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

Submission date
19/11/2021

Recruitment status
No longer recruiting

Registration date
25/11/2021

Overall study status
Completed

Last Edited
14/11/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
https://orcid.org/0000-0002-1770-6216

Contact details
Leeds Institute of Health Sciences
Level 10 Worlsey Building
Leeds
United Kingdom
LS2 9LJ
+447786857747
g.traviss@leeds.ac.uk

Additional identifiers

Integrated Research Application System (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

Primary study design
Interventional

Study design
Case series

Study type(s)
Treatment

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

Key secondary outcome(s)

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.

Completion date
31/10/2023

Eligibility

Key inclusion criteria
1. T2 diabetes diagnosis
2. Experience of binge eating within last 6 months
3. Aged ≥18 years
4. English literate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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 kg/m²
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
United Kingdom

England

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

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type

Charity

Funder Name
Diabetes UK

Alternative Name(s)
The British Diabetic Association, 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

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?
Results article		11/11/2024	14/11/2024	Yes	No
HRA research summary			26/07/2023	No	No
Other publications	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
Participant information sheet	version 2	10/11/2021	22/11/2021	No	Yes
Protocol file	version 2	10/11/2021	22/11/2021	No	No