

# Investigating the feasibility and acceptability of providing online guided self-help for binge eating in adults with type 2 Diabetes

<b>Submission date</b> 19/11/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/11/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/11/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Binge eating has been identified as a significant problem in people living with type 2 diabetes. People who binge eat are more likely to have obesity, raised blood sugar, find losing weight harder, and experience poorer mental health. Early intervention is crucial for eating disorders. The National Institute for Health and Care Excellence (NICE) recommends Guided Self-Help (GSH) as the first line of treatment for adults with binge eating disorder. Members of the current research team have developed and provided evidence for a brief psychological treatment for disordered eating called guided self-help. The POSE-D study has adapted this so that it is suitable specifically to address binge eating in people living with type 2 diabetes.

The current study aims to test whether it is possible to recruit to and deliver the adapted brief psychological treatment to people with T2 diabetes and binge eating and to see whether the treatment is acceptable to both patients and Guides.

### Who can participate?

We will invite adults from selected NHS sites across England (including GP practices, weight management, and diabetes services) to participate. Participants will be those living with type 2 diabetes, with experience of binge eating, and who speak English. People will not be able to take part if they are currently receiving psychological therapy, have had recent weight loss surgery, are low weight, or live with a learning disability, severe mental illness, or have hearing or sight difficulties.

### What does the study involve?

Participants will be invited to take part in an online brief psychological treatment for binge eating. The treatment comprises 7 online sessions, delivered over 3- months with tasks to complete between sessions which will be supported remotely by a trained Guide. Participants will complete questionnaires asking them about their eating, mood, and quality of life on three occasions: before, immediately after, and at 3 months after the treatment. Participants will also

be asked to visit their GP at the same time points for a blood sugar test (HbA1c) and to measure their height and weight. Both participants and Guides may be invited to be interviewed to talk about their experiences of the adapted treatment.

What are the possible benefits and risks of participating?

Taking part may help people living with type 2 diabetes gain better control over their eating. They may also experience improvements in mood, weight, and blood sugar control. Participant feedback will help to refine the Guided Self-Help treatment and so it will benefit others who are living with Type 2 diabetes and have difficulties controlling their eating.

However, the topic is sensitive, so there is a small chance that participants might feel uncomfortable talking about some of the issues relating to eating and mood.

Where is the study run from?

University of Leeds (UK)

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

December 2020 to October 2023

Who is funding the study?

Diabetes UK (UK)

Who is the main contact?

Dr Gemma Traviss-Turner

G.Traviss@leeds.ac.uk

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Gemma Traviss-Turner

**ORCID ID**

<http://orcid.org/0000-0002-1770-6216>

**Contact details**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

296694

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

IRAS 296694

## **Study information**

**Scientific Title**

Providing Online guided Self-help for Eating disorders in adults with type 2 Diabetes (POSE-D): a pilot study

**Acronym**

POSE-D

**Study objectives**

1. To test the feasibility of recruiting and delivering an online guided self-help intervention for people with T2 diabetes and binge eating
2. To determine the acceptability of the intervention from both a participant and Guide perspective

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 18/02/2022, Yorkshire & Humber Leeds East Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 2071048170; leedseast.rec@hra.nhs.uk), ref: 22/YH/0016

**Study design**

Case series

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**Study setting(s)**

Internet/virtual

**Study type(s)**

Treatment

**Participant information sheet**

See additional file

## **Health condition(s) or problem(s) studied**

Management of binge eating in adults with Type 2 diabetes

## **Interventions**

All participants will be offered the intervention. It comprises a 7 session guided self-help intervention completed over 3 months, accessed online, and supported in 7 x 1 h sessions via Zoom (or similar), phone or email by Guides (dietitians or other health professionals). Participants will complete the interactive materials for each section prior to seeing their Guide. Guides will receive mandatory training prior to supporting the intervention, by the research team and regular supervision during the intervention

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Binge eating measured using the Gormally Binge Eating Scale (BES) at 3 months

## **Secondary outcome measures**

1. Binge cessation measured using the Eating Disorder Examination Questionnaire (EDEQ v6) at baseline, 3, and 6 months.
2. Eating disorder behaviours and psychopathology measured using the 28-item Eating Disorder Examination Questionnaire EDE-Q (v6) at baseline, 3, and 6 months
3. Mood measured using the Patient Health Questionnaire -9 (PHQ-9) and Generalized Anxiety Disorder -7 (GAD-7) at baseline, 3, and 6 months
4. Health related quality of life measured using the EQ5D-5L at baseline, 3, and 6 months
5. Physiological markers of diabetes measured using weight, height, and HbA1c from blood samples at baseline, 3, and 6 months, unless they have had a recent test within the past 4 weeks.
6. Engagement and drop-out measured using documentation of participant uptake, drop-out, and withdrawal and digital usage data collected between baseline and 6 months. The study will utilise advanced interaction and tracking technology will be used to identify detailed interactions of the participants with the online self-help materials. This will include (but is not limited to) access times, progress markers, repeat access of specific materials, frequency of access and progress throughout the guided sessions. The data will be used to derive usage patterns, a detailed understanding of engagement with the material, and to help understand where further help and support may be needed within the guided self-help programme. The data collection is automated with the triggers embedded within the learning content which will provide a good standard for data coherence.

## **Overall study start date**

01/12/2020

## **Completion date**

31/10/2023

## **Eligibility**

### **Key inclusion criteria**

1. T2 diabetes diagnosis
2. Experience of binge eating within last 6 months
3. Aged  $\geq 18$  years
4. English literate

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

30

**Total final enrolment**

23

**Key exclusion criteria**

1. Current treatment for eating disorder
2. Current psychological therapy
3. Bariatric surgery in last 6 months
4. BMI  $< 18 \text{ kg/m}^2$
5. Identify as living with a learning disability
6. Severe mental illness
7. Hearing or visual impairment
8. Unable to speak English

**Date of first enrolment**

13/06/2022

**Date of final enrolment**

04/04/2023

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Leeds Community Healthcare NHS Trust**

Stockdale House  
8 Victoria Road  
Leeds  
United Kingdom  
LS6 1PF

**Study participating centre**

**Mid Yorkshire Hospitals NHS Trust**

Pinderfields Hospital  
Aberford Road  
Wakefield  
United Kingdom  
WF1 4DG

**Study participating centre**

**Bradford District Care NHS Foundation Trust**

New Mill  
Victoria Road  
Shipley  
Bradford  
United Kingdom  
BD18 3LD

**Study participating centre**

**Doncaster and Bassetlaw Hospitals NHS Foundation Trust**

Doncaster Royal Infirmary  
Armthorpe Road  
Doncaster  
United Kingdom  
DN2 5LT

**Study participating centre**

**Tees Esk and Wear Valleys NHS Foundation Trust**

Trust Headquarters  
West Park Hospital  
Edward Pease Way  
Darlington  
United Kingdom  
DL2 2TS

**Study participating centre**  
NIHR CRN Yorkshire and Humber  
8 Beech Hill Road  
Sheffield  
United Kingdom  
S10 2SB

## **Sponsor information**

**Organisation**  
University of Leeds

**Sponsor details**  
Worsley Building  
Clarendon Way  
Leeds  
England  
United Kingdom  
LS2 9LJ  
+44 (0)113-34-37587  
governance-ethics@leeds.ac.uk

**Sponsor type**  
University/education

**Website**  
<http://www.leeds.ac.uk/>

**ROR**  
<https://ror.org/024mrx33>

## **Funder(s)**

**Funder type**  
Charity

**Funder Name**  
Diabetes UK

**Alternative Name(s)**  
DIABETES UK LIMITED, British Diabetic Association

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

**Results and Publications**

**Publication and dissemination plan**

The Chief Investigator is required to submit an annual study report to Diabetes UK which will include results from this first phase of our research (adaptation of the GSH intervention through co-design). This will be within 2 weeks of the anniversary of commencement of the grant period (including the 8 week pause - Due February 2022). A final report will then be produced within 6 weeks of the end of the grant period which will include results of phase 2 (the pilot trial) (Due February 2023).

We propose to publish the results of our pilot trial in a peer-reviewed journal, along with a professionally produced YouTube animation summarising the results and easy-to-read summaries to disseminate to study participants. No participant-level data will be made available to participants. However, the full study report and protocol will be available on request from the Chief Investigator or Diabetes UK. We will use our PPI advisory group to inform dissemination activities. Diabetes UK recognises the benefits of making the results of research available as broadly as possible, including to people living with diabetes and their supporters. They therefore require grant holders to publish articles as open access within six months of their first publication. This will be done using the Green route i.e. the manuscript will be deposited in the White Rose Repository (available to members of Universities of Leeds, York, and Sheffield) and Europe PubMed Central. Diabetes UK will be acknowledged as a funder in all publications and presentations. The University of Leeds and grant holder (GTT) will give advanced notice of any press/media statement connected to the results of the grant and provide copies of all articles published.

**Intention to publish date**

30/04/2024

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from the Chief Investigator Dr Gemma Traviss-Turner (G.Traviss@leeds.ac.uk). Both quantitative data from questionnaires and qualitative data from interviews will be anonymised. Data will only be shared for research purposes for further analysis, at aggregated level for reviews or related studies as outlined in the informed consent form. All files will be encrypted.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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<a href="#">Participant information sheet</a>	version 2	10/11/2021	22/11/2021	No	Yes
<a href="#">Protocol file</a>	version 2	10/11/2021	22/11/2021	No	No
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Other publications</a>	Adapting the existing evidence-based guided self-help intervention to online remote delivery to address binge eating in adults with T2D	03/04/2023	14/11/2024	Yes	No
<a href="#">Results article</a>		11/11/2024	14/11/2024	Yes	No