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Emotion intervention for binge-eating

Submission date
03/04/2025

Recruitment status
Recruiting

Registration date
29/04/2025

Overall study status
Ongoing

Last Edited
07/07/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
This study aims to try out a brief, online support for managing difficult emotions with adult patients who binge-eat and are awaiting NHS treatment.
make up more than half the 3.4 million people in the United Kingdom with an eating disorder (ED). ED services are over-stretched with treatment waiting times averaging two years. Long waiting times lead to worse symptoms, higher healthcare costs and poorer response to treatment.
Difficulties with emotions can lead to binge-eating. Working with people with lived experience of EDs and with clinicians, we developed online support that aims to help people with EDs manage difficult emotions. It includes:
1. Seven short videos
2. A worksheets to help practice learning from videos
3. A booklet to support daily practice

We want to see:
• If the online support is acceptable to people who binge-eat and are awaiting NHS treatment and to ED healthcare staff.
• How it can be delivered across ED services in England.
Throughout this study we will work closely with a Stakeholder group (including an ED clinician, three psychologists, researchers, PPI lead and a person with autism and lived experience of ED) and our PPI group.

Who can participate?
Adults who binge eat and are currently waiting for NHS treatment and staff working at the South London and Maudsley Hospital trust or the Hampshire and Isle of Wight Healthcare NHS Foundation Trust with patients with eating disorders.

What does the study involve?
Part 1: Use LifeGuide+ (software tool) to make the online support interactive and engaging for patients.

Part 2:
i. Try out the online support with 15 adults awaiting treatment for binge-eating in a Hampshire NHS Trust. They will answer questions (ED behaviours, emotions) before/after the online

support, and tell us what they think about it at the end. We will make changes to it based on their feedback. We will repeat this with 15 adults awaiting treatment at a London NHS Trust.
ii. Hold discussion groups with staff (5-10) from two ED healthcare teams to explore views about the online support/its delivery.
iii. Send out a brief survey to adult ED services in England asking about care pathways/how waiting-lists are managed.
We will bring together the findings from i-iii.

Part 3: Working closely with Stakeholder and PPI groups we will make changes to the online support.
PPI
Nine people with lived experience of EDs helped develop this application (including people from ethnic minorities, with autism and males; groups often overlooked in ED research). They:
• Confirmed the need for online emotional support while awaiting face-to-face treatment
• Highlighted the various paths to care within England

Six people with lived experience of EDs have joined the study team and will be involved throughout (eg. developing patient information, interview questions, deciding on changes to the online support, analysing, writing-up, sharing findings).

What are the possible benefits and risks of participating?
The benefits and risks vary between phases of the study. For the main phase of the study the main benefit involves access to the emotion-based intervention from which we hope individuals will learn a lot about their emotions and ways to manage emotions. Risks entailed may involve the potential for individuals to find completing the questionnaires distressing (although they will likely have completed the same/similar questionnaires during the process of being diagnosed with their eating disorder) or finding the focus on emotions difficult. However, with this in mind, there is a section available throughout the intervention called 'I need help' which has links to support websites/phonelines.

Where is the study run from?
The study is run from Bournemouth University and involves NHS Trusts in London and Hampshire (UK)

When is the study starting and how long is it expected to run for?
July 2023 to July 2026

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

Who is the main contact?
Dr Laura Renshaw-Vuillier, lrenshawvuillier@bournemouth.ac.uk

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Principal Investigator

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
326396

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 57101, NIHR206149

Study information

Scientific Title
Refining and optimising a brief online emotion-based intervention to provide early support for adult patients with bulimia nervosa and binge eating disorder awaiting NHS treatment.

Study objectives

The main aim of this study is to assess and enhance the acceptability and early feasibility of an emotion-focused intervention for adults on an NHS waiting-list for treatment for binge-eating.

Our objectives are:
1. Embed the intervention into an online platform (LifeGuide+).
2. Determine the feasibility and acceptability of the intervention in two ED services with NHS patients (15 per service) on a waiting list for binge-eating treatment via an iterative case-series, semi-structured interviews, and quantitative outcome measures.
3. Explore ED health care staff perspectives of the intervention via two focus groups with members of a multidisciplinary team in two ED services.
4. Evaluate variations in care pathways and implementability via a National Survey of adult ED services.
5. Refine/optimise the online intervention based on collected feedback, and with input from the Stakeholder and PPI groups.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/04/2024, South West - Frenchay Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 2071048075; frenchay.rec@hra.nhs.uk), ref: 24/SW/0033

Study design
Interventional non randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet. There are multiple participant information sheets for the different phases of the study so please let us know the PIS you would like (general, interview, focus group or survey)

Health condition(s) or problem(s) studied
Eating disorders where behaviours include binge eating

Interventions
The project is divided into three phases:
Phase 1: Embed the Beta-version of the intervention within the LifeGuide+ platform
Phase 2: Evaluate the acceptability, engagement, risks, benefits, and implementability of the intervention

i. Iterative case series with ED patients
ii. Focus groups with ED healthcare staff
iii. National survey of ED services
Phase 3: Optimising Intervention

Phase 1: Embed intervention within LifeGuide+
This phase will involve embedding the Beta-version of the intervention within the LifeGuide+ platform. LifeGuide+ is a software platform that supports a person-based approach to intervention development and testing. We will embed the videos so they are easily accessible and will create a page for patients to practise the newly learnt skills. We will also convert our PDF workbook into an interactive embedded document to help patients reflect on the content of the videos.

Phase 2: Evaluate acceptability and implementability
i. Iterative case-series with patients
All new patients diagnosed with BN/BED and meeting the eligibility criteria will be identified by the clinical team. During their assessment feedback appointment, potential participants identified by the clinical team will be given a study information pack (Invitation letter, 'Key Facts' summary, participant information sheets, consent form (either online via LifeGuide+ or paper copies)), along with contact details of the study team (email/phone/pre-paid reply). It will be made clear to patients that this project is not part of their routine care and that opting in/out will not affect their clinical care. A member of the clinical team will then contact eligible participants by asking them for their consent to be contacted by the research team. We find that this works best so they do not have to contact someone and instead we contact them if they agree, to reduce the burden on participants.

The study Postdoctoral Research Assistant (PDRA) will contact those who express an interest in participation, describe the study in more detail, answer any questions and go through the consent form. Individuals will also be asked if they would be willing to be sent information about a follow-up interview (it will be explained that not everyone will be contacted).

After providing informed consent participants will be given access to LifeGuide+ and will be asked to complete baseline questionnaires. The first video will be made available immediately after the baseline questionnaires have been completed, after which each subsequent video will be unlocked for access the following day. This is because we think this format works best to maintain engagement and to ensure they watch each video in a logical order and have the time to process each one before moving onto the next. However, this will be reviewed with patients and PPI groups to ensure this works for them and changes in the way it is delivered may happen as a result of these consultations.

After completing each module, they will be invited to provide brief feedback online. A week after they have completed all 5 modules of the intervention (or after 5 weeks in case of non-engagement) they will be invited to complete the post-intervention questionnaires.

A purposive sample of 15-20 patients will be invited to take part in an interview (by phone or video conference depending on their preference). Interviews will be digitally audio-recorded. The topic guide will be developed working with the PPI group but is likely to include questions related to intervention content and format, changes in emotions and ED behaviours, and potential risks.

Patterns of use and engagement will also be captured and analysed via the LifeGuide+ platform.

We will make changes to the intervention based on feedback from patients, ED health care staff (see Strand ii) and with input from our Stakeholder and PPI groups, both after the first and second waves of the case-series (also see Phase 3 Optimising Intervention).

In order to obtain proof-of-concept data related to the intervention we will also ask participants to complete the following secondary outcome measures before and after completing the intervention (or at 5-weeks if they have not engaged with the intervention):
ED symptoms measured via the Eating Disorders-15 (ED-15) scale. This scale measures short-term changes in eating attitudes and behaviours. It is also used by clinicians in ED services so will be useful to them to follow progress of their patients. The ED-15 possesses good psychometric properties and convergent validity with other validated measures of ED symptoms.
Emotional knowledge and ability, assessed via three questionnaires. We will most likely use the Emotion Beliefs Questionnaire (EBQ) to measure changes in beliefs about emotions, the Toronto Alexithymia Scale (TAS-20) to measure changes in alexithymia, and the Difficulties in Emotional Regulation Scale (DERS-SF) to measure changes in emotion regulation.
We will discuss participant burden and relevance of the outcome measures with our PPI and Stakeholder groups and make changes to the questionnaire battery, if deemed necessary.

ii. Focus groups with ED staff
Participants
Both Hampshire and Isle of Wight Healthcare NHS Foundation Trust and the SLaM have a very large and diverse team consisting of psychiatrists, GPs, clinical and counselling psychologists, psychotherapists, nurses, dieticians, psychological well-being practitioners and several support workers.
We will hold 2 focus groups with ED staff (5-10 staff in total). We will aim to recruit across both Hampshire and Isle of Wight Healthcare NHS Foundation Trust and SLaM trusts and include at least one psychiatrist, one dietician, one clinical psychologist, one counselling psychologist and one psychological well-being practitioner to ensure we capture diverse perspectives.

Procedure
We will ask our Trust leaders to advertise the focus groups to their staff in an email containing an information sheet co-designed with our PPI group and consent form. Individuals will be made aware that participation is voluntary. The study PDRA will contact those who express an interest in participation, describe the study in more detail, answer any questions and go through the consent form. Once consent is obtained, participants will be offered dates for the online focus groups. We will aim to run two focus groups, with a maximum of five per group to ensure everyone has a chance to express their opinions. Individuals will be offered an interview as an alternative if preferred.

iii. National survey of ED services
Our PPI workshops highlighted that there are variations in pathways to care within ED services, also evidenced within our two partner Trusts for the current study. While they all follow NICE guidelines, they vary, for instance, in how they organise their waitlists which would influence the delivery of our intervention. We need to be aware of what is being delivered, when and from whom to ensure we offer access to our intervention at the right time and do not overburden patients with too many online tools.
We will develop a short online survey (using Qualtrics Online Surveys) and will email a survey link to all 56 adult ED services in England. The survey will include questions about patient numbers /caseloads, care pathways and how waitlists are managed, including whether any (and if so what) help is offered.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Our primary outcomes of interest relate to the following markers of feasibility and acceptability.
1. Uptake, recruitment and retention rates (Uptake and recruitment rates: proportion of people who were told about the study /were eligible for the study , who decide to take part. Retention rates: proportion of participants who complete T2 questionnaires)
2. Data analytics (patterns and duration of use) to measure engagement with intervention via LifeGuide+ embedded tools (measured throughout the course of the intervention)
3. Written feedback and associated rating scale completed by intervention users after watching the videos
4. Feedback from interviews with patients about the intervention and from focus groups with health care staff about its deliverability (Interviews will take place around 3 weeks after the individual has first accessed the intervention, focus groups will take place within 6/9 months of beginning to deliver the intervention)
5. Self-reported questionnaires related to the acceptability (Acceptability of Intervention Measure (AIM)) and feasibility (Feasibility of Intervention Measure (FIM)) of the intervention (Weiner et al., 2017) (Measured post-intervention)
6. Completion of outcome measures (see 'Secondary outcomes' below) in terms of levels of missing data and their acceptability and relevance

Secondary outcome measures
In order to obtain proof-of-concept data related to the intervention we will also ask participants to complete the following secondary outcome measures before and after engaging with the intervention:
1. ED symptoms measured via the Eating Disorders-15 (ED-15) scale (Tatham et al., 2015).
2. Emotional knowledge and ability, assessed via three questionnaires. The Emotion Beliefs Questionnaire(EBQ (Becerra et al., 2020)) - negative controllability subscale to measure changes in beliefs about emotions, Perth Alexithymia Questionnaire – Short form (PAQ-SF; Preece et al., 2023) to measure changes in alexithymia, and the Difficulties in Emotional Regulation Scale (DERS-SF, (Kaufman et al., 2016) to measure changes in emotion regulation.

Overall study start date
26/07/2023

Completion date
06/07/2026

Eligibility

Key inclusion criteria
Patients:
1. Aged 18 years and above
2. On an NHS waiting-list for treatment for BN or BED
3. Fulfil DSM-5 criteria for BN or BED as primary diagnosis
4. Ability to understand English to make an informed consent

Staff:
1. Working at the South London and Maudsley Hospital trust or the Hampshire and Isle of Wight Healthcare NHS Foundation Trust with patients with eating disorders.

Participant type(s)
Patient, Health professional

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Key exclusion criteria
Patients:
1. Patients with suicidal ideation will not be able to take part. This is necessary to protect participants until we can fully assess the risks of the intervention
2. Comorbidities and medication will be recorded but will not form part of the exclusion criteria.

Staff: None

Date of first enrolment
22/04/2025

Date of final enrolment
01/04/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hampshire and Isle of Wight Healthcare NHS Foundation Trust
Tatchbury Mount Hospital
Calmore
Southampton
United Kingdom
SO40 2RZ

Study participating centre
South London and Maudsley NHS Foundation Trust
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Sponsor type
University/education

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ROR
https://ror.org/05wwcw481

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal (e.g. the Journal of Eating Disorders) around a year after the overall trial end date and a funding application for a controlled feasibility study to pave the way for a future randomised control trial. How study data is collated and reported is still being decided (i.e. the number of papers produced and how phases of the trial will be written up together).

Intention to publish date
06/07/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository- BORDaR- Bournemouth University's research data repository. Quantitative data will be uploaded in a fully anonymised format. Participants provide consent for their data go be shared in this manner in the consent forms.

The qualitative datasets generated during and/or analysed during the current study are not expected to be made available (e.g. the qualitative transcripts from the focus groups and interviews) due to ethical considerations and namely the difficulty in fully anonymising such datasets.

IPD sharing plan summary
Stored in publicly available repository, Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 0.4	09/04/2025	08/05/2025	No	No
Protocol file	version 6	01/07/2025	07/07/2025	No	No