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Digital guided self-help for binge eating disorder

Submission date
05/07/2024

Recruitment status
No longer recruiting

Registration date
22/07/2024

Overall study status
Ongoing

Last Edited
01/12/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Binge eating disorder is a common mental health problem which can last a long time. It has a major impact on people's psychological and physical health and quality of life. It affects around 3% of the population: that is about 1.4 million people in England. A treatment called "guided self-help" is recommended as the first step in the treatment of binge eating disorder. It involves the person concerned following a self-help programme with support from a non-specialist worker whose role is to help the person follow the programme. Usually, the self-help programme is presented in printed form, often as a book.
A new digital programme has been developed by Rebecca Murphy and her research group. This can be used on a smartphone or computer. It is based closely on the leading face-to-face psychological treatment (also developed by this research group). A digital programme has a major advantage over a one-size-fits-all book, as it can be programmed to be interactive and provide advice adjusted to user concerns. Like conventional guided self-help, it will be accompanied by outside support. The support will be delivered over the telephone rather than face-to-face. This will avoid users having to make repeated visits to a clinic. This research will investigate this new digital approach.
Digitalising treatment for binge eating disorder is likely to improve its effectiveness and cost-effectiveness, and it may also make it easier to access. If true, this will reduce the suffering of people with binge eating disorder.
What is needed is a large study to test the effects of this new digital programme. This will involve people with binge eating disorder receiving either Digital GSH or being assigned to a waiting list (decided 'by chance'). The waiting list will provide a benchmark against which we can measure the effects of the treatment.
Before undertaking such a large study, a preliminary "feasibility study" is needed to check whether the large study is likely to work and how best to do it. A feasibility study is a piece of research carried out before a main study to answer the question "Can this study be done?". Individuals with Binge Eating Disorder have been involved in planning this study.
A feasibility study will be carried out to provide information on how best to recruit people; how best to measure if treatment has worked; how much people use the treatment; whether people are happy to remain in the study and complete the necessary questionnaires; and how to involve patients and the public in the large research study. Some of those participating in this feasibility study will be interviewed to understand what it is like taking part.

Who can participate?
People aged 18 years or above who have repeated episodes of binge eating and who can read and write in English.

What does the study involve?
The study will involve completing questionnaires and being randomly allocated to either:
1. The Immediate Access Group, who will be given access to Digital CBTe with support phone calls immediately OR
2. The Delayed Access Group, who will be asked to wait 12 weeks before using Digital CBTe independently, without support phone calls.
After completing Digital CBTe or waiting for Digital CBTe, participants will be invited to complete the same questionnaires again to see if things have changed. These groups will allow us to compare whether receiving Digital CBTe is better than not receiving anything. The Delayed Access Group will tell us what happens if someone does not receive anything during the waiting period, although people in this group will still have access to Digital CBTe after waiting.

What are the possible benefits and risks of participating?
Digital CBTe is a self-help version of one of the leading face-to-face treatments for binge eating problems. Although small studies suggest that most people who complete Digital CBTe see a significant reduction in binge eating, Digital CBTe has not yet been evaluated in a large clinical trial. Its effects are therefore not known with certainty. In fact, the purpose of this study is to plan a future large clinical trial and see whether this trial would be feasible to run. It is possible that participants will not benefit from Digital CBTe. If so, we will give them advice on what to do next. There are no anticipated risks associated with participating in this study.
The researchers do not know what the outcome will be, and this is why they are conducting the research. Therefore, it is possible that participants will not benefit directly from participating in this study. However, small studies suggest that most people who complete Digital CBTe see a significant reduction in their binge eating. Therefore, there may be an improvement in binge eating because of participating in this research study.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
January 2024 to December 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Rebecca Murphy, Rebecca.Murphy@psych.ox.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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National Institute for Health and Care Research (NIHR)
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Study information

Scientific Title
BE-GUIDED (Binge Eating - Guided): a feasibility randomised controlled trial to compare digital guided self-help against a waitlist control

Acronym
BE-GUIDED

Study objectives
To assess the feasibility of a randomized controlled trial (RCT) comparing digital guided self-help (GSH) with waitlist control for people with binge eating disorder (BED).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/11/2024, Medical Sciences - Research Services Ethics Committee (Research Governance, Ethics & Assurance Team University of Oxford, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB, United Kingdom; +44 1865 616575; ethics@medsci.ox.ac.uk), ref: R96150/RE001

Primary study design
Interventional

Study design
Single-centre feasibility unblinded two-arm parallel-group randomized controlled pilot trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Binge eating disorder

Interventions
Participants will be allocated to one of the trial arms using a 1:1 allocation ratio. Randomization will be conducted through a validated online system, Sortition, developed by the University of Oxford Primary Care Clinical Trials Unit. A block algorithm without stratification will be used for randomization. Data from this feasibility study will guide any future decisions regarding stratified randomization in a larger trial.

Intervention: Digital Guided Self-Help (GSH)
The intervention is a digital self-help program, accompanied by guidance adapted from a manual for guides delivering Printed GSH.

Control: Waiting List
Participants allocated to the control arm will remain on a waiting list for the duration of the program. After this period, they will have the opportunity to start the digital self-help program without guidance.

One-to-one allocation to Digital Guided Self-Help or to Waiting List in a single centre. Duration of intervention: 12 weeks.

Intervention Type
Behavioural

Primary outcome(s)
The primary aim is to assess the feasibility and acceptability of a future definitive randomised controlled trial (RCT) evaluating the clinical and cost-effectiveness of a Digital Guided Self-Help programme with waitlist control for adults with binge eating disorders (BED). This will help to inform planning for a fully powered trial.

Its primary outcomes are the feasibility of key trial components:
1. Recruitment: effectiveness and acceptability of the recruitment process assessed by evaluating how well the recruitment process identifies eligible participants, attracts willing participants and includes a diverse demographic range. This would include describing the number of participants identified through advertisements, approached based on initial screening, consented during recruitment, randomised after recruitment and completed end-of-treatment and follow-up assessments (12 and 24 weeks post-randomisation)
2. Outcomes: the meaningfulness of outcomes for a future trial evaluated by assessing the participants' perceived relevance and value of those selected via qualitative interviews at 12 weeks post-randomisation
3. Assessments: the acceptability of outcome measures (concerning completion rates and perceived burden via qualitative interviews) at 12 weeks post-randomisation
4. Treatment: the acceptability of the treatment assessed via qualitative interviews and rates of adherence (during the intervention) and completion at 12 weeks post-randomisation
5. PPI: future trial PPI refining by seeking feedback and reviewing the process at the end of the study (after write-up)

Key secondary outcome(s)
Measured at baseline, end-of-treatment, and 12-week follow-up:
1. Binge eating frequency, measured using the Eating Disorder Examination Questionnaire (EDE-Q)
2. Severity of general eating disorder features measured using the Eating Disorder Examination Questionnaire (EDE-Q)

3. Severity of secondary psychosocial impairment, measured using Clinical Impairment Assessment (CIA)
4. Severity of depressive features, measured using Patient Health Questionnaire (PHQ-9)
5. Self-reported productivity & healthcare costs, measured using a bespoke Costs & Resources Measure
6. Harms & adverse effects of intervention, measured using a bespoke intervention questionnaire

Completion date
01/12/2026

Eligibility

Key inclusion criteria
1. Participant provides informed consent for participation in the study
2. Aged 18 years or above (of any gender)
3. Recurrent objective binge eating for 3 months or more
4. Able to read and write in English

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Any self-induced vomiting or laxative misuse over the past 28 days
2. Severe low weight (<18.5 kg/m2)
3. Co-occurring condition or treatment which could interfere with day-to-day eating
4. Pregnancy
5. Severe depression
6. Suicidal or self-harm thoughts
7. Problem with substance misuse
8. Currently receiving (or waiting for) treatment for binge eating

Date of first enrolment
01/01/2025

Date of final enrolment
01/03/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Oxford
CREDO, Dept. of Psychiatry
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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as there is a risk of not protecting privacy. Even with de-identification, there is a risk of re-identification, especially with detailed datasets and a small sample size. Proper preparation of the data for public sharing (including de-identification, documentation, and ensuring data quality) would be relatively resource-intensive. It is unlikely to be worthwhile given that it is a feasibility study. It could be quite concerning for potential participants and deter them from enrolling, fearing misuse of their personal information. The datasets generated during and/or analysed during the current study will be stored in a non-publicly available BE-GUIDED Central Data Repository.

IPD sharing plan summary
Stored in non-publicly available repository