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Version: Accepted Version

Article:
Traviss-Turner, G. orcid.org/0000-0002-1770-6216, Bowes, E. orcid.org/0009-0004-6091-1938, Hill, A. et al. (6 more authors) (2024) Guided self help for binge eating in diabetes Binge eating and type 2 diabetes: POSE-D pilot. British Journal of Nutrition. ISSN 0007-1145

https://doi.org/10.1017/s0007114524002599

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https://doi.org/10.1017/S0007114524002599 Published online by Cambridge University Press

Accepted manuscript

Guided self help for binge eating in diabetes Binge eating and type 2 diabetes: POSE-D pilot

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This peer-reviewed article has been accepted for publication but not yet copyedited or typeset, and so may be subject to change during the production process. The article is considered published and may be cited using its DOI
10.1017/S0007114524002599
The British Journal of Nutrition is published by Cambridge University Press on behalf of The Nutrition Society

Abstract

People with type 2 diabetes are more likely to experience binge eating than the general population, which may interfere with their diabetes management. Guided Self-Help (GSH) is one of the recommended treatment options for binge eating disorder, but there is currently a lack of evidenced treatment for binge eating in individuals living with type 2 diabetes. The aims of this pilot study were to test the feasibility and acceptability of recruiting and delivering the adapted, online Working to Overcome Eating Difficulties GSH intervention to adults with T2 diabetes and binge eating. The intervention comprises GSH materials presented online in 7 sections delivered over 12-weeks, supported by a trained Guide. 22 participants were recruited in a case series design to receive the intervention and we interviewed 4 Guides and 5 participants afterwards. We measured binge eating, mental wellbeing, quality of life and weight at pre-post and 12-week follow-up. Results showed a significant reduction in binge eating at the end of the intervention, which continued to improve at follow-up. Before the programme 92% of participants scored above cut-off for binge eating. This reduced to 41% post-intervention and no-one at follow-up. These changes were accompanied by significant improvements in depression, anxiety and small changes in eating disorder symptoms. Participants reported making better lifestyle choices, eating more mindfully, and having increased self-confidence. The study shows preliminary evidence for online GSH tailored to the needs of individuals with T2D as a feasible and acceptable approach to improving binge eating, diabetes management and mental wellbeing.

Key words: Binge eating, Type 2 diabetes, Guided self-help, Psychological treatment, Eating control

Abbreviations:

GSH – Guided Self-Help

T2D – Type 2 Diabetes

BED – Binge Eating Disorder

PPIE - Patient Public Involvement and Engagement

https://doi.org/10.1017/S0007114524002599 Published online by Cambridge University Press

Introduction

Almost 4 million people in the United Kingdom (UK) live with Type 2 diabetes [1]. Current recommendations for the management of Type 2 diabetes focus on healthy eating, blood glucose monitoring and weight loss where necessary [2]. The focus on diet and monitoring means an association between Type 2 diabetes, obesity, and disordered eating is unsurprising. People with Type 2 diabetes are 3 to 6 times more likely to have obesity [3]. Binge Eating Disorder (BED) is the most commonly reported eating disorder in people with T2 diabetes and itself, is an independent risk factor for the development of Type 2 diabetes [4–6]. A systematic review of studies of eating disorder prevalence in patients with Type 2 diabetes suggests substantial variation in documented prevalence rates of BED (between 1.2 to 25.6%) [7]. However, an estimated 20% of individuals with Type 2 diabetes experience an eating disorder, the most common being BED [5].

Binge eating disorder is characterised by episodes of uncontrolled overeating (consuming unusually large amounts of food in a short space of time accompanied by feelings of 'loss of control' overeating) [8]. Binge eating (the key behavioural feature) is known to challenge the physical health of people with Type 2 diabetes. It is associated with an increased risk of raised HbA1c, raised blood pressure, decreased insulin sensitivity, higher BMI, and poorer response to weight loss interventions [5,9–12]. All of these 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 [13], reduced quality of life, and poorer social functioning [3]. BED often goes undiagnosed and untreated because of its secretive nature and associated feelings of shame and guilt. Therefore; individuals do not disclose their difficulties to medical professionals [14,15]. Less than half of patients with BED receive any form of treatment for their eating disorder [8].

There is currently a lack of evidence-based treatments that address BED specifically in people with Type 2 diabetes. The limited evidence that exists comprises small pre-post studies with female samples conducted outside of the UK [12]. Identifying and addressing this disorder in patients with Type 2 diabetes is a major challenge for healthcare providers. This is a product of the low levels of help-seeking and the observation that many of the medications targeting hyperglycaemia are associated with increased appetite and weight gain [16–19]. In addition, the

https://doi.org/10.1017/S0007114524002599 Published online by Cambridge University Press

standard treatment for Type 2 diabetes and obesity is to prescribe a rigid dietary intervention. There are concerns that this presents a risk for some of exacerbating binge eating [15,20]. Consequently, there has been a marked interest in how to best manage binge eating for people with Type 2 diabetes [15,21–23]. Diabetes-UK highlighted the need to develop interventions tailored to the needs of individuals with diabetes and eating disorders [24].

Early intervention is critical [25,26]. With a known demand-capacity gap in the treatment of eating disorders, there is a need for less resource intensive interventions [27]. 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 [28]. A systematic review and meta-analysis of 30 randomized controlled trials of GSH for eating disorders showed significant effects of GSH in 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 [29].

The current team developed the Working to Overcome Eating Difficulties GSH intervention for use with adults (aged 16+) with disordered eating behaviours. This is a 12-week CBT-based programme, comprising a GSH manual along with 7 guidance sessions delivered face-to-face by a trained Guide. Randomized controlled trial evidence showed that the intervention led to reductions in eating disorder psychopathology, key behaviours, and global distress, with treatment gains maintained at 3 and 6 months [30]. Recent research has demonstrated effectiveness when delivered within a Tier 3 specialist weight management service for helping people living with obesity to manage their binge eating [31].

In an earlier phase of this research, we adapted the original Working to Overcome Eating Difficulties GSH intervention using principles of co-design, with input from expert patients and healthcare professionals working with individuals with T2D and/or disordered eating, so that it was delivered online and tailored specifically for people with Type 2 Diabetes [32]

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The current research is a first step in evaluating the adapted online GSH intervention. The pilot study specifically aimed to:

1. Test the feasibility of recruiting and delivering the online guided self-help intervention to people with T2 diabetes and binge eating
2. Determine the acceptability of the intervention from both a participant and Guide perspective.

Methods

The study was registered with the ISRCTN registry (https://www.isrctn.com/ISRCTN12377526) and was conducted according to the guidelines laid down in the Declaration of Helsinki and all procedures involving human subjects were approved by the Yorkshire & The Humber - South Yorkshire Research Ethics Committee (22/YH/0016/296694) and HRA and Health and Care Research Wales. Written informed consent was obtained from all subjects.

The adapted Working to Overcome Eating Difficulties GSH intervention

As in the original intervention, the adapted version adopted a transdiagnostic approach. It covered a range of disordered eating features and was based largely on cognitive behavioural principles. The current intervention was an online treatment with guidance and comprised three components: adapted online GSH materials, Guide training and supervision tailored to working with people with T2 diabetes and remote Guidance sessions for patients. Further details of the intervention and adaptation are provided in Coales et al 2023 [32]

GSH Materials

The GSH materials were hosted on the https://mytransitions.co.uk/ website. The materials were divided into seven sections; an introduction and sessions on eating disorders, physical and psychological health, food, negative thoughts, self-esteem and relapse prevention (see Appendix 1). Service users were required to complete homework tasks in each section prior to the session with their Guide. The intervention took place over 12 weeks, with content being released for

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completion in a phased manner. Chapters 1-4 were made available a week apart, with gaps of 2 weeks between chapters 4, 5, and 6 and longer between 6 and 7. There was a scrapbook area to make notes and a messaging facility for communicating asynchronously with the Guide. A template 'eating diary' was available for download. A vignette of a character called Sam who lives with type 2 diabetes ran throughout the intervention. Sam was used to make the content of the intervention more relatable to users living with T2 diabetes.

Guidance

Participants received seven, 60-minute remote guidance sessions with a trained Guide, via phone or video-conferencing. Guides were healthcare professionals such as dietitians, psychologists and nurses who completed training to support this specific intervention. During the guidance sessions, Guides discussed the homework tasks and helped troubleshoot any difficulties encountered. Guidance sessions were delivered in the same phased pattern as the sections of the intervention.

Guide training

Guide training was delivered in half a day. The training covered the content of the intervention, the rationale for GSH, the role of the Guide, key skills to elicit behaviour change such as motivational interviewing, and ways in which individuals living with diabetes may have difficulties with their eating. Guides were provided with access to the online GSH platform and a paper copy of the materials. The training was supplemented with ongoing, 1-hour supervision sessions with a specialist eating disorders clinician to discuss case examples. Technical support was provided throughout the study by the platform developers. For the purposes of this study, training also included the requirements of the evaluation process.

Recruitment and Procedure

Pilot study

We used a hybrid recruitment approach. Recruitment occurred between August 2022 and April 2023. Participants were recruited through a targeted mailout in primary care from a general

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practice, direct recruitment through NHS Specialist Weight Management and Diabetes services, and by a campaign circulated on social media sites (Facebook, Instagram, Twitter and LinkedIn).

All participants were provided with a Participant Information Pack, either electronically or by mail. Those who provided their consent to be contacted, were phoned by a member of the study team to provide full informed consent, complete screening questions to confirm eligibility and collect some basic demographic information.

Inclusion/exclusion

In order to be included, individuals had:

- T2 diabetes diagnosis
- Experience of binge eating within last 6 months confirmed by first two items of BEDS-7 (episodes of excessive overeating AND accompanied by feelings of distress)
- Were 18 years +
- Were English literate

Participants were excluded if they had:

- Current treatment for eating disorder
- Current psychological therapy
- Bariatric surgery in last 6 months
- BMI <18 kg/m2
- Identified as living with a learning disability
- Severe mental illness
- Hearing or visual impairment
- Pregnant or living with gestational diabetes

Participants' provided consent for clinicians to be notified of their involvement in the study and requested that the HbA1C tests and height/weight measurements were booked in. Participants

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received log-in details for the online platform and were allocated to a trained Guide by the research team.

Measures

Participants were required to complete a series of standardized outcome measures pre-intervention (baseline), post intervention, and at 12-week follow-up. The measures were administered via Online Surveys. Participants were contacted by email and invited to complete the measures online. They could also request to complete them over the phone with a researcher or receive a paper copy if preferred. The measures outlined below were completed at all time points.

Primary outcome

Gormally Binge Eating Scale (BES) The primary outcome was the Gormally Binge Eating Scale (BES) [33]. This offers a well validated measure of the severity of binge eating. The 16-item BES measures the presence and severity of binge-eating behaviours that may be indicative of an eating disorder. Total scores range from 0 to 46 points. We used a cut-off of 17 which has high sensitivity (94%) and specificity (76%) for detecting BED [34]. BES cut scores proposed by [35] were used to classify study participants into 3 severity subgroups: none or mild (≤ 17), moderate (18 to 26), and severe (≥ 27). We assessed the proportion falling below the cut-off of 17.

Secondary outcomes

Psychological measures

Eating Disorder Examination Questionnaire EDE-Q (v6) [36] is a 28-item self-report questionnaire that measures the range, frequency and severity of eating disorder behaviours and associated psychopathology. The measure comprises 4 subscales (restraint, eating, weight and shape concern) and a global score, with higher scores indicating more problematic eating difficulties. The measure has good psychometric properties with good internal consistency (α = .81 - .93 across the subscales) [37–42].

Patient Health Questionnaire -9 (PHQ-9) [43] is a 9-item measure of depression symptoms and severity. Items refer to the past 2 weeks and are rated from 0 (not at all) to 3 (nearly every day), therefore the measure is scored from 0 to 27. Total scores of 5, 10, 15, and 20 represent cut

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points for mild, moderate, moderately severe and severe depression with a cut-off score of ≥10, which has a sensitivity and specificity for major depression of 88%. The measure has demonstrated good psychometric properties with excellent internal reliability (α = .89) [44].

Generalized Anxiety Disorder -7 (GAD-7) [45] is a 7-item screening and monitoring tool for generalised anxiety symptoms. Items refer to the past 2 weeks and are rated from 0 (not at all) to 3 (nearly every day), therefore scores range from 0 to 21, with higher scores indicating more severe anxiety. The GAD-7 has high internal consistency (α = .92) and test-retest reliability (*r* = .83) and demonstrates a sensitivity of 89% and specificity of 82% at a cut-off score of ≥10 [45]. The GAD-7 is increasingly being used as a screening measure of non-specific anxiety disorders in primary care clinical practice at a cut-off point of ≥8 (which indicates 'moderate' anxiety) [46].

EQ5D-5L [47] is a standardized measure of health-related quality of life. It comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems. This results in a 1-digit number that expresses the level selected for that dimension. The digits for the five dimensions can be combined into a 5-digit number that describes the patient's health state. This can be converted into a single index value which can be used to facilitate calculation of quality-adjusted life years (QALYs). The measure has acceptable internal consistency (α = .89) [48].

Physiological measures

GPs or trained Guides booked an appointment to assess weight, height and physiological markers of diabetes (HbA1c) at the 3 time points (unless participants had been tested within the last 4 weeks).

Engagement and drop-out

We assessed participant's engagement with the intervention using advanced interaction and tracking technology within the online platform. This included the number of sessions and proportion of online material completed and frequency of access on the platform. We also

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documented the number who dropped-out of the intervention or withdrew from the study, and their point of withdrawal.

Qualitative interviews

Participants who completed the intervention, non-completers and Guides (who had supported at least one participant to completion), were invited to take part in an interview. Those eligible to be interviewed were contacted via email and/or telephone, and reminder was sent. They were asked to provide informed consent to take part in an interview. Interviews lasted around 45 minutes and were conducted remotely at a time to suit the participant. They were recorded and transcribed using the auto-transcribe function on Microsoft Teams or Zoom. We used semi-structured interviews with topic guides tailored for Guides, completers and non-completers. The topic guides reflected on individuals' current health, the recruitment process, experience of working through the intervention (including working with their Guide, the online platform and any changes they made as a result), and the research process and outcome measures. In addition, the Guides version focussed on experiences of training and supervision and ending the intervention.

Analysis

Quantitative

The flow of participants through the study is detailed in a CONSORT style diagram (Figure 1). The number of individuals withdrawing from the intervention and/or study and reasons for withdrawal was documented.

Participant's individual responses to pre-intervention, post-intervention, and 12-week follow-up measures were scored in line with the guidance for each outcome measure, as outlined in the section above.

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Participant baseline characteristics are reported using Mean and Standard Deviation (SD) or N and percentage (%). These were cross-tabulated against completeness of data: that is full data (3 time points), pre and post only, or baseline only.

For primary and secondary outcomes, we used mixed-effects modelling; a mixed-effects model was fitted for each 'continuous' outcome measure (Gormally BES, EDE-Q, PHQ-9-7, GAD, EQ5D, and weight). The outcome measure was regressed upon discrete time (pre, post, follow-up) as a fixed effect with a random intercept for participant. The discretisation of time, that is three time points, permitted non-linear time effects and the random effect for participant accounted for the clustering of measurements within participants. We used a Wald test (*t*-test) for the coefficients for time (post and follow-up).

Platform user data are reported in terms of the number of sessions completed and the number of times participants accessed the platform.

Qualitative

Data were generated through interviews, managed in NVivo 12, and analysed using the thematic Framework method.

The Framework method is a structured, matrix-based approach to the analysis of qualitative data [(49)]. This method ensured we were led by the data to generate our coding index and themes in a structured way and could illustrate them using quotations from participants.

Two researchers were involved in the data collection and analyses (EC, GTT) and followed the five interconnected stages. The first stage was ***familiarisation*** with the data. Both researchers read all transcripts and made notes on interesting or significant findings. Secondly, independently the researchers reviewed the notes in relation to the research questions and topic guide. These were used to ***construct the initial thematic framework*** or 'coding index' of themes and subthemes in NVivo. The third stage ***(indexing and sorting***) involved applying the agreed initial coding index to the transcripts. This was an iterative process, so themes/subthemes were

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merged, split and renamed as appropriate in this process. Data were then ***summarised and displayed*** in a matrix. Themes were displayed in rows and participants in columns with quotes lifted from the transcripts. Finally, together the researchers used Post-it notes on flip chart paper to ***map and interpret*** the data in relation to similarities and differences between participants and Guides experiences. Data were presented in three matrices showing themes, which were unique to participants and Guides, and those that were shared between the groups.

Patient Public Involvement Group (PPIE)

Throughout the process, we involved our PPIE group. They helped inform the recruitment materials. Key suggestions were made around the language and images used. The group advocated using terms such as 'control of eating' where possible rather than 'binge eating'. And removal of images that had connotations of greed or blame. We adapted the language accordingly in both the recruitment materials and online intervention.

Results

Quantitative

Participants

A total of 32 participants were recruited to the study, 22 were eligible, completed the baseline questionnaires and commenced the GSH intervention (Figure 1). Thirteen participants were recruited through NHS Specialist Weight Management and Diabetes Services, three were recruited through GP practice mailout and six through social media. Seventeen participants (77%) completed the post-intervention questionnaires and twelve (55%) completed the 12-week follow-up questionnaires.

The characteristics of participants at each time point are summarised in Table 1. Participants comprised of a range of ages, ethnicities, marital status, and education levels. The average length of time since type 2 diabetes diagnosis was 6.78 years.

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Binge eating

In the mixed effects model for binge eating (Gormally BES) which included observations from all participants, Wald tests showed individuals scored 26.8 (SE = 2.07, t=13.0 p<0.001) at baseline, which decreased to 15.1 (SE = 2.45, t=-4.77, p<0.001) post-intervention and 9.7 (SE = 2.73, t=6.26, p<0.001) at 12-week follow-up.

At baseline, 91.9% of participants scored above the cut-off for moderate or severe binge eating (>17). At post-intervention, this decreased to 41.2% and further decreased to 0% at the 12-week follow-up (Figure 2).

Psychological measures

Mean scores and standard errors for all measures and time points are presented in Table 2.

Eating Disorder Examination Questionnaire - The mixed effects model showed a small change in eating disorder severity on all EDEQ subscales and on the Global score. This was not significant at post-intervention (t= -1.46, p<0.157) but reached significance at 12-weeks follow up (t=-3.53, p<0.001) (see Table 2).

Depression – The mixed effects model showed PHQ-9 depression scores improved post-intervention (t= -2.42, p<0.023) and continued to improve at 12-week follow-up (t=-3.42, p<0.002).

Anxiety **–** The mixed effects model showed GAD-7 anxiety scores improved between baseline and post-intervention (t=-3.19, p<0.005) and were then maintained at 12-week follow-up (t=-2.70, p<0.012).

EQ5D-5L – There was no significant change on the visual analogue scale for quality-of-life scores by time at post intervention (t=1.88, p<0.071) or at 12-week follow-up ((t=0.897, p<0.38).

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Physiological measures

There was no significant change in weight (kg) between baseline and post-intervention (t=-1.25, p<0.221) and between baseline and 12-week follow-up (t=-0.34, p<0.740).

Our data for HbA1c at follow-up time points was poor (59% at baseline, 35% post-intervention, 17% at follow-up), therefore we cannot report this measure accurately.

Engagement and drop-out

Seventeen out of 22 (77%) participants completed the post-intervention measures, 12 (55%) completed all 3 time points. Those who completed all time points had lower Gormally and PHQ 9 scores at baseline (Table 3).

However, an independent 2-sample t-test between completers and non-completers showed a significant difference in Gormally scores between baseline (M = 22.77; SD = 8.79) and 12-week follow-up (M = 7.17; SD = 4.90) in individuals who completed all three time points ($t(11)$ = 5.60; p <0.001). This indicates that when controlling for high scores dropping out of the intervention, binge eating behaviours still improved.

In terms of intervention engagement, 17 participants completed the full intervention. 22 participants completed the introduction, 21 completed chapter 1, 19 completed chapter 2, 17 completed chapter 3, 16 chapter 4, 12 chapter 5 and 11 chapter 6 (Figure 1). The mean number of log-ins to the platform was 13.21 (SD = 8.34). For participants who completed all 6 sessions (additional to the introduction), the mean was 19 (SD = 7.92). Results show that across the sample, participants took longer to complete later chapters, spending a mean of 1.73 days (SD = 2.28) on the introduction compared to a mean of 3.40 days (SD = 5.04) for chapter 3 and a mean of 7.09 days (SD = 10.03) for chapter 6.

Qualitative

Participants

Four Guides (EB, YR, MH, VC) and five participants (CB, PW, SC, GM and BJ) took part in qualitative interviews. All Guides were female with a professional background in dietetics/nutrition and had completed the intervention with at least one participant. All

participants were intervention completers, three were male and two female. Themes are presented separately for Participants and Guides and then those described by both groups and summarised in Figure 3.

Participant Themes

Changes as a result of the intervention

Reduced binges – "*I still had a couple of times where I've binged because I've been under stress and I've come home and it's been cold. Put the heating on got under a blanket type of thing and just had some crisps or whatever, do you know? But they are not as bad as what they were before" (CB)*

Better diabetes management – "*I've just had a diabetes annual review. And um, I've dropped over 10 points. It's a figure which I'm really proud of myself for doing." (PW)*

Wider lifestyle changes – "*Of lifestyle, not just eating." (PW)*

"I have started sort of keeping moving and moving more, walking more, even if it's just a rather than coming straight home I'll go." (CB)

Mindful eating- "*Hey, but yeah, and also being mindful about what I'm eating.****" (CB)***

Necessity of having a Guide

Good relationship – "*The fact that she used her first name […]. It felt very much so that it was a partnership. [...] Genuine interest and um, genuine empathy back." (SC)*

"The communication was really quite clear and I think partly she was much more interested in me as a person than just how was I responding to having gone through an exercise." (GM)

Support navigating sections *– "Yeah, it was very interesting going through the materials because there were a number of times where I felt that it wasn't engaging me." […] And so there*

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were bits where it kind of felt a little bit excluding." (GM). And the participant inferred the Guide kept them going.

Guide knowledge – *"I think with her knowledge outside of the program that allowed her to help me rationalize some of my thoughts." (SC)*

Supported wellbeing – "*How I felt about it and everything else, and she (Guide) was very, very good that way. But she talked to me and asked if there was anything else I wanted to talk to her about. Like [...] the options to either talk about something different or about the work I've done. But it's worked really, really well." (PW)*

The research process

Recruitment process acceptable – "*it was promoted to me really well, I thought, you know, and it sounded really interesting. And then I wanted to get help for other people as well as myself." (CB)*

Outcome measures acceptable - "*quite straightforward" (CB)*

Ending the intervention

"Yeah, I think I could do with another session cause the last one was a month, weren't it? So I think maybe another session a couple of months or you know three months or something like that afterwards, where what you've learned." (CB)

Guide Themes

Patient engagement

Challenges to engagement – "*A challenge in how to structure some of the sessions is that um, if you can't get a participant to have the expectation of reading the chapters ahead of time early on." (EB)*

"There was a bit of a problem around kind of motivation and patient understanding what they actually are expecting from the services as well." (MH)

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Large amount of information - *"My overall kind of experience and in terms of feedback from the participants was that it was, an awful lot of work for them to do. (...) I'm not sure they realized and I realized how big that workbook was and how much of it a commitment it was because I think when people really are struggling with their mental health, maybe it's just a bit unrealistic to commit to something like that. (YR)*

"Maybe more bite sized chunks might have made it a bit more successful." (YR)

Drop out after sessions 1-2 - *"The highest amount of dropout, or at least you know, choosing not to go ahead with the study seems to occur sort of around that chapter one, chapter two and I think perhaps that's because those chapters are a little bit more therapeutic and they're sort of really introducing them to the intervention." (EB)*

Guide training and supervision

Half day sufficient -*"about right, I mean it would be nice to have longer to spend on these things, but you don't in your clinical caseload. So and it was probably about right for what I needed. And like I said, I've done a lot of behaviour change and motivational interviewing" (VC)*

Training positive - *"in terms of the training, yes, it was all very thorough" (VC)*

"Yes, it definitely gave a good outline of what, what would be covered during the intervention."(MH)

Refresher before first participant - *"for myself and my colleague, there was quite a lapse between the training and us recruiting our first patient ...And so I think I probably could have done with a little bit of recap, but particularly on the digital platform." (VC)*

Platform log-in session before training - *"I think it was more the platform that I needed a bit of help with." (VC)*

Helpful to feel connected - *"it's always good to kind of you know, kind of stay connected and share information like that."" (YR)*

Helpful to learn and share ideas- *"there were quite a few useful hints I remember from the clinical practice" (MH)*

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"I'd always learn something and it'd quite often be relevant to a scenario that I'd come across" (EB)

" it's always useful to share" (VC)

More support needed - *"I know that it's difficult to prevent it obviously because we are trying to individualize it as much as possible. But I think it would be really, really good to have not even a session plan, but maybe like a bit of an outline of what could potentially be covered " (M)*

Background of the Guide impacting outcome

"I'm not employed by the NHS and I don't have the sort of power of referrals." (EC)

"I've done a lot of behaviour change and motivational interviewing and so bread and butter"" (VC)

Joint Themes

Suitability for the intervention

Disordered eating vs eating disorder – *"I found that with chapter one I often gave it a bit of a caveat because it does jump straight into talking about eating disorders and because quite a few of the participants, even though they were displaying binge eating disorder behaviours, they didn't like the idea of identifying themselves as having an eating disorder, particularly because for a lot of people they thought of eating disorder is only anorexia and Bulimia and that any other recent behaviours is a whole different sphere." (EB)*

Stress eaters – *"I try my best but it's not always good enough. You know, I'm a stress eater and I do binge very badly at times when I'm under stress." (CB)*

Physical symptoms of diabetes - *"Very tired and at the moment my knees, my feet it's just really bad at the minute." (CB)*

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The Online platform

Easy to use – *"It was pretty much plug and play. It was easy to navigate and you know I would just go in and activate the chapters for the participant." (YR)*

"In the platform it's really kind of straightforward you know what you're looking for if that makes sense. I think definitely a positive um aspect of the platform was the fact when you complete an intervention and think about it from the participant point of view that it does look kind of professional." (MH)

Physical copy backup – *"If what I'd had was a physical journal that I'd gone through and that I was taking the physical journal and then meeting with somebody, I think it would have been much more about what do you mean when you've talked about this." (GM)*

"It's the joy of doing face to face with the physical thing is that at that point, all you're needing to do is translate what the scribbles overwritten mean." (GM)

Multimedia - "*there were parts where I was like, this seems to me something that would have come over more clearly by somebody doing a video of it than getting me to read 5 pages and might have engaged me more in that process." (GM)*

The intervention structure

Phased approach good - *"I felt that the weekly going down to fortnightly, going down to monthly, going down to a bit longer and that uh got me used to having longer time without checking in." (SC)*

Sufficient time – *"So I think the number was sufficient." (GM)*

"*I didn't feel rushed at all, although I think most of the sessions were around about an hour." (SC)*

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Discussion

This is one of the first studies to address binge eating in people with T2 diabetes and specifically to evaluate the feasibility and acceptability of using a brief, tailored psychological guided self-help approach.

The adapted online guided self-help intervention resulted in large reductions in binge eating in those with mild-moderate difficulties. Results indicate that those with severe binge eating may have dropped out. Participants who completed all time points had lower binge eating scores at baseline compared the wider cohort and lower PHQ 9 scores. As such, part of the improvement in these measures may have been due to those with higher scores dropping out. However, there was still a significant improvement in scores in the participants who completed all time points. Both binge behaviours and depression continued to improve further at follow-up which shows promise for the longevity of changes. This is in line with our previous [30] where people reported revisiting the materials in times of relapse. There were similar but less pronounced improvements in anxiety. The small changes in eating disorder psychopathology were only significant after the intervention and may well reflect the fact that high scorers were not seen at follow up. Or perhaps it takes longer than 12 weeks for these more engrained cognitive processes to start to change. There was no change in weight, which is unsurprising in such a brief intervention. The focus of GSH is not on weight loss, but on establishing a regular eating pattern and therefore gaining better control of eating by understanding the underlying psychological processes.

Overall, participants engaged well with the intervention. They felt the platform was easy to use and that number and length of sessions was sufficient. The intervention adopted a staged approach whereby there was a longer duration between later chapters and their corresponding guidance sessions. User data showed participants spent longer completing the later chapters, indicating that participants were accessing these chapters further in advance of their guidance sessions and perhaps spending more time on behaviour change and engaging with the intervention materials themselves. This is congruent with the feedback from Guides suggesting that the crucial time to work on engaging clients was in the earlier sessions. Guides also recommended allowing some flexibility to combine and break up sessions, such as the

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introduction with session 1 and sessions 5 & 6. This allowed participants to make progress at their own pace, and to spend more time reviewing the more complex topics.

In addition to reductions in binge eating and mental wellbeing, our qualitative findings suggest that participants made wider lifestyle changes as a result of the intervention including walking more and drinking less alcohol. Fundamentally, they reported better diabetes management. Whilst we were unable to measure this objectively, continuous glucose monitoring (CGM) may be an option for future studies in this area (see Limitations section below). Future research could also investigate which of the components of guided self-help (e.g. psychoeducation, activities directed at behaviour or emotions) underpinned improvements in diabetes management.

The qualitative findings highlighted the necessity of having a Guide in the diabetes context and their role in navigating the relevant information. The Patient Public Involvement Group and Guides suggested that due to the range of disordered eating that a modular approach might be useful. Both participants and Guides also spoke about the Guides' fundamental role in setting expectations. They acknowledged that whilst offered as a 'brief intervention,' GSH was a large commitment. The importance of terminology was identified as fundamental in the recent UK Consensus Statement [(27)], whereby the potential effectiveness of such treatments should not be undermined by calling them 'brief' or 'low intensity' but rather 'focussed and programme-led'. The former terms imply that the problem is mild, that patients are receiving a suboptimal form of treatment, that the intervention is 'low level' and that others might be receiving 'more' treatment.

Some participants were reticent about taking part in a programme that specifically referred to eating disorders or had a perception that only anorexia nervosa and bulimia nervosa are eating disorders. We therefore recommend adding a section in the introduction clarifying the language around binge eating, loss of control overeating and the spectrum of eating disorders to participants.

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Strengths

Among the strengths of our work was the hybrid recruitment approach. Like in many existing studies, the sample was not limited to primary or secondary care. The adapted online intervention was feasible to deliver and well accepted by participants. In line with recommendations made by [27], digital, programme-led interventions have the potential to widen the reach of such evidence-based interventions and particularly to underserved groups. While digital interventions are being offered at scale in the NHS for weight management and remission, the research evidence is still in its' infancy and the effectiveness, acceptability, and sustainability of these approaches is not yet known [27]. This work goes some way to addressing this knowledge gap.

Furthermore, retention rates at post-intervention and 3-month follow-up were good - 77% and 55% respectively. This is in line with, if not slightly higher than, other guided self-help studies ([30,50]. Results from the quantitative and qualitative analyses shed some light on reasons for dropping out (severe binge eating, depression, a larger commitment than expected, motivation) and help us better understand for whom online GSH might be most suitable. Our qualitative findings suggest it is well suited to stress/emotional eaters, those with physical symptoms of diabetes, and those with severe loss of control. In contrast the quantitative data suggests that it may be less suited to those with severe binge eating and high depression scores. Therefore, further work is needed to explore the level of severity for which it is suitable.

Feedback from the intervention design [32] showed that participants preferred the GSH materials to be more generic, with tailored T2D training being offered to Guides. This may allow the intervention to be generalisable for other long-term conditions such as monogenic diabetes including MODY diabetes, and for people who have both type 1 and type 2 diabetes (“double diabetes”).

Limitations

The COVID-19 pandemic impacted the capacity of NHS Trusts and relevant support groups to participate in research, limiting the sample size and certainty of conclusions. The mixed-effects model approach and Wald-test (t-test) for the coefficients for time, require an assumption of missing at random (MAR) to be fully valid and this is unlikely to be the case in this context.

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Participants with higher Gormally scores were more likely to have missing data at 12 and 24 weeks, hence the models should be taken as a guide only.

Participants were recruited from both primary and secondary care, as well as outside of NHS care when recruited via social media. The variety of participant care systems and challenges with arranging HbA1c tests with practices resulted in this data being poorly collected. We were therefore unable to analyse this data. HbA1c as a measure has its limitations as it measures average glucose levels therefore cannot reflect glycaemic variability or hypoglycaemia exposure [51]. Moreover, HbA1c fails to assess early response to a new management strategy as it reflects average glycaemia over an approximate average of 3 months, resulting in delays of therapy escalations. Future studies may consider continual glucose monitoring as this can record hypo and hyperglycaemic exposure accurately, assessed as time below range and time above range [52].

Future steps

The study shows preliminary evidence for online GSH tailored to the needs of individuals with T2 diabetes as a feasible and acceptable approach to improving binge eating, to supporting people living with diabetes and mental wellbeing.

Our work provides evidence for the feasibility and suitability of using GSH for disordered eating outside of traditional eating disorder services as part of an integrated care approach to diabetes management. The recent UK Consensus statement for brief and programme-led interventions for eating disorders [27] highlights the need to explore innovative ways to increase access to such interventions (social media, self/carer-referral or online screening, bypass primary care) and to consider treatment matching. That is, to understand the patient characteristics of people who do well with GSH, of which our work provides some preliminary indicators. Finally, there is a need to better understand the components of behaviour change and mechanisms of action in order to effectively tailor and improve outcomes with this intervention. Further research is necessary to refine the intervention and evaluate the clinical effectiveness, social, educational and economic benefits of this approach in a fully powered trial.

https://doi.org/10.1017/S0007114524002599 Published online by Cambridge University Press

Declaration of interests

Andrew Hill reports receiving payment for advice given to Slimming World (UK).

Authorship

GTT was principle investigator. The following authors were involved in formulating the research question(s) (GTT, AH, CG, MM, SHE, IB) designing the study (GTT, AH, CG, MM, SHE, IB), carrying out the study (GTT, EB, JR, RW), analysing the data (GTT, EB, RW), interpreting the findings (GTT, EB, RW) and writing the article (GTT, AH, CG, MM, SHE, JR, IB, RW).

Acknowledgements

We would like to thank members of our Patient Public Involvement Group who were actively engaged through the study. The clinicians who gave up their time to be part of the Expert Consensus Group. Service leads at Leeds Community Healthcare NHS Trust (Gayle Forsyth/Sue Lawrenson) who piloted the recruitment process. Ursula Philpot, the consultant dietitian who facilitated supervision with SHE throughout the study.

Financial support

This work was supported by Diabetes UK (grant number 19/0006125). Diabetes UK had no role in the design, analysis or writing of this article.

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Appendix 1. Summary of the POSE-D: Working to Overcome Eating Difficulties online platform

Session	Title	Key topics
1	Introduction: Working to Overcome Eating Difficulties	Introduction to the programme; Readiness for change; Introduction to Guided Self-Help.
2	Chapter 1: Eating Disorders and this Treatment Approach	Background on eating disorders and their causes; Cognitive Behavioural Therapy (CBT) and the Transdiagnostic Approach.
3	Chapter 2: Physical and Psychological Health	Impacts of restriction and binge-restrict cycle; Compensatory behaviours; Keeping an eating diary.
4	Chapter 3: Food and Health, and Unwanted Behaviours	Determinants of body weight; Role of different nutrients in the body; Eating for health with diabetes; Recognising hunger and stopping compensatory behaviours.
5	Chapter 4: Thoughts	Identifying unhelpful thoughts; Psychological flexibility; Mindfulness.
6	Chapter 5: Learning to Feel Good About Yourself	Emotions in Cognitive Behavioural Therapy; Self-soothing when stressed; Improving relationships; The role of mobile apps in eating problems.
7	Chapter 6: Planning for the Future	Meeting goals and maintaining change; Building resilience.

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Table 1. Baseline characteristics of sample at each time-point

Characteristic	Pre *N=22*		Post *N=17*		12-week FU *N=12*		Interview *N=6*	
Gender	n	%	n	%	n	%	n	%
Female	14	63.64	10	58.82	6	50.0	3	50.0
Male	8	36.36	7	41.18	6	50.0	3	50.0
Age category								
25-34	2	9.09	1	5.88	0	0.00	0	0.00
35-44	7	31.82	5	29.41	4	33.33	1	16.67
45-54	6	27.27	5	29.41	3	25.00	1	16.67
55-64	6	27.27	5	29.41	4	33.33	4	66.67
65+	1	4.55	1	5.88	1	8.33	0	0.00
BMI								
<25 kg/m2	1	4.55	1	5.88	1	91.67	0	0.00
>25 kg/m2	20	90.91	16	94.12	11	8.33	6	100.00
Ethnic origin								
White	20	90.91	15	88.24	11	91.67	6	100.00
Black or Black British	1	4.55	1	5.88	0	0.00	0	0.00
Asian or Asian British	1	4.55	1	5.88	1	8.33	0	0.00
Marital status								
Single/never married	9	40.91	6	35.29	3	25.00	1	16.67
Married/partnered	10	45.45	9	52.94	7	58.33	4	66.67
Divorced	2	9.09	1	5.88	1	8.33	1	16.67
Widowed	1	4.55	1	5.88	1	8.33	0	0.00
Highest level education								
GCSE	2	9.09	1	5.88	1	8.33	0	0.00
A-Levels, BTEC	10	45.45	7	41.18	7	58.33	3	50.00
Undergraduate	9	40.91	7	41.18	3	25.00	2	33.33
Postgraduate degree	1	4.55	1	5.88	1	8.33	1	16.67
Years since T2D diagnosis	*M*	SD	*M*	SD	*M*	SD	*M*	SD
	6.78	6.07	6.15	5.64	6.13	5.40	4.52	6.83

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Table 2. Questionnaire scores at each time point

Time point	Pre (N=22)		Post (N=17)		Follow-up (N=12)	
	Mean	SE	Mean	SE	Mean	SE
Gormally	26.82	2.07	15.12	2.45	9.74	2.73
EDE Q restraint	2.60	0.33	1.85	0.45	1.40	0.50
EDE Q eating	2.62	0.34	1.65	0.50	0.64	0.55
EDE Q shape	3.59	0.48	3.82	0.46	2.14	0.51
EDE Q weight	3.20	0.38	2.54	0.37	1.84	0.41
EDE Q global	2.96	0.35	2.42	0.37	1.51	0.41
Weight (kg)	106.30	5.87	108.84	6.43	106.32	8.80
PHQ 9	14.10	1.37	10.42	1.52	8.31	1.69
GAD 7	10.41	1.39	6.61	1.22	6.72	1.37
EQ 5D VAS	48.00	5.17	61.12	6.98	54.92	7.72

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Table 3 –Baseline scores of completers vs non-completers

		Baseline only N=6		**Baseline + post N=4**		**All time points N=12**	
		Mean	SD	Mean	SD	Mean	SD
Gormally binge eating scale	Mean, SD	30.17	5.78	36.75	5.12	21.83	8.47
	% <17	0.00		0.00		16.70	
	% >17	100.00		100.00		83.30	
EDE Q global score	Mean, SD	2.22	0.49	4.41	1.34	2.59	1.54
	% <2.7	100.00		25.00		50.00	
	% >2.7	0.00		75.00		50.00	
Weight	Mean, SD	99.92	21.54	120.90	17.74	107.36	30.90
PHQ 9	Mean, SD	12.67	8.26	21.75	4.43	12.25	6.08
GAD 7	Mean, SD	8.00	8.90	17.50	4.73	9.25	5.08

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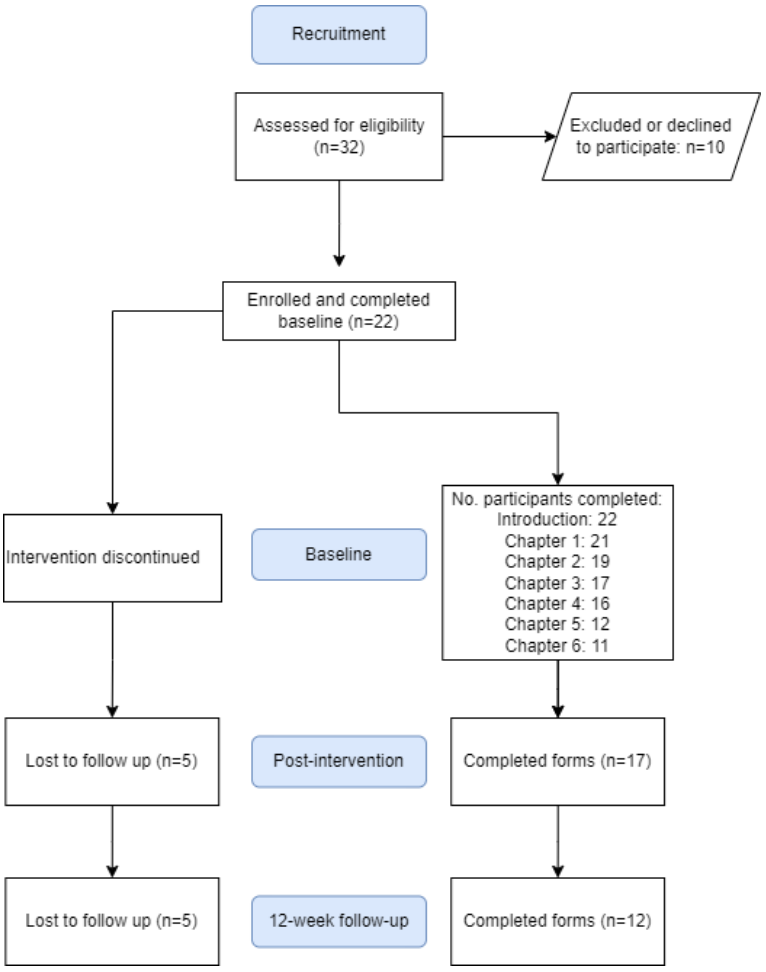

Figure 1. Consort diagram

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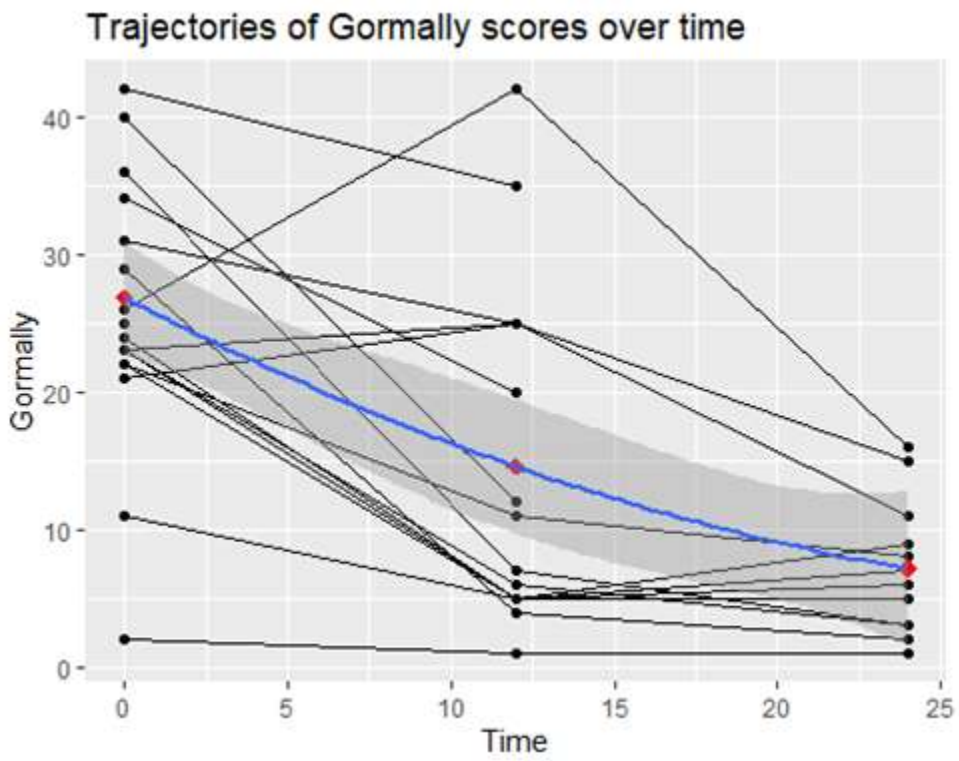

Figure 2. Trajectories of Gormally binge eating scores over time

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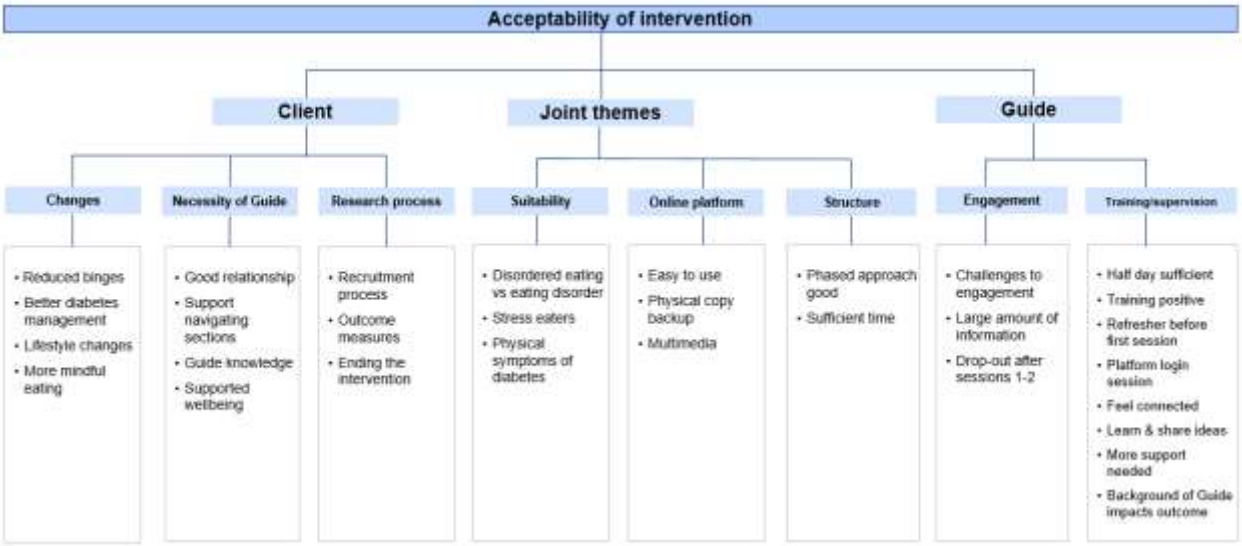

Figure 3. Qualitative interview themes relating to acceptability of the intervention

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