Providing Online guided Self-help for Eating disorders in adults with type 2 Diabetes: pilot study

PROTOCOL VERSION NUMBER AND DATE

Version 2.0 10/11/2021

RESEARCH REFERENCE NUMBERS

IRAS Number:	296694
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FUNDERS Number:	19/0006125
ISRCTN Number:	TBC
KEY WORDS:	Type 2 Diabetes; Binge Eating; Guided self-help; Eating Disorder; Online

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 requirements including HRA and REC compliance.

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 publicly 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:

...../...../.....

.....

Name (please print):

.....

Position:

.....

Chief Investigator:

Signature:  Date:

...../...../.....

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Name: (please print): Dr Gemma Traviss-Turner

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LIST of CONTENTS

KEY STUDY CONTACTS

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Grant Co-applicants	Prof Andrew Hill [1] Dr Michael Mansfield [4] Dr Claire Grace [5] Ian Beeton [6]	a.j.hill@leeds.ac.uk michael.mansfield@nhs.net clare.grace@nhs.net ianbeeton@hotmail.co.uk
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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**
Diabetes UK	**£120,593.51**

ROLE OF STUDY SPONSOR AND FUNDER

The University of Leeds will act as sponsor for the study, assuming overall responsibility for the employment of staff and the initiation, conduct and management of the study.

Diabetes UK are providing funding for additional staffing, equipment and to support the conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

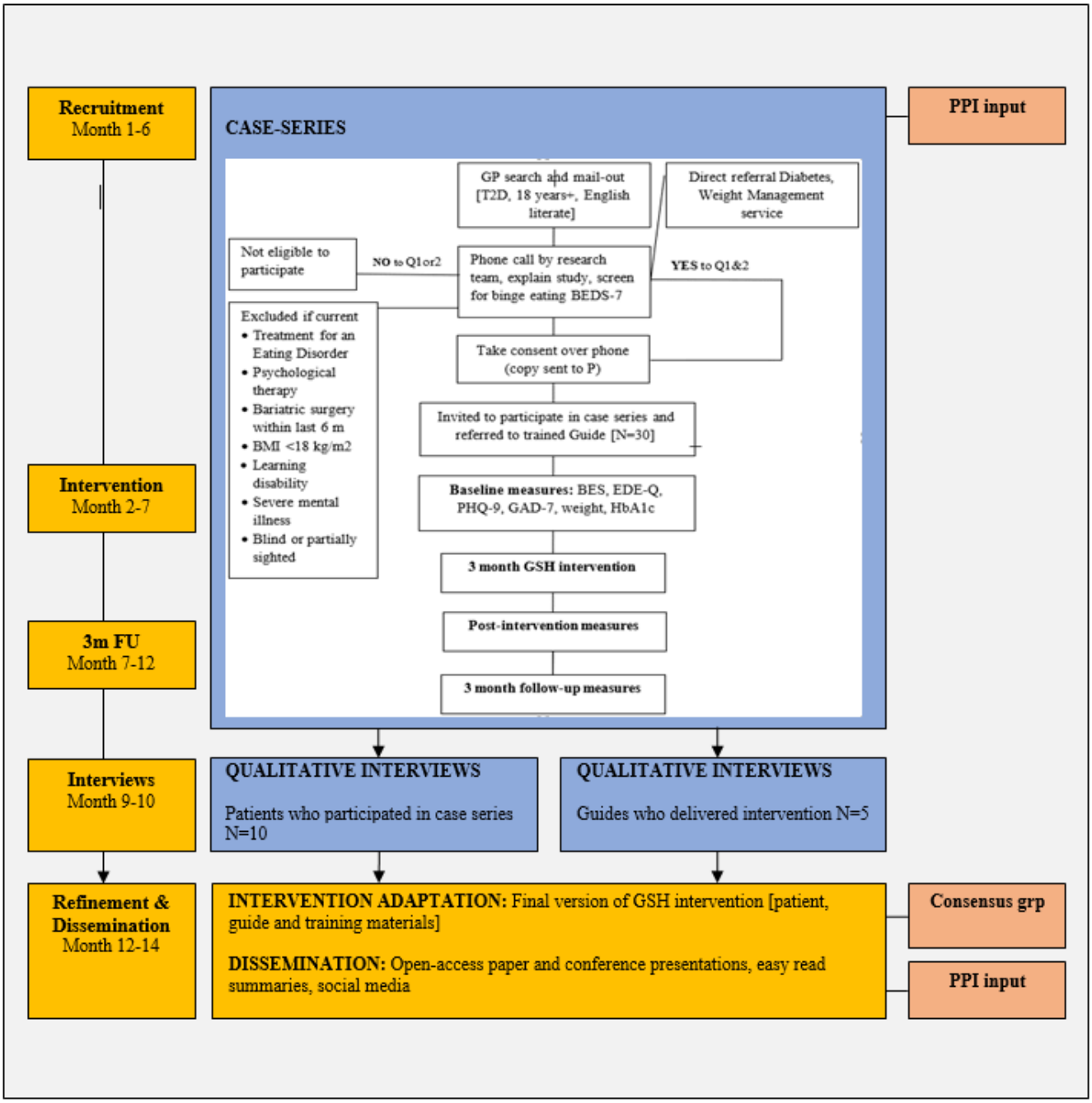
ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Project Management Group will comprise all co-applicants, collaborators and a member of the Patient and Public Involvement (PPI) advisory group where possible. They will meet quarterly and will be responsible for oversight of the project; making key decisions, ensuring procedures are followed and the project is completed on time.

Patient & Public Involvement Advisory Group will comprise 6-8 volunteers recruited through Leeds Diabetes UK support Group. The group will meet twice over the course of the project. The group lead (co-applicant IB) will act as the Service User Involvement Facilitator responsible for recruiting members and communicating with the group. The PPI advisory group have had input into the study design and will be responsible for reviewing participant materials and informing dissemination activities.

Expert Consensus Group will comprise a patient and healthcare professional (HCP) representative from each co-design workshop, commissioners and health care professionals including diabetes and mental health specialists. The group will meet twice over the course of the project. They will be responsible for using study findings and expert knowledge/experience to achieve consensus on the; Content of the adapted intervention; Delivery of the intervention: who, how, where?; Structure and content of Guide materials and training and how the intervention will be integrated into local services for a pilot trial.

STUDY FLOW CHART



STUDY PROTOCOL

Providing online guided self-help for eating disorders in adults with type 2 diabetes: pilot study

1 BACKGROUND

Diabetes and binge eating

An estimated 3.3 million people in the United Kingdom (UK) live with Type 2 diabetes (T2 diabetes) (NHS Digital 2019) and a further 940,000 remain undiagnosed (Public Health England 2016). Diabetes is described as one of the fastest growing health conditions in the UK, with the prevalence of T2D almost doubling over the last decade (Zghebi, Steinke et al.).

There are well-established links between obesity, disordered eating and T2D. People with T2D are more likely to lose control over their eating and to have obesity. Reviews show there is substantial variation in the prevalence rates of binge eating disorder (BED) between studies (1.2 to 25.6%) (Abbott, Dindol et al. 2018). Binge eating is known to potentially impair the physical health of people with T2D. It is associated with an increased risk of raised HbA1c, raised blood pressure, higher BMI and poor response to weight loss treatment (Meneghini, Spadola et al. 2006, Chao, Wadden et al. 2017). All which are predicted to increase the risk of long-term vascular complications of diabetes. Binge eating is also associated with significant psychological costs such as comorbid mental health problems, reduced quality of life, and poorer social functioning (Kessler, Berglund et al. 2013).

BED is characterised by uncontrolled overeating which is recurrent (at least 1 day a week for 3 months) and is associated with marked distress (American Psychiatric Association 2013). This leaves individuals feeling uncomfortably full, embarrassed, disgusted and guilty and is therefore associated with a reluctance to seek help.

A scoping search identified only one study evaluating a psychological intervention for binge eating problems in people with T2D (Kenardy, Mensch et al. 2002). The Australian study provides preliminary evidence that a group cognitive-behavioural approach may be effective for reducing binge eating in the short term compared to a therapy with no theoretical underpinning. However, the study was small, had no long-term follow-up, and was not conducted in the National Health Service in the United Kingdom.

Early intervention is crucial for eating disorders. People who access evidence-based treatment within the first 3 years, have better treatment outcomes (Treasure, Stein et al. 2015, Royal College of Psychiatrists 2019). Primary care staff play a key role in detecting and managing both T2D and eating disorders. Therefore, they appear well placed to offer medical and psychological support for both conditions.

The National Institute for Health and Care Excellence (NICE) recommends Guided Self-Help (GSH) as the first line of treatment for adults with BED. This should use cognitive behavioural self-help materials, focus on adherence to the self-help program and should be supplemented with brief supportive sessions (National Institute for Health and Care Excellence 2017). In a systematic review and meta-analysis of 30 randomized controlled trials of GSH for eating disorders there were significant effects of GSH on reducing global eating disorder psychopathology (overall relative risk -0.46) and binge abstinence (-0.20). The main moderator of binge abstinence was a diagnosis of BED, affirming the value of GSH in managing this disorder (Traviss-Turner, West et al. 2017).

Adapted GSH Intervention for people with T2 diabetes

Members of the current research team developed and evaluated a brief online GSH intervention for eating disorders. The intervention is patient-led, and Guide supported, and the content is based on the principles of cognitive behavioural therapy. It comprises two key elements. The first is the package of patient materials: a manual and a food diary. In the version that will be the focus of this study, will be available to participants online, hosted on the platform http://mytransitions.co.uk/. The second is a training package for people to act as Guides: their training, materials and supervision.

The online manual is divided into 7 sections; (1) an introductory session followed by sections titled; (2) What are eating disorders, (3) Physical and psychological health, (4) Food, health and unwanted behaviours, (5) Negative thoughts: identifying and challenging, (6) Learning to feel good about you, and (7) Relapse prevention: preparing for the future. These sections are made available a week apart, but with gaps of 2 weeks between sessions 4, 5, and 6 (possibly longer between 6 and 7). The intervention takes place over a 3-month period. Participants are required to engage with cognitive-behavioural tasks in the relevant sections prior to each appointment. A 30 minute session with the Guide accompanies each of these sessions via Zoom or similar. During these contacts, the Guide discusses the task completions with the participant and helps troubleshoot any difficulties encountered. The online platform has built-in tracking and evaluation data to monitor interaction with the system. Data gathered by the

platform is hosted securely on NHS accredited servers and the platform is IG and Cyber Security compliant and has been through the NHS Data Security and Protection toolkit (DSP). The data storage methodology is in line with current GDPR legislation and has been ratified by our security team.

In a randomized controlled trial of people presenting with disordered eating, we found a reduction in eating disorder psychopathology, key behaviours, and global distress, with treatment gains maintained at 3 and 6 months (Traviss, Heywood-Everett et al. 2011). More recently, we showed that GSH can be used effectively when delivered within a weight management service in Leeds for helping people with obesity to manage their binge eating problems (Traviss-Turner, Philpot et al. 2018).

Given the aforementioned difficulties experienced by people with T2 diabetes, Diabetes-UK commissioned our team to adapt this intervention through co-design, so that it is suitable specifically for managing binge eating in adults with type 2 diabetes.

Our proposed research is to pilot the adapted intervention with a small number of people who have both binge eating and type 2 diabetes, to assess the feasibility and acceptability of delivering this and to provide the necessary parameters for a full scale trial. This work is important because it speaks to the national research priorities of both Diabetes UK (Wylie, Shah et al. 2019) and the James Lind Alliance and build on an existing evidence-based resource, therefore has potential as a highly efficient way of filling the identified gaps in knowledge and provision.

2 RESEARCH AIM(S)

To pilot an online guided self-help intervention for the management of binge eating in adults with T2 diabetes.

2.1 Objectives:

To test the feasibility of recruiting and delivering an online guided self-help intervention for people with T2 diabetes and binge eating

To determine the acceptability of the intervention from both a participant and Guide perspective.

3 METHODS

PHASE 1: PILOT STUDY

3.1 Design

This will be an external pilot study. We will trial the adapted intervention as a case series, followed by qualitative interviews with a sample of participants and Guides.

3.2 Study Setting

In order to assess the feasibility of our recruitment and delivery processes, the study will take place in a range of services across England. Participants will be recruited using a hybrid approach through (1) GP practices recruited through our local CRN network and (2) by direct recruitment through weight management and diabetes services who express an interest in being trained and delivering the intervention.

3.3 Sample

We will recruit 30 participants through purposive sampling using the eligibility criteria described in Section 3.3.1: through GP surgeries and weight management and diabetes services. This is to ensure that the sample of patients is representative of those who will use the intervention. Computerised searching of GP records will be conducted to identify patients with a confirmed diagnosis of T2D. Potential participants will then be screened to confirm experience of binge eating within the last 6 months.

3.3.1 Eligibility Criteria

We aim to keep the eligibility criteria broad in order to capture a range of experiences.

Inclusion criteria for patients

- T2 diabetes diagnosis
- Experience of binge eating within last 6 months
- 18 years +
- English literate

Exclusion criteria

- Current treatment for eating disorder
- Current psychological therapy
- Bariatric surgery in last 6 months
- BMI <18 kg/m2
- Identify as living with a learning disability
- Severe mental illness
- Hearing or visual impairment
- Unable to speak English

3.4 Recruitment

3.4.1 Sample identification and consent

A hybrid recruitment approach will be adopted with participants recruited through (1) targeted mailouts from GP practices and (2) direct recruitment through weight management and diabetes services. As part of the evaluation, we will record return rates from both approaches to inform a larger trial.

(1) GP practices will be identified using our local CRN network who will reach out to GP practices. Practices will conduct a pre-specified search of their patient lists. A GP will then review the list and exclude any patients who are deemed unsuitable based on our criteria. Information packs containing participant information sheets (PIS) and consent forms will be distributed via Docmail®. In line with REC

requirements, the PIS will provide full details of the study, what is expected of participants, their rights during the study and any potential risks. It will also contain the lead researchers contact details should participants need to ask questions. Participants will receive a reminder by text message after 2 weeks. The PIS will contain a QR code which individuals can scan. This will link to an electronic consent form hosted by Online Surveys where participants can complete consent and provide their basic details to be contacted by a member of the research team or allocated member of the local Clinical Research Network.

(2) Similarly, within interested weight management and diabetes services, potential participants will be identified by the healthcare professional, who will briefly inform the individual about the study and issue the participant a physical numbered participant information pack (with QR code).

Individuals will be contacted by the lead researcher, research assistant or allocated member of the local Clinical Research Network by phone, to assess their eligibility. They will be asked the first two questions of the Binge Eating Disorder Screener – 7 item (BEDS-7 Herman et al 2016. See below). Individuals who answer YES to the following key questions will be invited to participate. They will be asked to provide verbal consent to participate in the intervention. A researcher will create an electronic copy which will be stored securely (and send the participant signed copy), along with some basic demographic information. GPs will be notified of the participants involvements and will request the participant book and appointment for a HBA1C test and height and weight measurement. Then they will be allocated to a trained Guide.

Binge Eating Disorder Screener – 7 (BEDS-7) (Herman, Deal et al. 2016)

1. Over the last 6 months have you had any episodes of excessive overeating (eating significantly more than what other people would eat in a similar period of time)?	Yes	No
Note: If you answered No to Question 1 you may stop, the remaining questions do not apply to you.		
2. Do you feel distressed about your episodes of overeating?	Yes	No

It is estimated that a total of 1000 invitations will need to be sent out through Docmail. It is expected that 15% of these will agree to participate (n=150). These individuals will be screened using the BEDS-7 key questions. Based on prevalence rates in the Kenardy paper (2001) where 20% binged at least once per week for 3 months, this should give us 30 participants. We will operate a first come, first serve basis and in the unlikely event that we are oversubscribed, we will offer participants the opportunity to contribute to ongoing PPI activities and they will receive their treatment as usual.

Participants will be allocated a code, their identifiable data (contact details) will be entered into a password protected Excel spreadsheet and stored securely on the University of Leeds OneDrive separately to other data from participants (See section 4.4 for further information on data storage) and kept for 10 years.

3.5 Intervention

The intervention (structure, materials and procedure) will be adapted from that outlined in the background section and in our previously published work (Traviss et al., 2011), based on the analysis of Workstream 1 and consensus group decisions. We anticipate a 7 session intervention completed over 3 months, accessed online and supported in 7 x 1 hour 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. Guides will be asked to contact the patients GP if any concerns arise during the intervention.

3.6 Measures and Follow-up

Participants will be required to complete a series of standardized outcome measures pre and post intervention and at 3 month follow-up.

3.6.1 Primary outcome

The primary outcome will be the proportion falling below cut-off on the Gormally Binge Eating Scale (BES) (Gormally et al., 1982). This offers a well validated measure of the severity of binge eating. The 16-item BES measures the presence and severity of binge-eating behaviors that may be indicative of an eating disorder. Total scores range from 0 to 46 points. We will use a cut-off of 17 which has high sensitivity (94%) and specificity (76%) for detecting BED

(Grupski et al., 2013). BES cut scores proposed by Timmerman were used to classify study participants into 3 severity subgroups: none or mild (≤ 17), moderate (18 to 26), and serious (≥ 27).

3.6.2 Secondary outcomes

Psychological measures

Secondary outcomes include binge cessation, eating disorder behaviours and psychopathology (28-item Eating Disorder Examination Questionnaire EDE-Q (v6) (Fairburn & Beglin 2008); mood (Patient Health Questionnaire -9 (PHQ-9) (Kroenke and Spitzer, 2002) and Generalized Anxiety Disorder -7 (GAD-7) (Spitzer et al., 2006) and health related quality of life (EQ5D-5L, (Herdman et al., 2011).

Physiological measures

GPs will request participants book an appointment to assess weight, height and physiological markers of diabetes (HbA1c) pre-post and at 3 months, unless they have had a recent test within the past 4 weeks.

Engagement and drop-out

We will assess uptake of the intervention and participant interaction with the platform. We will utilise advanced interaction and tracking technology to identify detailed interactions of the participants with the online self-help materials. This will include (but isn't 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 tiggers embedded within the learning content which will provide a good standard for data coherence. We will also document the number who drop-out of the intervention and withdraw from the study.

3.7 Analysis

A detailed statistical analysis plan will be drafted before data analysis is conducted. Proposed analyses are briefly described here. The flow of participants through the study will be detailed in a

CONSORT style diagram. The number of individuals withdrawing from the intervention and/or study and reasons for withdrawal will be documented. Means and standard deviations will be used to describe the characteristics of the sample. The primary outcome (Gormally BES) will be analysed using a linear mixed model, including assessments at pre and post-intervention and 3 month follow-up. The model will provide an estimate of the overall treatment effect over time as well as estimates at individual time points, which will be reported as estimates with 95% confidence intervals. Secondary outcomes will be analysed using similar methods. We will use regression analyses to determine whether user data from the platform predicts outcome.

PHASE 2: QUALITATIVE INTERVIEWS

To evaluate acceptability of both the intervention and research process (including outcome measures), qualitative interviews will be conducted with participants and Guides on intervention completion. This will follow the basic procedure of our previous process study (Traviss et al., 2013). Interviews will be carried out remotely via Zoom (or similar).

3.8 Sample

We will invite 5 Guides who have delivered the intervention along with upto 10 participants to take part in a semi-structured interview. We will use purposive sampling to try and capture a range of experiences (age, gender, ethnicity, job role, site location, those who completed and those who dropped out of the intervention).

3.9 Consent

Following completion (or drop-out) of the intervention, a member of the research team will contact Participants and Guides by phone or email (their preferred method) to invite them to take part in an interview. Interviews will take place via zoom (or similar).

At the beginning of the interview, a member of the study team will take verbal consent for participation in an interview (and recording) before the interview commences. This will involve participants/Guides confirming to the researcher that they have received the study information, had the opportunity to ask questions, agree to the consent statements on the example consent form and they agree to participate in the study. The interviewing researcher will document this verbal consent electronically and send a copy to the participant. Basic demographic information (e.g. age, gender and ethnicity) will be obtained by the interviewer at the time of the interview.

3.10 Topic guide

Interview topic guides have been developed to help structure the interviews. Key questions with prompts will explore; acceptability of the intervention, Guide training, barriers and facilitators to delivery of the intervention and how the intervention might be integrated within health care settings. Topic guides vary slightly for the different groups (completers, non-completers, Guides). An additional question around reasons for non-completion will be asked to those who decided not to continue with the intervention. Interviews will be conducted by the PI or research assistant and will take approximately 45 minutes.

3.11 Analysis

Interviews will be recorded, anonymised using the participant code and stored securely in encrypted files on the University OneDrive. They will be transcribed and analysed using Thematic Framework Analysis (Ritchie and Spencer, 2002). Analysis will be conducted by the study research assistant under the supervision of GTT and AH.

3.12 Expert consensus group

The Expert consensus group composition is outlined on page vi. The group will meet following delivery of the intervention. They will be responsible for using study findings and expert knowledge/experience to achieve final decisions on the; Content of the adapted intervention; Delivery of the intervention: who, how, where?; Structure and content of Guide materials and training and how the intervention will be integrated into local services.

4 ETHICAL AND REGULATORY CONSIDERATIONS

4.1 Assessment and management of risk

The study population does not represent a vulnerable group; therefore, we do not anticipate any major ethical issues. We have designed exclusion criteria in an attempt to exclude anyone who might be vulnerable. Therefore, where study participation is felt to be detrimental to health and wellbeing, we will not make an approach to participate. All participants will receive their usual care for T2 diabetes, and so no treatment will be withheld by participating in the study.

Some participants may benefit from the study intervention as this is not routinely offered to our target group. By participating, participants will also receive a more intensive level of monitoring than that normally received. The benefit to Guides will be the additional training in eating disorders and behaviour change techniques that they will receive as part of the study to equip them to work with this client group in the future.

There will be a negligible risk that participants who lose control over their eating may feel uncomfortable discussing their eating difficulties during the program, completing questionnaires relating to their mood or during qualitative interviews. At the start of the intervention and before interviews are conducted, participants will be reminded that they are free to withdraw at any point without giving a reason but that their data up until the time of withdrawal may still be used anonymously. Study researchers and Guides will be trained in identifying risk and a clinically qualified member of the study team (SHE) will be available on call to offer support and guidance should concerns arise. Participants will also be provided with a list of contact details for local mental health services and signposting to their GP should they require them. Guides will also be asked to notify the patients GP should any issues arise.

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

This phase of the study will take place within NHS services, accessing NHS patients, therefore, before the start of the study, the Chief Investigator will submit the relevant information to gain a favourable ethical opinion from the NHS ethics committee and the HRA using the Integrated Research Application System (IRAS).

For any amendments to the study, the Chief Investigator will submit the relevant amendment form along with amended documentation. If the amendment requires HRA approval this will be done by submitting the draft IRAS generated amendment form along with amended documents through the IRAS system which gets submitted to the HRA. Any changes will not be implemented until approval has been granted

and other mechanisms are in place to implement at site. All correspondence with the REC will be retained. The Chief Investigator (GTT) will produce annual and final reports to the ethics committee as required and notify them of the end of the study. Amendment history will be documented using an amendment log (See Appendix 2). This will outline document versions relating to each amendment.

4.3 Patient & Public Involvement

Patients and Public will be involved throughout the research process. The PPI approach will combine [1] collaboration with a lead PPI representative who is a co-applicant (IB) and [2] consultation with a larger PPI group – the Patient Public Advisory Group.

[1] The PPI lead will contribute to two PPI meetings and also provide feedback at the quarterly study team meetings. This approach will ensure the study team's interpretations of meetings and workshops are accurate from a patients' perspective.

[2] The PPI Advisory Group consisting of 6-8 members living with T2 diabetes and experience of loss of control over eating in the last 2 years has already been established through Leeds Diabetes Support Group.

Our PPI Advisory Group will be involved at two stages of the research. Firstly in the set-up stage, developing the study documentation and providing constructive feedback on the protocol, participant information sheets and branding. Secondly, by contributing to dissemination activities in addition to academic audiences such as, helping to identify fora and groups through which they might seek advice about T2 diabetes, eating and their weight. Social media activity will also be critical to ensure the results are made widely available in formats accessible to networks of people with T2D, their supporters, and the practitioners who work with them. Members of the PPI Advisory Group will be reimbursed for their time and travel in line with the INVOLVE good practice guidelines.

4.4 Data protection and patient confidentiality

All investigators will comply with the GDPR rules, those specifically issued by the University of Leeds and the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information. Participant contact details from permission to contact will be stored securely in encrypted files, in a separate database to outcome data, demographic information, and transcripts, which will be anonymised using the same ID code. Participants will be given an ID code

(starting with P for participants and HCP for healthcare professionals followed by a number). All data will be stored on the University of Leeds OneDrive which is a secure area permitted by the University Information Security Policy. All documents will be encrypted with passwords and in the case of emails, passwords will be issued separately. Databases will be accessed using University of Leeds computers or via the secure Remote Desktop application which uses Duo-Protected authentication for access and is provided by University of Leeds if working remotely from the university site. The data will only be accessible to the research assistant and supervisors (GTT, AH and JR). Once analysed the data will not be identifiable, therefore can be transmitted to sponsors, co-investigators and used for purposes of publication.

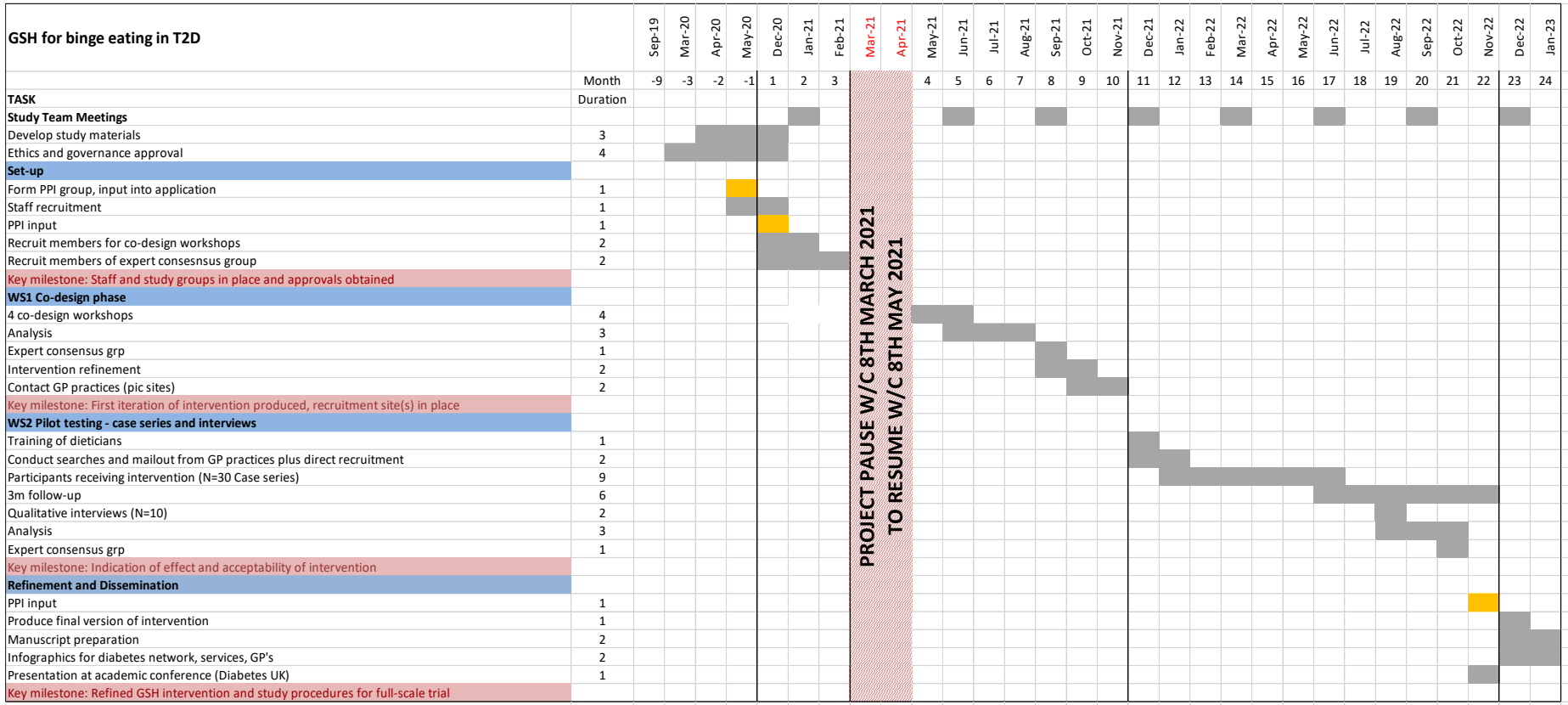
Any paper copies of study documentation will be held securely for a period of 10 years at the University of Leeds. Electronic copies of anonymised study data will be held indefinitely in line with open access data policies. Data that is no longer needed will be deleted or destroyed including emails and electronic files.

4.5 Indemnity

The University of Leeds has agreed to act as sponsor for the research and therefore the University Indemnity arrangements will apply. This will include any harm to participants arising from the design, conduct or management of the research.

4.6 Timeline

Recruitment for this workstream will run from December 2021 to end January 2023


GSH for binge eating in T2D
Sep-19
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Month
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TASK
Duration
Study Team Meetings
Develop study materials 3
Ethics and governance approval 4
Set-up
Form PPI group, input into application 1
Staff recruitment 1
PPI input 1
Recruit members for co-design workshops 2
Recruit members of expert consesnsus group 2
Key milestone: Staff and study groups in place and approvals obtained
WS1 Co-design phase
4 co-design workshops 4
Analysis 3
Expert consensus grp 1
Intervention refinement 2
Contact GP practices (pic sites) 2
Key milestone: First iteration of intervention produced, recruitment site(s) in place
WS2 Pilot testing - case series and interviews
Training of dieticians 1
Conduct searches and mailout from GP practices plus direct recruitment 2
Participants receiving intervention (N=30 Case series) 9
3m follow-up 6
Qualitative interviews (N=10) 2
Analysis 3
Expert consensus grp 1
Key milestone: Indication of effect and acceptability of intervention
Refinement and Dissemination
PPI input 1
Produce final version of intervention 1
Manuscript preparation 2
Infographics for diabetes network, services, GP's 2
Presentation at academic conference (Diabetes UK) 1
Key milestone: Refined GSH intervention and study procedures for full-scale trial
PROJECT PAUSE W/C 8TH MARCH 2021
TO RESUME W/C 8TH MAY 2021

5 DISSEMINIATION POLICY

5.1 Dissemination policy

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 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.

5.1.1 Author eligibility

Author eligibility will be informed by guidance produced by the International Committee of Medical Journal Editors (ICMJE). Authorship will be based on the following 4 criteria and all co-applicants will be given the opportunity to contribute:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND

- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

6 REFERENCES

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7 APPENDICES

Appendix 1- Required documentation

Appendix 2 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made