This protocol has regard for the HRA guidance and order of content

FULL/LONG TITLE OF THE STUDY

A brief online emotion-based intervention to provide early support for adult patients with binge eating disorders awaiting NHS treatment: intervention acceptability, early feasibility and optimisation

SHORT STUDY TITLE / ACRONYM

Emotion intervention for binge-eating

PROTOCOL VERSION NUMBER AND DATE

- **Version 0.4 date: 09/04/2025**

RESEARCH REFERENCE NUMBERS

IRAS Number:	3263969
SPONSORS Number:	RED I.D. 13268
FUNDERS Number:	NIHR206149

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:

.....

.....

Date:

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Name (please print):

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.....

Position:

.....

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Chief Investigator:

Signature: 

Date:

09/01/2024

Name: (please print):..Laura Renshaw-Vuillier..

LIST of CONTENTS

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Funder(s)	NIHRCC Grange House 15 Church Street Twickenham TW1 3NL Tel: 020 8843 8000 Email: rfpb@nihr.ac.uk www.nihr.ac.uk
Key Protocol Contributors	Laura Renshaw-Vuillier, Principal Academic in Psychology

Committees	Stakeholder group with CI (details above) and all co-applicants: Ulrike Schmidt: ulrike.schmidt@kcl.ac.uk Liz May: liz.may@southernhealth.nhs.uk Maddy Greville-Harris: mgrevilleharris@bournemouth.ac.uk Sarah Thomas: saraht@bournemouth.ac.uk Mel Hughes: mhughes@bournemouth.ac.uk Rachel Moseley: rmoseley@bournemouth.ac.uk We will also convey a PPI group as part of the project

STUDY SUMMARY

Study Title	A brief online emotion-based intervention to provide early support for adult patients with binge eating disorders awaiting NHS treatment: intervention acceptability, early feasibility and optimisation
Internal ref. no. (or short title)	Emotion intervention for binge-eating
Study Design	Mixed method
Study Participants	Outpatients with either bulimia nervosa or binge-eating disorder, awaiting treatment on the NHS
Planned Size of Sample (if applicable)	30 outpatients with either bulimia nervosa or binge-eating disorder. 10-15 of them will be invited for a follow-up interview 5-10 health care staff working in eating disorder services
Follow up duration (if applicable)	N/A
Planned Study Period	18 months

Research Question/Aim(s)	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.

Study brief summary:

Eating disorders (EDs) affect up to 3.4 million people in the UK, with towering mortality rates and healthcare costs. Patients suffer from “traumatic” long waiting times, leading to worsening of symptoms, even higher healthcare costs, and lower likelihood of responding to treatment. Current recommended treatment does not address the underlying emotional difficulties faced by patients with EDs, which could explain the high relapse rates of 50-60%. We have created a brief online psychoeducational intervention that targets difficulties in emotional functioning, with promising initial feedback. Its acceptability and feasibility remain to be tested.

This study aims to assess and enhance the acceptability and early feasibility of a brief emotion-focused intervention for adults on an NHS waiting list for treatment for binge-eating through the following objectives:

1. Assess acceptability and early feasibility of the intervention
2. Explore ED health care staff views around barriers to adoption of the intervention
3. Determine variations in ED care pathways in England
4. Refine the online intervention based on findings
5. Assess the acceptability of study processes and clinical outcomes and look for signs of clinical improvement

Method:

Fifteen adults who binge-eat and are awaiting treatment at Hampshire Isle of Wight Healthcare NHS Foundation Trust will be given access to the intervention. They will complete questionnaires (about ED behaviours and emotions) before/after the intervention and provide feedback (via an interview) at the end. After each video, participants will be asked to provide feedback on how informative they found the video and answer some open text questions on the LifeGuide+ platform. Patterns/duration of use will be recorded by the LifeGuide+ platform. Feedback will be used to make changes to the intervention. A second wave of the case-series will be undertaken with 15 adults awaiting treatment at SLaM Trust (South London and Maudsley NHS Foundation Trust).

Two focus groups with 5-10 healthcare staff from the two NHS Trusts will explore risks, benefits, and barriers to adoption of the intervention in an NHS setting.

A brief online survey sent to all adult ED services in England will ask about their care pathways/management of waiting lists.

An integrative analysis will consider feasibility and acceptability of the intervention, study processes and outcome measures.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
NIHRCC Grange House 15 Church Street Twickenham TW1 3NL Tel: 020 8843 8000 Email: rfpb@nihr.ac.uk www.nihr.ac.uk	Financial support

ROLE OF STUDY SPONSOR AND FUNDER

Bournemouth University will act as Sponsor, ensuring that the research is conducted in accordance with the protocol, the UK Policy Framework for Health and Social Care Research and Good Clinical Practice standards. As per the framework and GCP standards, the Sponsor has taken the overall responsibility for the initiation, management and for arranging the financing of this research project.

The Sponsor has taken responsibility for overseeing the study design and will oversee study conduct, ensuring that results are disseminated appropriately as per internal Standard Operating Procedures (SOPs) and in accordance with the framework and GCP standards.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

The Chief Investigator will chair the Study Management Group (SMG) (comprising all co-applicants, including the public co-applicant, a PPI member, and a representative from the sponsor) which will meet four times over the 15-month project via video conference/hybrid.

The SMG will monitor study progress against milestones and seek solutions to any problems that may arise.

We will convene a Stakeholder Group comprising all co-applicants (a psychiatrist, an ED clinician, three psychologists, a PPI lead, and a person with autism and lived experience of ED). This group will focus on aspects related to the intervention, its implementation in clinical practice and safety.

We also have a PPI group comprising six people with lived experience of ED. With the UK Standards for Public Involvement as our overarching framework, our PPI lead will work in partnership with our PPI group and public co-applicant and provide a single-point of contact. Three hours training (delivered by Bournemouth University's Public Involvement in Education and Research (PIER) partnership) at the project start will help ensure members feel confident to influence the project through a lived experience lens and identify and address any specific access and support needs (e.g. wi-fi extenders etc). PPI meetings have been costed to include 1.5-hours' time for preparation, breaks, and support, to further build confidence and in recognition of the emotional sensitivity of the topic.

PPI activities will be embedded throughout the project lifecycle. While the exact nature of involvement will depend upon interests, skills and preferences, we envisage PPI members will be involved in the following activities:

- Attending bimonthly online PPI meetings
- Capturing inputs/reflections in PPI impact log
- Attending SMG meetings (one member, rotational)
- Co-developing dissemination/impact strategy
- Reviewing intervention once deployed on LifeGuide+
- Reviewing patient-facing materials
- Considering patient safety/ safeguarding issues; review distress protocol
- Reviewing recruitment strategy (consideration of EDI and digital exclusion)
- Co-producing interview topic guide
- Contributing to analysis of interview data
- Discussing/prioritising changes in Table of Changes
- Drafting Plain English Summaries, co-authoring reports/journal articles
- Co-presenting at conference with CI
- Working with the research team to agree next steps at project end.
- Reflecting on PPI process (what went well/improvements)

PROTOCOL CONTRIBUTORS

Bournemouth University will act as Sponsor, ensuring that the research is conducted in accordance with the protocol, the UK Policy Framework for Health and Social Care Research and Good Clinical Practice (GCP) standards. As per the framework and GCP standards, the Sponsor has taken the overall responsibility for the initiation, management and for arranging the financing of this research project.

The Sponsor has taken responsibility for overseeing the study design and will oversee study conduct, ensuring that results are disseminated appropriately as per internal Standard Operating Procedures (SOPs) and in accordance with the framework and GCP standards.

Patients with an eating disorder were involved in designing the research project and henceforth protocol.

Laura Renshaw-Vuillier and Suzy Wignall are the only two contributors of this document

KEY WORDS: Emotion; emotion regulation; binge eating disorder; bulimia nervosa; waitlist; online toolkit

STUDY FLOW CHART

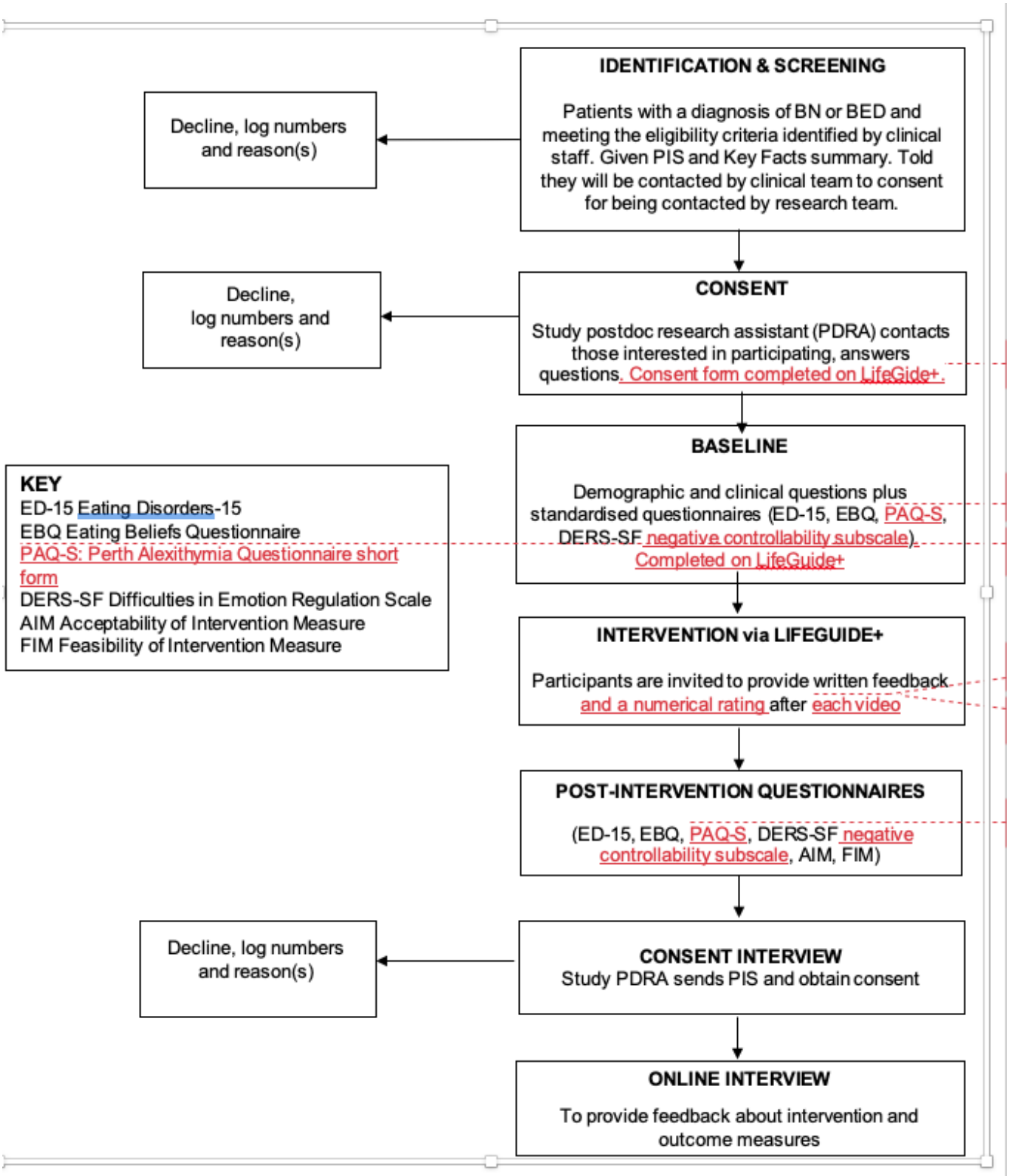
IDENTIFICATION & SCREENING
Patients with a diagnosis of BN or BED and meeting the eligibility criteria identified by clinical staff. Given PIS and Key Facts summary. Told they will be contacted by clinical team to consent for being contacted by research team.
Decline, log numbers and reason(s)
CONSENT
Study postdoc research assistant (PDRA) contacts those interested in participating, answers questions. Consent form completed on LifeGide+.
Decline, log numbers and reason(s)
BASELINE
Demographic and clinical questions plus standardised questionnaires (ED-15, EBQ, PAQ-S, DERS-SF negative controllability subscale). Completed on LifeGuide+
KEY
ED-15 Eating Disorders-15
EBQ Eating Beliefs Questionnaire
PAQ-S: Perth Alexithymia Questionnaire short form
DERS-SF Difficulties in Emotion Regulation Scale
AIM Acceptability of Intervention Measure
FIM Feasibility of Intervention Measure
INTERVENTION via LIFEGUIDE+
Participants are invited to provide written feedback and a numerical rating after each video
POST-INTERVENTION QUESTIONNAIRES
(ED-15, EBQ, PAQ-S, DERS-SF negative controllability subscale, AIM, FIM)
Decline, log numbers and reason(s)
CONSENT INTERVIEW
Study PDRA sends PIS and obtain consent
ONLINE INTERVIEW
To provide feedback about intervention and outcome measures

Figure 1: Flow chart

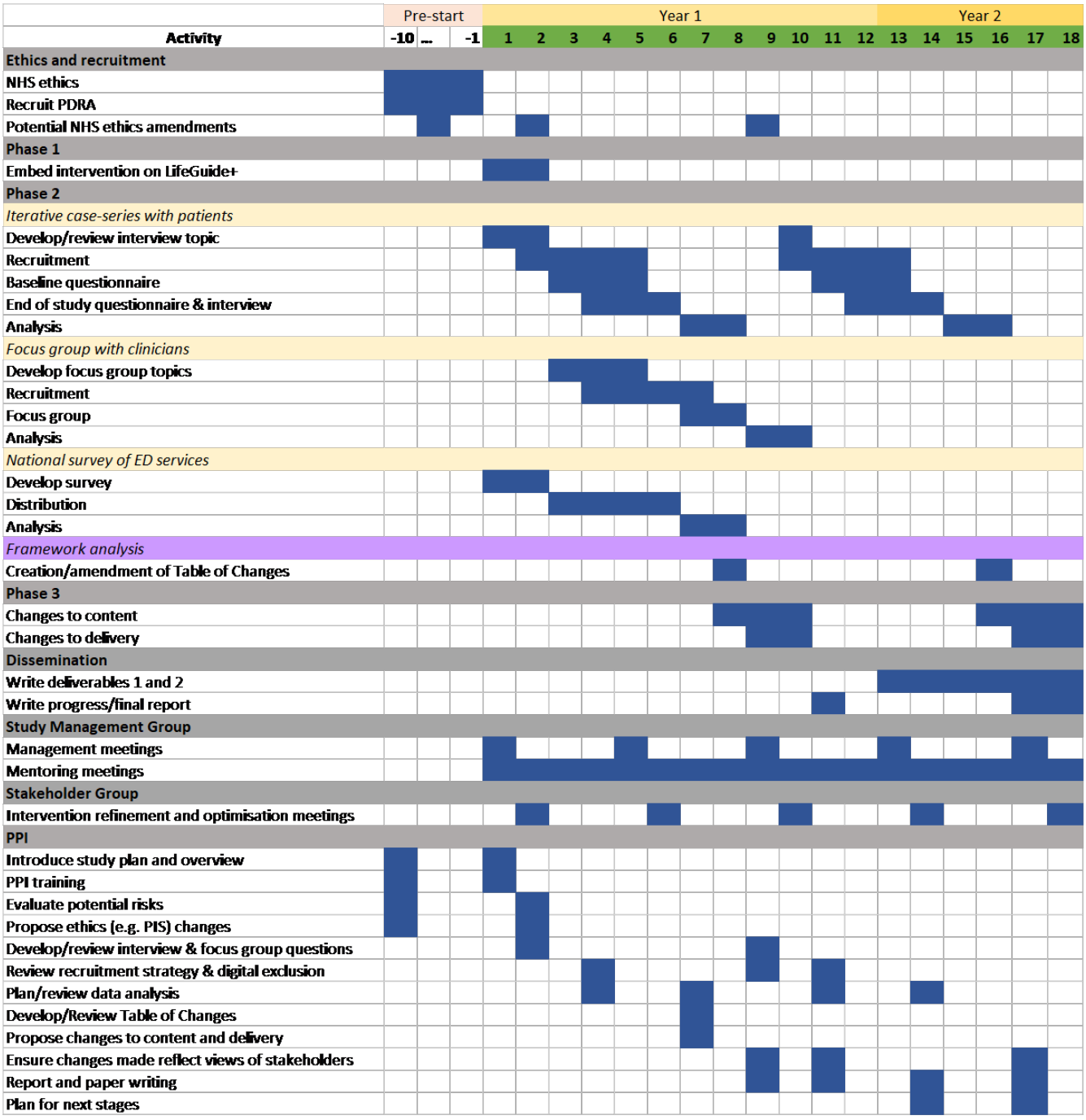

Figure 2: Gantt chart

STUDY PROTOCOL

A brief online emotion-based intervention to provide early support for adult patients with binge eating disorders awaiting NHS treatment: intervention acceptability, early feasibility and optimisation

1 BACKGROUND

“Disabling, deadly, and costly” (Treasure et al., 2020). These words describe the staggering impact of eating disorders (EDs), which affect up to 3.4 million people in the UK (Priory, 2018). EDs have among the highest mortality rates of all psychiatric illnesses, with suicide a major cause of death (Smith et al., 2018), and result in annual healthcare costs almost double those of the general population (van Hoeken & Hoek, 2020). Recent reviews suggest that demand far outstrips the capacity of present adult ED services in the UK (Viljoen et al., 2022), leaving the majority of individuals with ED to suffer “traumatic” long waiting times of around two years (BBC News, 2022). Regrettably, long waiting times translate into worsening of symptoms, higher total healthcare costs, lower treatment uptake, and less likelihood of responding positively to treatment (Austin et al., 2021).

While EDs receive far less research funding than almost all other mental health conditions (Group, 2021), people who binge-eat are much more likely to be relegated to this overlooked group (Group, 2021). Bulimia nervosa (BN) and binge-eating disorder (BED) are characterised by recurrent binge-eating episodes, wherein an unusually large quantity of food is eaten within a discrete time period, accompanied by a sense of loss of control. While anorexia nervosa (AN) is the most commonly *known* ED, BN and BED are five times more commonly *diagnosed* than AN (Beat, 2022) and their waiting time for treatment is at least twice that of AN (Austin et al., 2021).

The All-Party Parliamentary Group on EDs reports that ED research, particularly research on people who binge-eat, is underfunded with *“just 1% of UK mental health research funding allocated, despite people with eating disorders accounting for around 9% of the total number of people with a mental health condition”* (Group, 2021). Their report also highlights the need to develop novel approaches to treatment. This is echoed by the James Lind Alliance (James Lind Alliance, 2022) which currently has relevant Priority Setting Partnerships in Australia and the Netherlands that highlight the need for research investigating therapies addressing *underlying problems* for people who binge-eat as well as to develop early interventions.

This position is also supported by a recent Australian Delphi study of patient and clinician priorities (Hart & Wade, 2020), which additionally stresses the need to research *emotional*

factors in ED. Indeed, it is now widely acknowledged that people with BN or BED have difficulties identifying (Westwood et al., 2017) and managing their emotions (Prefit et al., 2019), and use binge-eating as a way to regulate unpleasant feelings (Leehr et al., 2015; Prefit et al., 2019). While current evidence-based treatments for EDs principally work on ED thoughts and behaviours (e.g. Cognitive Behavioural Therapy, CBT (NICE guideline, 2020)), new therapies working specifically on emotions are emerging. Emotion-focused therapies such as Dialectical Behavioural Therapy (DBT) address the underlying emotion difficulties which are believed to give rise to and maintain binge-eating (Leehr et al., 2015; Wallace et al., 2014) as well as co-occurring mental illnesses like depression, which can precipitate and maintain ED pathology (Elran-Barak & Goldschmidt, 2021).Using the current empirically-supported evidence-based treatment (i.e. CBT), over 60% of patients with BN (Linardon & Wade, 2018) and 50% of patients with BED (Linardon, 2018) do not obtain complete abstinence from core eating disorder symptoms. It is therefore imperative to try to bring change to our current care pathway, and findings from the literature suggest that working with emotional beliefs and skills is the way forward in developing more effective treatments (Berking et al., 2022; Holmqvist Larsson et al., 2020; Leppanen et al., 2021).

DBT treatment focuses on emotional non-acceptance and offers strategies to help manage emotions. It has been shown to work well to reduce binge-eating behaviours, (Ben-Porath et al., 2020) and seems at least equally efficacious and less associated with relapse at 6-month follow-up compared to CBT (Lammers et al., 2022). However, it does not address in detail other difficulties such as beliefs about emotions which are linked to eating psychopathology (Vuillier, Joseph, et al., 2021) and co-morbid anxiety and depression (Deplancke et al., 2022) or alexithymia (difficulties identifying/describing feelings) which is highly prevalent in EDs and may actually underpin emotion dysregulation in this population (Westwood et al., 2017). Interventions designed to target beliefs about emotions seem effective for people with EDs (Glisenti et al., 2023) and treatments specifically focusing on alexithymia have been found to decrease binge-eating and may even be more effective for people who binge-eat than CBT (Clyne et al., 2010). However, no treatment currently targets all aspects of emotional functioning that are affected in EDs.

2 RATIONALE

Our team has created a brief online intervention that targets all the above difficulties in emotional functioning, including beliefs about emotions, alexithymia and emotion regulation skills. Figure 3 explains a typical cycle for someone with a binge-eating disorder. The “problem” starts with a situation that gives rise to a primary emotion (e.g. anxiety about an upcoming meal for a birthday). People who binge-eat often hold beliefs that unpleasant emotions such as anxiety or anger should not be expressed, and that they cannot be

controlled and should be endured (*Beliefs*), which can give rise to secondary unhelpful emotions (e,g, feeling ashamed about feeling anxious – *Secondary emotions*). They also often have difficulties identifying and describing how they feel (*Alexithymia*), which results in an amplified emotion that takes over and becomes really distressing to deal with. Finally, and relatedly, they tend to have limited resources of helpful strategies to use in such situation (*Emotion regulation*), which all together leads them to using a "solution" that works well in the short term to reduce their anxiety: engaging in binge-eating, purging or self-harm. This short-term reduction in emotional turmoil then reinforces these maladaptive behaviours (e.g. there are no other ways to manage emotions) and makes them lose touch with their emotions (i.e. they have not learnt to deal with their emotions; they just push them away but the next time a difficult emotion arises they still have not learnt how to effectively deal with it).

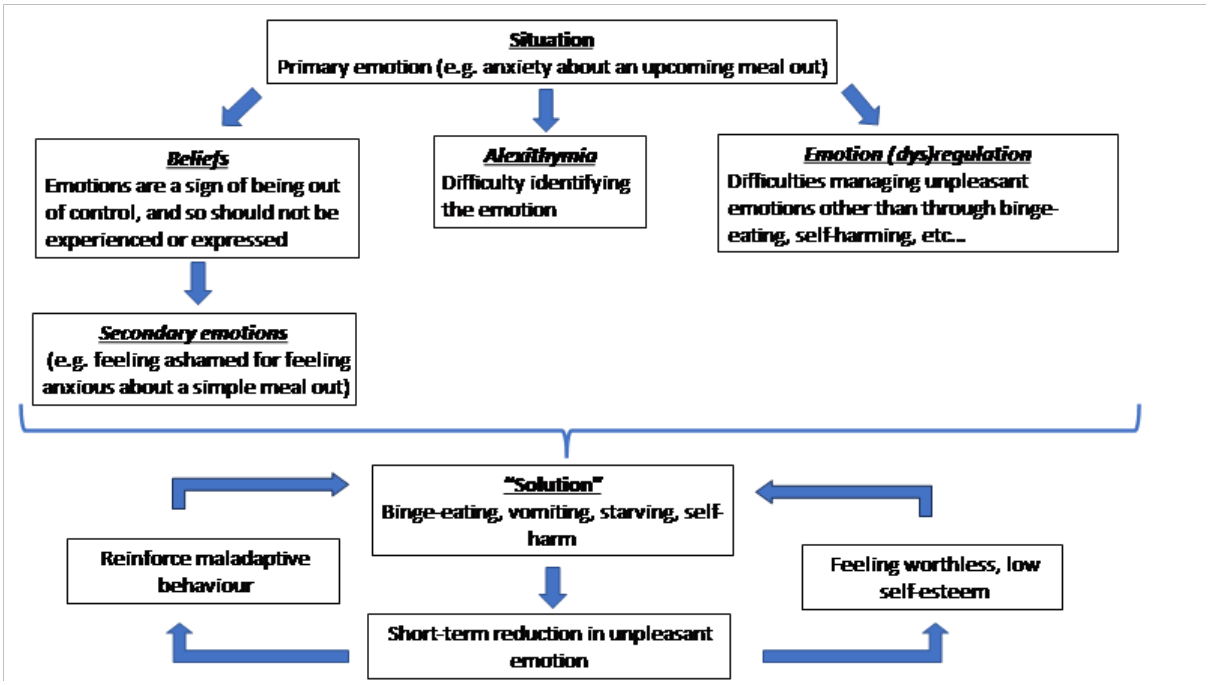

Figure 3: The relationship between emotions and eating difficulties

We developed the online Beta-version of the intervention with expertise from people with lived-experience and clinicians. The self-paced intervention works through seven short videos that each target a specific aspect of emotional difficulties and consists of the following five modules:

- Video 1: Emotions have a purpose and are temporary (targeting *Beliefs* about emotions)

- Video 2: How to label emotions to reduce their impact (targeting *Alexithymia*)
- Video 3: Secondary emotions and their links with binge-eating (most people from the pilot reported having an “a-ha moment” here)
- Video 4 and 5: Strategies to manage emotions instead of using binge-eating (targeting *Emotion Regulation*)
- Video 6: Self-care activities to lower emotional intensity
- Video 7: How to stay well (focus on bringing everything together and relapse prevention/how to cope with lapses)

The intervention also incorporates a workbook summarising the content of the videos to improve accessibility (our PPI work showed some preferred reading the summaries beforehand), and a booklet to support practice of the newly acquired skills. Preliminary feedback about the intervention modules from people at various stages of their journey with an ED (n=37) recruited and reimbursed via an online platform (Prolific) was promising, suggesting good engagement and reductions in self-reported ED thoughts and binge-eating episodes after one week's access to the intervention. However, in the current proposal we seek to address three areas of uncertainty:

- Participants in our pilot study were at various stages of their illness rather than awaiting treatment and were paid for their time taking part in the research. Therefore, we need to test engagement and acceptability in an NHS setting under real life conditions
- Our PPI work highlighted the need for health care professionals (HCPs) to review the patient’s progress on the intervention. The views of healthcare staff on the feasibility and barriers to adoption in an NHS setting therefore need to be explored.
- Our PPI work highlighted variations in care pathways and waitlist management. Therefore, we aim to survey ED services in England to ensure our intervention can be implemented at the right time and in the right context across the country.

3 THEORETICAL FRAMEWORK

A multifaceted link between difficulties with emotions and EDs is now widely established. Firstly, people with EDs struggle to *identify* and *describe* their emotions, a tendency known as alexithymia (Westwood et al., 2017). Secondly, they often struggle to *regulate* their emotions (Prefit et al., 2019), seeming to over-rely on maladaptive emotion regulation strategies such as suppression or rumination while under-utilising adaptive strategies such as acceptance (Prefit et al., 2019; Vuillier, May, et al., 2021) or cognitive reappraisal (Petersson et al., 2021);

indeed, lower use of cognitive reappraisal appears to be associated with higher severity of restrictive symptoms (Vuillier et al., 2022). Thirdly, people with EDs also differ in their *beliefs* about emotions, such as whether emotions are controllable or uncontrollable, and whether they are good or bad which both have implications for emotion regulation strategies (Ford & Gross, 2019). As such, people with EDs tend to believe that emotions are not something they can control or manage, with stronger beliefs around the uncontrollability of emotions being linked to greater ED psychopathology (Vuillier, Joseph, et al., 2021), as well as higher levels of anxiety and depression (Deplancke et al., 2022). The other dimension of beliefs about emotions concerns the extent to which they are good or bad, or perceived as acceptable or threatening. Maladaptive beliefs about the threat posed by emotions leads to emotional non-acceptance and can incur secondary emotions which have both been associated with EDs (Corstorphine, 2006; Leppanen et al., 2022). While primary emotions are natural and adaptive responses to the environment (e.g. feeling sad when losing something or someone you care about), secondary emotions (e.g. feeling guilty for feeling sad because feeling sad is 'bad') are learnt responses which do not always make sense (e.g. the lingering emotion of *guilt* rather than sadness when losing something or someone you care about) and are known to be associated with ED behaviours (Corstorphine, 2006). Figure 3 summarises how each of these factors may contribute to ED behaviours.

There is evidence to support that at least some of these emotion difficulties, such as emotion regulation problems, are premorbid longitudinal predictors of disordered eating and EDs (Henderson et al., 2021; Warne et al., 2023). Moreover, these concepts and difficulties are linked: for instance, being unable to identify emotions makes it harder to know how to regulate unpleasant feelings (Brown et al., 2018; Sfärlea et al., 2019), and believing emotions are uncontrollable influences the ways in which people attempt to regulate their emotions, if they try at all (Ford & Gross, 2019; Gutentag et al., 2017). However, these processes are also distinguishable. For example, alexithymia or maladaptive beliefs about emotions are not a prerequisite for difficulties with emotion regulations, which can happen at any and all stages of the emotion regulation cycle (Gross, 2015). Therefore, we believe that interventions developed to help people with EDs better understand and manage their emotions should address all these concepts.

The foremost treatment recommended for EDs is Cognitive Behavioural Therapy (NICE guideline, 2020), which principally works by directly targeting ED thoughts and behaviours (Murphy et al., 2010). However, newer therapies such as DBT aim to address underlying emotion difficulties, which are believed to give rise to and maintain ED thoughts and behaviours, as well as treating co-occurring psychopathologies (e.g. anxiety, depression) that also contribute to the development and maintenance of EDs (Elran-Barak & Goldschmidt, 2021). DBT treatment focuses principally on emotional non-acceptance and offers strategies to help manage emotions. It has been shown to work well to improve emotion regulation skills and reduce eating psychopathology in EDs (Rozakou-Soumalia et al., 2021) and seems at

least equally efficacious and less associated with relapse at 6-month follow-up compared to CBT (Lammers et al., 2022). However, it does not always resolve more fine-grained, underlying emotion processes, such as beliefs about emotions or alexithymia which can maintain ED behaviours and seem to act as a negative prognostic factor in ED recovery (Speranza et al., 2007). There is emerging evidence that interventions specifically targeting beliefs about emotions (Glisenti et al., 2023) or alexithymia (Becker-Stoll & Gerlinghoff, 2004) are effective for people with EDs and may lead to a higher probability of patients' recovery (Pinna et al., 2015). As of yet, however, these emotion-focused approaches are not yet recognised or recommended by the National Institute for Health and Care Excellence (NICE); nor, to the best of our knowledge, has an intervention including *all* these significant aspects of emotional functioning, including beliefs about emotions, been developed.

Moreover, we do not know of an intervention that combine all these elements in an *online* platform, despite evidence showing that internet-based self-help approaches are effective to help reduce eating psychopathology (Jenkins et al., 2021; Rohrbach et al., 2022; Yim & Schmidt, 2019b, 2019a). This is relevant because ED services are overstretched, with demand for treatment far outstripping capacity (Striegel Weissman & Rosselli, 2017; Viljoen et al., 2022). Online self-help interventions offer the possibility to provide faster help to those waiting for treatment, and at potentially reduced cost (Lynch et al., 2010). With long waiting times translating into worsening of symptoms (Vollert et al., 2019), higher total healthcare costs (Bothe et al., 2022), and lower treatment uptake (Flynn et al., 2021), providing treatment early without intensive clinical input could be an effective way to reduce the long waiting times (Austin et al., 2021).

4 RESEARCH QUESTION/AIM(S)

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.

4.1 Objectives

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.

4.2 Outcome

Our primary outcomes of interest relate to the following markers of feasibility and acceptability.

1. Uptake, recruitment and retention rates
2. Data analytics (patterns and duration of use) to measure engagement with intervention via LifeGuide+ embedded tools
3. Feedback from interviews with patients about the intervention and from focus groups with health care staff about its deliverability (see Strand ii below.)
4. 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).
5. Completion of outcome measures (see 'Secondary outcomes' below) in terms of levels of missing data and their acceptability and relevance

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 3-weeks if they have not engaged with the intervention):

1. *ED symptoms* measured via the Eating Disorders-15 (ED-15) scale (Tatham et al., 2015). 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 (Rodrigues et al., 2019)

2. *Emotional knowledge and ability,* assessed via three questionnaires. We will most likely use the Emotion Beliefs Questionnaire (EBQ (Becerra et al., 2020)) 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.

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.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

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

6 STUDY SETTING

Two NHS Trusts have given their approval in principle to take part in the study: Hampshire and Isle of Wight Healthcare NHS Foundation Trust and the South London and Maudsley (SLaM) NHS Foundation Trust – through the support of Professor Ulrike Schmidt. We already have an ongoing collaboration with the former, which sees about 300 BN or BED patients with BN/BED per year, of which about 10% are male and 10% of ethnic minorities background. The latter was added for diversity purposes as it has been shown to screen patients with a wider range of ethnicities and socio-economic status. It sees about 250 people with BN or BED each year, and of these approximately 10% are male and 12% of ethnic minorities background.

At the SLaM, the wait for assessment (and diagnosis) is about 6-12 months. Patients then wait another 4-months for guided self-help, or about a year for face-to-face treatment. The

SLaM offers workshops and a once weekly online-support group while patients are on the waitlist. However, none of these workshops or support groups provide help with emotional functioning.

At the Hampshire and Isle of Wight Healthcare NHS Foundation Trust, the wait for assessment is about 6-months and then another 6-months for treatment. Once diagnosed, patients receive access to the 'Keeping Safe Program' while awaiting treatment. This program helps patients challenge their cognitions around food and body image but does not provide help with emotions.

7 SAMPLE AND RECRUITMENT

i. Iterative case series with ED patients

7.1 Eligibility Criteria

All new patients diagnosed with BN/BED and awaiting treatment for their eating disorder will be eligible.

We aim to recruit 15 patients per trust, for a total sample of 30 participants.

7.1.1 Inclusion criteria

- Aged 18 years or above
- Fulfil DSM-5 criteria for BN or BED as primary diagnosis
- On an NHS waiting list for treatment for BN or BED
- Proficient in English to make an informed consent

7.1.2 Exclusion criteria

- Suicidal ideation at the time of taking part in the study. This is necessary to protect participants until we can fully assess the potential risks of the intervention
- Comorbidities and medication will be recorded but will not form part of the exclusion criteria.

ii. Focus groups with ED healthcare staff

Both Hampshire 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 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.

7.2 Sampling

i. Iterative case series with ED patients

7.2.1 Size of sample

Given that the aim of this mixed methods study is to assess *early* feasibility and acceptability of the intervention, and because the intervention may change between waves, we consider a sample size of 30 is sufficient for our planned objectives (Julious, 2005) and is line with other similar studies assessing early feasibility of interventions (eg.(Lester et al., 2022; O'Gara et al., 2022))

Moreover, given the relatively specific sample (people diagnosed with BED or BN) and the narrow focus of the interviews (i.e. about their specific experience of the platform), we expect the dialogue to be of strong depth and quality, meaning we expect to gain sufficient information power (Malterud et al., 2016) and reach saturation within 15-20 interview (Hennink & Kaiser, 2022).

7.2.2 Sampling technique

Any participant meeting the inclusion & exclusion criteria will be accepted to take part in the study given that they are happy to proceed and have reached an informed decision before agreeing to participate.

Both NHS sites see about 250 to 300 patients with BN or BED per year, so 20 to 25 patients per months. We have given ourselves a total of eight months to recruit all 30 participants, so roughly 3 or 4 per month. This means that we need one in five participants screened to agree to take part to reach this target, which we believe is feasible.

We will aim to use purposive sampling to recruit males and participants from ethnic minorities to ensure our sample is representative.

ii. Focus groups with ED healthcare staff

Focus groups are particularly suited for obtaining several perspectives on a topic. As the aim of this strand is to seek a range of perspectives from the multi-disciplinary ED team, purposive sampling will be used to ensure a mix of professions and years of experience. The decision to hold 2 focus groups is pragmatic but Hennink (Hennink & Kaiser, 2022) suggests that with a narrow focus like ours, this should be adequate to achieve code saturation.

7.3 Recruitment

7.3.1 Sample identification

i. Iterative case series with ED patients

Patients will be recruited from existing waiting lists. All new patients diagnosed with BN/BED and meeting the eligibility criteria will be identified by the clinical team.

During their assessment feedback appointment or shortly afterwards, potential participants identified by the clinical team are provided with an outline of the study and a copy of the study advertisement (containing a link to a short video explaining the study). A member of the clinical team will contact eligible participants asking for consent to be contacted by the research team, and participants have the option to contact the research team themselves directly. Those interested have the option to be sent a copy of the participant information sheet, along with contact details of the study team (email). 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. The study Postdoctoral Research Assistant (PDRA) will then contact those who express an interest in participation, describe the study in more detail and answer any questions. Consent is given electronically on the LifeGuide+ platform and participants have the option to download the PIS for their own records. 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). Participants will give their consent to take part in the interviews online, using online survey software such as JISC.

Flow of recruitment/data sharing in HIOWH:

1. Participants who may be eligible to take part are identified by the eating disorder teams during/following routine diagnostic assessments
2. In their weekly meeting eligibility is discussed and confirmed between clinicians
3. Where participants are eligible to take part in our study, in follow up phone calls with clinicians they are asked if they consent for their details to be passed onto the research team or participants have the option to contact the research team directly

4. After weekly meetings Eilidh and Laura are emailed via their NHS email addresses with names and email addresses of those who have provided consent for this information to be passed on by Isaac / Lauren
5. Clinical team members keep a record of how many individuals did not consent to be contacted by the research team/were not interested in taking part in the study. They also keep a record of names and NHS numbers etc who do consent to be contacted in their own spreadsheet.
6. Participants will be contacted by the study research assistant to answer any questions they may have
7. Consent is given electronically via Lifeguide+
8. Regularly, study team member to email relevant staff at HIOWH the names and dates of those who provided consent, using template email/letter (using NHS email addresses)
9. Relevant staff at HIOWH to update RIO with information sheet and empty consent form for those who consented to take part in the study and updates LPMS periodically
10. Eilidh/Laura update Central Portfolio MS at least monthly with updated number of participants recruited

ii. Focus groups with ED healthcare staff

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 post-doc will contact those who express an interest in participation, describe the study in more detail, answer any questions and go through the consent form. Participants will give their consent to take part in the interviews online, using online survey software such as JISC. 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.

7.3.2 Consent

Participants will be given a participant information sheet (PIS) that they will be able to keep and will be asked to sign an electronic consent form.

In accordance with GCP standards, the participant will be given sufficient time to consider the information provided so that they may make an informed decision before agreeing to participate. The participants will also be given contact details they may use to discuss any queries they may have before confirming their interest in participating. All prospective participants will be told that

participation is voluntary and that their participation or otherwise will have no impact on the care that they normally receive.

8 ETHICAL AND REGULATORY CONSIDERATIONS

The risks and benefits are clearly explained in the PIS form, and summarised below. Participants will need to sign a consent from before they can partake in the study.

Risks

We believe the risks involved in taking part in the study are minimal. The questionnaires participants will answer deal with some sensitive subjects, but it is highly likely that they may have encountered them before, for example in the process of them being diagnosed with an eating disorder. Spending some time thinking about their emotions may make them feel upset, but so far, the people who have received this toolkit have said that it helped them. The online toolkit also has a section entitled “I need help”, which contains links to mental health charities we recommend you contact if you feel distressed. Please note that we will not be monitoring the content of what you write on the online toolkit. This means we won’t be able to know if you feel distressed, so please directly contact the charities or your GP if you need urgent help.

Benefits

They will not receive any financial reward, because we want to test this intervention in real life conditions. However, they will receive financial compensation (£25) if they take part in the follow-up interview. We also hope that they will learn a lot from the toolkit, and that it will help them with their emotions.

8.1 Assessment and management of risk

- First, participants with known suicidal ideation will not be allowed to take part. If they do become suicidal during the study and if we realise this (for example during the interview) we will mention that we will need to inform their clinical team (which they have to agree with being contacted to start taking part in the study). We are also making it clear that we are not able to read what they write as part of the emotion practice exercise, to ensure they do not expect that this information will be flagged up.
- All participants will also be able to access a page on LifeGuide+ called “I need help” with supporting information. Information given includes Beat, the leading UK eating

disorder charity, Mind and the Samaritans, as well as links to the relevant NHS page (https://www.nhs.uk/nhs-services/mental-health-services/where-to-get-urgent-help-for-mental-health/). They will also be told to contact their GP or clinical team.

- Relatedly, participants' clinical team for a further safety net in case they feel distressed.
- Two members of our research team are clinical psychologists and will be available to offer help and support to our participants, although not 'urgent' help, because they cannot be available 24/7, as opposed to dedicated charities which are designed for that purpose.
- Participants will be told that they can withdraw at any point during the study without it affecting in any way the care they receive as per the statement below in the PIS "Remember you can withdraw from the study at any point and that this will not affect the care you receive".

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from a REC for the study protocol, informed consent forms and other relevant documents.

Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.

All correspondence with the REC will be retained.

The Chief Investigator will produce the annual reports as required. An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.

The Chief Investigator will notify the REC of the end of the study. If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.

Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

We state that:

- Before any site can enrol patients into the study, the Chief Investigator will ensure that appropriate approvals from participating organisations are in place.

- For any amendment to the study, the Chief Investigator, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator will work with sites so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Amendments

Amendments to the study will be categorised in accordance with the definitions of substantial and non-substantial amendments as defined on the HRA website and within GCP guidelines. All amendments will be submitted by the sponsor, for consideration by the REC and HRA (as required) via the IRAS system.

8.3 Peer review

The proposal has been externally reviewed by Professor Katherine Appleton (at Bournemouth University but independent of the research team) and a team of expert reviewers within NIHR who is funding this project.

8.4 Patient & Public Involvement

PPI for intervention and proposal development

We recruited a group of nine people who binge-eat and were awaiting treatment to help develop the current proposal. We involved people often under-represented in ED research, including those with neuro-divergence (N=1), those from ethnic minority groups (N=2), and males (N=1). We ran three workshops (funded by NIHR RDS-SW) at different times to suit everyone's needs. In these workshops, we asked about experiences of having a binge-eating disorder (BN or BED) and about experiences of awaiting treatment. They highlighted three points which we address in the current study.

First, they confirmed the need for an intervention to bridge the gap between assessment and face-to-face treatment. Some of our PPI contributors had been waiting for over 2 years with no contact from ED services and said they felt *'like a burden'* which amplified their low self-esteem and ED symptoms. They also mentioned that they have difficulties with their emotions but were not sure what to do about this. This reinforced our belief that our intervention should be delivered while patients are awaiting treatment to provide self-help tools for managing emotions and ED symptoms.

Second, they expressed the need for their progress on the intervention to be reviewed by a clinician. For example, one said *"I want someone to check the exercises to make me accountable".* The original intervention was designed to be self-guided with no clinical support (due to the current pressures on ED services). We will explore this further in the interviews with patients and the focus groups with health care professionals.

Third, they made us aware of the wide variation in care pathways across the UK. For instance, some of our PPI contributors had received help via SilverCloud (online cognitive behavioural therapy programme) while others had received nothing. We therefore added a national survey of adult ED services as a third strand to our study design to find out more about national variations in care pathways and how our intervention could be embedded within.

PPI for the current project

The PPI group comprises six people with lived experience of ED.

With the UK Standards for Public Involvement as our overarching framework,[51] our PPI lead (MH) will work in partnership with our PPI group and public co-applicant and provide a single-point of contact. Three hours training (delivered by Bournemouth University's Public Involvement in Education and Research (PIER) partnership) at the project start will help ensure members feel confident to influence the project through a lived experience lens and identify and address any specific access and support needs (eg. wi-fi extenders etc). PPI meetings have been costed (in line with CED rates) to include 1.5-hours' time for preparation, breaks, and support, to further build confidence and in recognition of the emotional sensitivity of the topic.

PPI activities will be embedded throughout the project lifecycle (see Gantt chart). While the exact nature of involvement will depend upon interests, skills and preferences, we envisage PPI members will be involved in the following activities:

- Attending bimonthly online PPI meetings
- Capturing inputs/reflections in PPI impact log
- Attending SMG meetings (one member, rotational)
- Co-developing dissemination/impact strategy
- Reviewing intervention once deployed on LifeGuide+
- Reviewing patient-facing materials
- Considering patient safety/ safeguarding issues; review distress protocol
- Reviewing recruitment strategy (consideration of EDI and digital exclusion)
- Co-producing interview topic guide
- Contributing to analysis of interview data

- Discussing/prioritising changes in Table of Changes
- Drafting Plain English Summaries, co-authoring reports/journal articles
- Co-presenting at conference with CI
- Working with the research team to agree next steps at project end.
- Reflecting on PPI process (what went well/improvements)

Active, asset-, and partnership-based involvement throughout the project will ensure maximum opportunities for the project to be shaped and influenced by those with lived experience expertise. We will report on PPI using the GRIPP-2 checklist (Staniszewska et al., 2017)

8.5 Protocol compliance

We state that:

- Accidental protocol deviations can happen at any time. In the event of a deviation, this will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

- Deviations from the protocol which are found to frequently recur are not acceptable, and will require immediate action. Such deviations could potentially be classified as a serious breach which will be reported as per GCP guidelines.

8.6 Data protection and patient confidentiality

We state that all investigators and study site staff must comply with the requirements of the General Data Protection Regulations and Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

We will collect email addresses to send the information sheet and login details. Participants will also login into the online platform using their email address (experience told us that participant forget their anonymous ID and that they prefer logging in with their email address).

We will then create a Masterfile linking email addresses with a random unrelated sequence of characters. This Masterfile will be password protected and only accessible to the CI and post-doctoral research associate. All data will then be available anonymously for analysis.

The data with corresponding email will however be saved on LifeGuide+ which complies with GDPR regarding the information collected. Their servers run RHEL with an active support contract. The servers are configured to automatically install security updates without operator intervention and are monitored with Microsoft Defender Advanced Threat Protection. In addition, their IT department run regular vulnerability scans including on-server scans for outdated software components. They also follow the OWASP Top Ten guide for securing web services: The servers are behind the institutional firewall with only HTTP/HTTPS ports visible to the general internet. Secure Shell (SSH) is configured to reject weak algorithms and access is restricted to LifeGuide staff only. All LifeGuide services are delivered over HTTPS and researcher/participant passwords are stored using BCrypt.

We will limit access to the minimum number of individuals necessary for quality control, audit, and analysis.

Our anonymous data will be also be deposited in BORDaR (Bournemouth Online Research Data Repository), a secure and open access repository offered by Bournemouth University, to comply with data reuse and sharing. It will be deposited once all the data is collected and analysed (around February 2026) and will be available for 10 years minimum (or renewed every time someone accesses it). This is in accordance with the Concordat on Open Research Data.
Dr Laura Renshaw-Vuillier (CI) is the data custodian.

8.7 Indemnity

Bournemouth University holds Public Liability insurance to cover the legal liability of the University as Research Sponsor in the eventuality of harm to a research participant arising from management of the research by the University.

Bournemouth University also holds Professional Indemnity insurance to cover the legal liability of the University as Research Sponsor and/or as the employer of staff engaged in the research, for harm to participants arising from the design of the research, where the research protocol was designed by the University.

Bournemouth University's Public Liability and Professional Indemnity insurance policies provide an indemnity to our employees for their potential liability for harm to participants during the conduct of the research.

8.8 Access to the final study dataset

Only the research team conducting the analysis will be able to access the dataset.

There will not be any restriction of access to any team member.

The consent form states that: “I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.” In case the data is used for secondary analysis.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

We state that:

- The CI and all Co-Is will own the data arising from the study.
- On completion of the study, the data will be analysed and tabulated and a Final Study Report prepared and sent to the REC that granted original favourable opinion.
- The PI will have the rights to publish any of the study data. The other collaborators will be authors on all publication.
- There will be no time limit or review requirements on the publication.
- NIHR will be acknowledged as funder of the study
- Participants who agreed to be contacted on the consent from will be sent the published articles. They will not however be given access to their private data
- The full anonymised dataset will be openly accessible through Bournemouth Data repository service BORDaR once the data are anonymised and analysed.

9.2 Authorship eligibility guidelines and any intended use of professional writers

The Chief Investigator and all Co-Is will be authors on all publications. Anyone else involved in the study will be offered the option to be an author on each publication.

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11. APPENDICIES

11.1 Appendix 1- Required documentation

The clinician who is based at each of the two PICs will be provided with the information pack (including information letter, PIS and consent) to give to eligible participants. The PIC will likewise be provided with the study protocol and correspondence/approvals of the appropriate approval bodies, for their records.

11.2 Appendix 2 – Schedule of Procedures

Procedures	Intervention	Interview	Staff focus group
Informed consent	x	x	x
Interview		x	
Focus Group			x
Demographics	x		x
Questionnaires	x		

13.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	2		Eilidh Grant	Clarification that for focus groups and interviews consent will be taken using online survey platforms
2	3	25/02/2025	Eilidh Grant	Change of name from Southern Health to Hampshire Isle of Wight Healthcare NHS Foundation Trust
3	4			

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.