technologies (for example, people with neurodiverse conditions, learning disability, visual, hearing or cognitive impairment or problems with manual dexterity, or who are less used to digital technologies in general)<br><br>We will accept the definition of 'children' and/or 'young people' as reported by the authors of the included studies. Studies involving a mixed population (i.e. both adults and children/young people) will be considered eligible for inclusion. Where possible, data will be extracted separately for children/young people and adults. |
| **Clinical condition** | • Disordered eating, binge eating disorder or OSFED with similar symptoms, bulimia nervosa or OSFED with similar symptoms |

| | |
|---|---|
| **Technologies under investigation** | Digital technologies offering NICE-recommended CBT-ED based self-help in a digital format, without healthcare professional support:<br>• Digital CBTe<br>• Overcoming Bulimia Online<br>• Worth Warrior |
| **Comparator intervention** | Usual care. This may involve GP support or contact with voluntary, community and social enterprise organisations that offer support to people with eating disorders, books or online resources, local groups or telephone helplines for additional support, further appointments at the eating disorder service (for people with a referral), as well as being placed on a waiting list for referral to specialised assessment (for people assessed in primary care) or referral to appropriate treatment (after specialist assessment). |
| **Outcome measures** | **Intermediate outcomes**:<br>• Time to treatment<br>• Treatment completion rate and reasons for not completing the treatment<br>• Treatment adherence and/or compliance<br>• Proportion of people that need further treatment or no longer need support<br>• Size and duration of eating disorder treatment waiting list (for any eating disorders)<br><br>**Clinical outcomes:**<br>• Eating disorder psychopathology (measured for example by Eating Disorder Examination [EDE])<br>• Time to improvement in eating disorder psychopathology<br>• Binge eating episodes<br>• Compensating for binge eating (for example vomiting, using laxatives or diuretics, fasting, excessive exercise)<br>• General functioning (measured for example by Global assessment of functioning [GAF] or Clinical impairment assessment [CIA])<br>• Social, occupational or family functioning<br>• Remission<br>• Relapse<br>• Depression<br>• Anxiety<br>• Weight (although weight may be measured as an outcome in a research study, it is important to note that people with different body size, shape and weight can have an eating disorder)<br>• Bariatric surgery |

| | |
|---|---|
| | • Dental outcomes<br>• Mortality<br><br>**Patient-reported outcomes:**<br>• Health-related quality of life (EQ-5D-3L, eating disorder-related quality of life)<br>• Service user acceptability, views, experience and satisfaction<br>• Parent and carer acceptability, views, experience and satisfaction<br><br>**Costs and resource use:**<br>• Cost of technology<br>• Cost of treatment and management<br>• Cost of training<br>• Staff time at different specialisms and levels of pay<br>• Staff costs at different specialisms and levels of pay<br>• Health service use in different settings<br>• Cost of health service use in different settings |
| **Study design** | • Randomised controlled trials (RCTs) and comparative observational studies assessing the effectiveness of the technologies of interest. Because this is an early value assessment, the currently available evidence base is likely limited. We will, therefore, include non-comparative observational study designs (cohort studies, case series) if we do not identify sufficient RCT evidence and/or comparative observational studies. When possible, we will also include any relevant unpublished evidence.<br>• Studies of any design assessing participants' acceptability, views and experiences. |
| **Healthcare setting** | Primary care and specialist eating disorder services. |

### *2.2 Search methods for identification of studies*

A sensitive literature search strategy will be developed by an Information Specialist to identify published peer-reviewed studies. Major electronic databases will be searched, including MEDLINE, Embase, Cochrane Library, Web of Science, and CINAHL. The search will initially focus on the approved devices listed in the NICE final scope; search facets defining the population of interest will be included. There will be no restrictions on the language of publication at the time of the search. However, the search results may be limited by the period the technologies have been available or in development. The reference lists of

included studies will be screened for additional studies. Major clinical trial registries will be searched to identify relevant ongoing trials. Websites of manufacturers of relevant technologies, professional organisations, regulatory bodies and HTA organisations will be searched to identify additional relevant reports. Any additional information on potentially relevant evidence provided by the manufacturers of the technologies of interest will also be considered. All references will be exported to Endnote for recording and deduplication. A draft MEDLINE search is detailed in Appendix 1. The MEDLINE search will be adapted to search other electronic databases.

### *2.3 Study selection and data extraction strategies*

One reviewer will screen all citations identified by the search strategies. A second reviewer will independently screen a random 20 % sample to ensure consistency. Full-text articles will be retrieved for all citations deemed potentially relevant. Two reviewers will then independently assess each article for eligibility based on the pre-specified inclusion criteria. Multiple publications of the same studies will be linked and considered together. Reasons for the exclusion of full-text articles will be documented. The study selection process will be illustrated using a PRISMA flow diagram.[3]

Data will be extracted from each eligible study by one reviewer and checked for accuracy by a second reviewer, using a customised data extraction form developed specifically for this assessment.

The following information will be recorded from each study:

1. Characteristics of studies: first author, year of publication, country, language, setting, inclusion and exclusion criteria.
2. Characteristics of study participants: age, sex, number of enrolled participants, number of participants analysed, number of dropouts and reasons for withdrawal, setting and will be guided by the PRO EDI initiative for considering equality, diversity and inclusion of participant characteristics in evidence syntheses.[4]
3. Characteristics of the intervention: digital platform, details of the technology, content of therapy, structure and number of sessions to be completed, duration and type
4. Characteristics of the comparator/control intervention
5. Relevant patient-reported, clinical and intermediate outcome measures, and information related to the use of digital technologies.

### *2.4 Quality assessment strategy*

We will use the Risk Of Bias instrument for Use in SysTematic reviews for Randomised Controlled Trials (ROBUST-RCT) to assess the methodological quality of randomised controlled trials evaluating the clinical utility of the digital technologies under investigation.[5] To assess the quality of non-randomised evidence reporting quantitative data on the technologies under investigation, we will use the checklist developed by the Health Services Research Unit (now Aberdeen Centre for Evaluation), University of Aberdeen, in partnership with the NICE Review Body for Interventional Procedures (ReBIP). The ReBIP checklist, adapted from several sources,[6-9] comprises 17 items that evaluate the following domains: generalisability, sample definition and selection, description of the intervention, outcome assessment, adequacy of follow-up, and performance of analyses. We will use the Joanna Briggs Institute Checklist for Qualitative Research to assess the quality of qualitative evidence.[10] One reviewer will conduct the quality assessment for the included studies and a second reviewer will independently verify and validate the judgments made by the first reviewer.

Any disagreements between reviewers during study selection, data extraction and quality assessment will be resolved through consensus or, if necessary, by consulting a third reviewer.

### *2.5 Methods of analysis/synthesis*

When appropriate, we intend to summarise the results of relevant RCTs assessing the clinical effectiveness of digital CBT-ED self-help technologies using standard meta-analysis methods.[11] If substantial clinical or methodological heterogeneity is observed between studies, we will conduct a narrative synthesis of results. We will also provide a detailed description of any gaps in the evidence base and methodological limitations of the existing studies. This will help inform recommendations for future evidence generation and requirements for a full assessment.

## 3. Report methods for synthesising evidence of cost-effectiveness

The economic evaluation for this assessment will be an early value assessment that aims to assess the potential cost-effectiveness of digital technologies offering NICE-recommended

CBT-ED based self-help in a digital format, without healthcare professional support, specifically Digital CBTe, Overcoming Bulimia Online, and Worth Warrior. The specific health economic objectives are:

1. To review and critically appraise any existing economic evaluations of digital technologies offering NICE-recommended CBT-ED, as specified in the final scope for the assessment
2. To narratively review and summarise existing economic evaluations of treatments for disordered eating, binge eating disorder and bulimia (as defined in the final scope) to inform an appropriate economic model structure for the assessment.
3. To develop and parameterise, as far as is possible, a decision analytic model that can be flexibly adapted for disordered eating, binge eating disorder and bulimia to estimate the short-term costs and benefits, from treatment initiation up until the next stage in the treatment pathway, of digital therapies, compared with usual care following initial assessment in primary or specialist settings.
4. To develop the structure of an appropriate long-term decision model that could be used in future research to capture the long-term costs and benefits of early initiation of treatment with digital technologies on long-term cost and QALY outcomes. It is expected there will not be sufficient evidence to populate this long-term model, therefore, the full Markov modelling will be developed up to model conceptualisation stage.
5. Where insufficient data are available to populate the model in health economic objective 3 (e.g., if it is not possible to build a network of evidence in line with the NICE scope comparators), the economic model will be used to identify the key drivers of cost-effectiveness and to prioritise areas for future research to reduce residual uncertainty regarding the optimal treatments.

### *3.1 Identifying and systematically reviewing published cost-effectiveness studies.*

Comprehensive search strategies will be developed to identify full economic evaluations of digital CBT-ED self-help technologies for individuals with disordered eating, bulimia, binge eating disorder or OSFED. The following databases will be searched with no restrictions on date, language, or publication type:

- Ovid MEDLINE
- Ovid EMBASE
- NHS Economic Evaluations Database

- International HTA Database (INAHTA)
- Research Papers in Economics
- Cost-Effectiveness Analysis (CEA) Registry

Two draft MEDLINE search strategies are presented in Appendix 1 (one for the specific technologies and one for economic evaluations more generally for disordered eating, binge eating disorders and bulimia) and they will be adapted to search other relevant databases. The websites of relevant professional organisations (e.g., ISPOR Scientific Presentations Database) and health technology agencies - such as NICE, CADTH, PBAC, ICER and others - will be searched for supplementary reports. Furthermore, reference lists of all included studies will be manually reviewed to identify additional relevant studies. Any additional data or information provided by the companies will be assessed for relevance to the decision problem and will be included in the final report where appropriate.

The review will include full economic evaluations with population, intervention and comparators as described in Table 3 above. Full economic evaluations are defined as comparative analyses of costs and outcomes within the framework of cost-utility, cost-effectiveness, cost-benefit, or cost-minimisation analyses. Economic evaluations conducted alongside single effectiveness studies or decision analysis models will be included.

The key findings from included economic evaluations will be summarised in a tabular format and synthesised narratively. All included studies will be appraised using the NICE reference case checklist for economic evaluations.[12] The reporting quality of studies will be assessed using the Consolidated Health Economic Evaluation Reporting (CHEERS) checklist,[13] while the decision models' quality will be assessed using the Philips et al. (2004) checklist.[14]

The appropriateness of full economic evaluations for addressing the research questions specified in the NICE final scope will be assessed. If deemed suitable, study authors of included decision modelling studies will be contacted to request access to model files, which could be adapted or re-populated for this assessment.

The broader search of economic evaluations for people with binge eating disorder or bulimia will not be fully quality assessed or formally data extracted. Instead, this search will be used

to inform the structure and parameterisation of the economic model to be built for this assessment.

### *3.2 Development of a health economic model*

For objective 3, a single decision analytic model, in the form of a decision tree, will be developed using TREEAGE Pro software, to compare the potential costs and benefits of digital technologies offering NICE-recommended CBT-ED based self-help in a digital format, without healthcare professional support, specifically: Digital CBTe, Overcoming Bulimia Online, and Worth Warrior, with usual care. Due to anticipated lack of data to inform the impact of delay in requirement for specialist support on long-term costs and QALYs, a short-term time horizon, up until referral to the next stage in the treatment pathway will be used. Two settings will be considered.

- **Setting 1:** After initial assessment in primary care, for individuals with mild symptoms who do not require immediate referral to specialist services. In this setting the digital technologies will be compared to usual care, which may include support from GPs and/or use of charities services or basic self-help materials. The model's time horizon will extend up to the point where the individual progresses to needing specialist assessment by eating disorder services or no longer requires support.

- **Setting 2:** After assessment within eating disorder services, for individuals awaiting first-line psychological treatment, where CBT-ED-based self-help is considered appropriate. In this setting, the digital technologies will be compared with usual care. Usual care may include contact with GP or specialist eating services, charities or other organisations offering additional support. The model's time horizon will extend until the decision point regarding whether further treatment escalation is needed.

For objective 4, we will conceptualise and outline the structure of long-term economic evaluation models that could be used in future research to inform a comprehensive assessment of cost-effectiveness. These models would estimate separate ICERs for disordered eating (including anorexia), bulimia and binge eating disorder. Developing and populating such models is not feasible within the scope of this early value assessment.

For objective 5, the economic model will be used to identify the key cost-effectiveness drivers. Multiple scenario analyses will be conducted to identify priority areas for future research aimed at reducing any residual uncertainties in the cost-effectiveness evidence base.

### 3.3.1 Model structure

The specific details of the model type, pathway, and structure will be developed during the appraisal. The conceptual cost-effectiveness model structure will be informed by NICE guidance for anorexia, binge eating disorders and bulimia (NG69) and will be validated with the EAG and NICE clinical expert advisors for this assessment. For OFSED, it will be assumed that the disorder with the closest definition (bulimia or binge eating disorder) will be used. Therefore, there will not be a separate model for OFSED. We envisage that we will build a decision-tree model, capturing costs and benefits of treatments, in helping to reduce the impact of the specific disorders, up until the next stage in the treatment pathway. A single model will, therefore, be used, but with the parameterisation of shorter-term management of the eating disorder. Where data permit, separate parameterisation will be carried out for disordered eating, bulimia and binge eating disorder. The modelled pathways will reflect the potential impact of treatment on outcomes such as the need for further treatment, referral to the next stage in the treatment pathway and associated consequences. Clinical validation of the model structure may require several iterations and adaptions and will ensure that the model structures demonstrate good face validity, ensuring that they appropriately reflect the current NHS practice and pathway.

### 3.3.2 Model parameterisation

The decision tree model will be populated with data on event probabilities sourced from the literature; intervention costs obtained from the companies, operating manuals and supplementary literature; and event costs and, if feasible, utilities from the literature where available. Additional targeted searches will be undertaken, where appropriate, to inform the choice of key model parameters. It is not anticipated that the model will report QALYs but will instead focus on outcomes that may include (i) proportion of the cohort requiring referral to the next stage in the treatment pathway at specified time points, e.g. 1,2 and 5 years; (ii) mean time to referral to the next stage in the pathway. Where multiple sources of parameter estimates exist, priority will be given to data from systematic reviews (or updates of existing reviews) that are consistent with the NICE reference case, followed by other published literature. Where sufficient published data are not available, we will use data from conference

presentations, unpublished data from the companies, and clinical expert elicitation as necessary to populate key model parameters.

Treatment effect sizes for application to the modelled health states (e.g. relative risk [RR] of hospitalisation or treatment referral) will be derived from the systematic review of clinical effectiveness studies, where such data are available. If optimal data to parameterise effect sizes are not available from published sources, study authors will be contacted to request access to data in a format compatible with the preferred model structure. In the absence of such data, a range of assumptions and alternative economic modelling approaches will be explored to maximise the use of the available clinical evidence. Where no data exist for specific parameters, estimates will be informed by clinical expert opinion, incorporating appropriate measures of uncertainty, and sourced from NICE specialist committee members and EAG expert advisors.

Resource use and costs associated with intervention delivery will be obtained from the companies, product manuals and relevant published literature. A micro-costing analysis of the digital technologies will be undertaken, including device costs, additional training costs, and any associated NHS staff resource costs that might be required. Resources and costs associated with adverse events, long-term routine management and health state-specific costs will be identified through a review of current clinical guidelines, published sources, and input from clinical experts. All resource use data will be costed using nationally available average unit costs. The model will not report QALY outcomes.

### 3.3.3 Analyses and reporting of results

The base case results of the model will be presented in terms of expected total costs, expected proportion of people experiencing eating disorder episodes, and where possible, the severity of episodes linked to the need to access healthcare services over the modelled time horizon, up to the point of referral to the next stage in the treatment pathway. The model will be fully probabilistic. Results will be presented as pairwise comparisons of each intervention vs. standard care. Incremental cost-effectiveness ratios, in the form of incremental cost per QALY gained, will not be reported.

We anticipate a lack of robust data across multiple assumptions and model parameters. Where data are unavailable, parameter estimates will rely heavily on clinical expert opinion.

This approach may introduce a considerable degree of uncertainty, which we will explore through a range of deterministic sensitivity and scenario analyses.

Whilst it will not be possible to deliver a full cost-effectiveness model, that covers both positions in the treatment pathway, for disordered eating, bulimia and binge eating disorders separately, within the assessment timelines, we will conceptualise, and draft the structure of long-term economic evaluation models, likely in the form of Markov cohort models that could be used following progression to the next stage in the treatment pathway. It is envisaged that such a model would be designed to be used in future research to estimate incremental cost per quality-adjusted life year (QALY) gained over a lifetime horizon from a UK NHS and personal social services (PSS) perspective. This model conceptualisation will help inform the evidence generation plan for the assessment.

## 4. Handling information from the companies

Following a request for evidence by NICE, any 'commercial in confidence' data provided by a company and specified as such will be highlighted in blue and underlined in the assessment report (followed by an indication of the relevant company name, e.g., in brackets). Any academic-in-confidence data provided will be highlighted in yellow and underlined. We will only include information received by **May 9th** in the assessment report. If confidential information is included in the economic model, the EAG will provide a copy of the model with 'dummy variable values' for the confidential values (using non-confidential values).

## 5. Competing interests of authors

None

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## Appendix 1 Literature search strategies

### MEDLINE search for the review of clinical effectiveness evidence

1. exp *"Feeding and Eating Disorders"/
2. ((feeding or eating or binge) adj4 disorder*).tw,kf.
3. ("binge-purge" or "binge eating" or bulimia or anorexia or "addictive eating" or OSFED).tw,kf.
4. 1 or 2 or 3
5. Digital Health/ or telemedicine/ or distance counseling/ or mental health teletherapy/ or telerehabilitation/ or internet/ or internet-based intervention/
6. ((digital* or virtual* or online or internet or "web-based" or "e-health" or ehealth or "m-health" or mhealth or "e-mental health" or "emental health" or "e-therapy" or etherapy or telehealth) adj5 (intervention? or treatment? or therap* or counsel* or (cognitive adj3 therap*) or CBT or program*)).tw,kf.
7 (OBO or "Worth Warrior" or "Overcoming Bulimia Online")
8. 5 or 6 or 7
9. 4 and 8

### MEDLINE search for the review of economic effectiveness evidence

1. exp *"Feeding and Eating Disorders"/
2. ((feeding or eating or binge) adj4 disorder*).tw,kf.
3. ("binge-purge" or "binge eating" or bulimia or anorexia or "addictive eating" or OSFED).tw,kf.
4. 1 or 2 or 3
5. Digital Health/ or telemedicine/ or distance counseling/ or mental health teletherapy/ or telerehabilitation/ or internet/ or internet-based intervention/
6. ((digital* or virtual* or online or internet or "web-based" or "e-health" or ehealth or "m-health" or mhealth or "e-mental health" or "emental health" or "e-therapy" or etherapy or telehealth) adj5 (intervention? or treatment? or therap* or counsel* or (cognitive adj3 therap*) or CBT or program*)).tw,kf.

7. 5 or 6

8. 4 and 8

9. *economics/

10. exp *"costs and cost analysis"/

11. (economic adj2 model*).mp.

12. (cost minimi* or cost-utilit* or health utilit* or economic evaluation* or economic review* or cost outcome or cost analys?s or economic analys?s or budget* impact analys?s).ti,ab,kf,kw.

13. (cost-effective* or pharmacoeconomic* or pharmaco-economic* or cost-benefit or costs).ti,kf,kw.

14. (life year or life years or qaly* or cost-benefit analys?s or cost-effectiveness analys?s).ab,kf,kw.

15. (cost or economic*).ti,kf,kw. and (costs or cost-effectiveness or markov).ab.

16. or/9-15

17. 8 and 16