

Digital guided self-help for binge eating disorder

Submission date 05/07/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/07/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/11/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 2025

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

Dr Rebecca Murphy

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

NIHR301553

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

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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

Study design

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

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community, University/medical school/dental school

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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 measure

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)

Secondary outcome measures

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

Overall study start date

01/01/2024

Completion date

01/12/2025

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

120 Years

Sex

Both

Target number of participants

70

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

01/09/2025

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Oxford

CREDO, Dept. of Psychiatry

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Sponsor information

Organisation

University of Oxford

Sponsor details

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Sponsor type

University/education

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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

Publication and dissemination plan

Findings will be published in a peer-reviewed journal

Intention to publish date

01/09/2026

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, Not expected to be made available