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Navigating the food environment: Lived experiences of managing Type 2 Diabetes Mellitus through dietary change

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Doctorate in Clinical Psychology
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Submitted in part fulfilment of the degree of Doctorate in Clinical Psychology at the University of Edinburgh, May 2023

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Abstract Thesis Portfolio

This thesis portfolio aimed to understand the lived experiences of individuals with T2DM who make changes to their diet and lifestyle, to lose weight as a way to manage their T2DM condition. The first chapter is a systematic review, using a thematic synthesis methodology to explore individual's experiences of proposed dietary modifications with a weight loss focus. Four themes were identified that helped us to understand the commonalities and differences in people's experiences of this approach. We learned that providing tailored nutritional information that is comprehensible and culturally appropriate needed to be prioritised. We also identified a number of additional avenues for research exploration, and consideration from a policy perspective, given the variability in guidance offered for individuals. The second chapter built upon what was learned from this review, and specifically focused on one weight loss focused intervention delivered in NHS Lothian, Scotland. An interpretive phenomenological approach was employed, which allowed the researchers to explore patients' experiences on a case-by-case basis, and in depth. The research provides two vantage perspectives by participants of the programme showcasing the experience of those beginning and ending the weight management intervention. The findings allow a greater depth of understanding of the emotional voyage of being diagnosed with T2DM and undertaking this programme to make health behaviour change. There are a number of insights that provide scope for future research avenues and clinical considerations.

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A Reflexive Commentary for Undertaking this Research

As a woman in a diet-centric society the weighing scales held a power for far too long. Through working clinically within a weight management service, I began to realise the shame, guilt, self-criticism that was so present for patients I was working with, in relation to their weight and relationship with food. Often referred by their GP, or a drive to lose weight to resolve complex psychological and medical difficulties, my frustration grew as I read paper after paper with authors speaking about the need for those with diabetes living in a larger body to just lose weight. As voiced by a participant in this research, which has titled the empirical paper, patients were being told time and time again to “just do it by diet”, without considering their individual circumstances, and what type of support would be most helpful. Blanket recommendations have been made across the literature that all those living in a larger body with T2DM need to ‘adhere to diets’ and lose weight through any means possible. My knowledge of ingrained weight stigmatization that permeates healthcare systems questioned ‘what about their well-being?’. People being repetitively told they need to lose weight because of the health complications associated with unmanaged diabetes is a noteworthy cause for concern. I wondered how they make sense and internalize these messages from their healthcare team? What impact does it have on their relationship with food?

My drive to conduct this research was to give space to the experiences of people who live in larger bodies, who have been diagnosed with Type 2 Diabetes Mellitus, and who are offered a weight loss focused intervention to manage their condition. I wanted to know what participants might perceive a meaningful outcome to be. To listen and learn about their experiences navigating this system and approach of care.

A qualitative methodological approach: Qualitative methods allow us a privilege to connect with and try to understand the rhythm through which people are experiencing life. For a moment we can stand beside another human as they help us to see the world through their lens. So often I have heard how much we as researchers want to give voice to a particular group, those who have been silenced as a result of harmful societal structures or an upholding of beliefs that only serve the interest of those who gain in profit. In my approach, I hope to stand authentically and to acknowledge the weight of my responsibility in how I represent the experiences of people who have shared their vulnerability, their internal world.

Lay Summary

Type 2 Diabetes Mellitus (T2DM) is a health condition which is developed in adulthood. People can be more vulnerable to developing the condition because of their genetics, however, lifestyle factors are considered to play the largest role in how they are diagnosed. Researchers over the past ten years have discovered that individuals who lost a significant amount of weight over a short space of time could reduce their blood glucose (sugar) levels and achieve what researchers and clinicians are naming 'remission'. Although not all people agree on how to define 'remission', some groups are referring to it as a reduction in glucose levels below the level required for a diagnosis of T2DM, if the same readings stay the same for a period of time.

Chapter one of this thesis involved a review of research studies that have gathered information from participants using a qualitative method which usually involves interviews or open-ended questions. This review focused on studies that aimed to learn about people's experiences of trying to make changes to their diet and lose weight. Following a search of the literature we found nine studies that allowed me to understand this group of people's experiences. We learned that despite all having the same condition, T2DM, there was significant variability in the guidance they were provided by healthcare professionals. We learned that everyone's path in managing their diabetes through diet is unique and must be tailored to their individual needs. There were a number of challenges that arose from a cultural and socio-economic perspective for some participants which were not acknowledged by other researchers. The research also highlighted a new perspective on the potential harms of such dietary approaches, and raised questions on how we could best support people to make health promoting behaviour change.

Chapter two of this research involved interviewing two groups of participants from a weight loss focused intervention that is being delivered to people with T2DM. This programme lasts for two years, with the first three to five months consisting of a replacement of all food with different flavours of liquid shakes. People have a session with a dietician every two weeks to talk about how they are managing to make change. Sometimes they see a psychologist before, during or after the programme. The hope is that weight loss will help them to achieve remission. Five people beginning the programme and five people finishing the programme agreed to be interviewed and share their experience of engaging with the programme. The analysis that we used allowed us to be really involved in making sense of their understanding of their experience. Each participant brought their expertise of living with T2DM and engaging with this programme, and we brought knowledge of the area and research skills. Together we worked to make sense of their experience. We learned that there were a number of important things

people hoped to gain and did gain from engaging with the programme that contributed to their well-being and quality of life. We learned about different needs that arose for participants depending on their stage of the programme and we also identified areas where researchers and clinicians could pay further attention to. These might be helpful to explore further in the future.

Chapter 1. Systematic Review

Experiences of Diet Modification to Manage Type 2 Diabetes Mellitus: A Systematic Review

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3. Declaration of conflicting interests

The Authors declare that there is no conflict of interest.

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5. Ethics approval

As this was a systematic review of the evidence base and no individual's were directly involved in primarily research, no ethical approval was sought.

6. Pre-registration

This systematic review was prospectively registered on PROSPERO (CRD42022306989) on the 26/01/2022.

7. Data availability statement

The current systematic review article is accompanied by the relevant raw data generated during and/or analysed during the review process, including the required files detailing the review process and the complete database of extracted data. These files are available in the Figshare repository and accessible as Supplemental Material via the SAGE Journals platform. If there are any required ethics approvals, participant permissions, or other relevant approvals for the data sharing accompanying this systematic review then these have all been granted.

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Abstract

Introduction: Research into achieving Type 2 Diabetes Mellitus remission through weight loss efforts has grown steadily in the past decade. Most of this research has focused on the effectiveness of weight loss as a method to achieve remission, rather than considering individuals' experiences of engaging with such change. This paper aims to review the qualitative research on individuals' experience of proposed dietary modifications with a weight loss focus.

Methodology: Six databases were searched for qualitative and mixed-methods research studies, and studies were subject to analysis following Thomas and Hardin's (2008) guidelines.

Results: The search yielded 2,945 results, of which 47 were reviewed in full, and nine were included for analysis. Four analytical themes were identified; variability in support; choosing dietary change; re-negotiating the food relationship; and looking beyond weight loss.

Discussion: Providing tailored nutritional information that is comprehensible and culturally appropriate must be the premise of the interventions offered. Supporting patients to understand their relationship with food and identify meaningful goals beyond weight loss is an important starting point.

Keywords: T2DM, low-calorie diets, diet modification, weight loss, calorie restriction, systematic review.

Background

Type 2 Diabetes Mellitus (T2DM) is a complex metabolic disorder characterised by chronic hyperglycaemia that can cause serious medical difficulties if left untreated which can have a significant impact on an individual's quality of life (Carrier & Beverly, 2021; Trikkalinou et al., 2017). Historically, it was considered an irreversible, chronic and progressive condition; however, an accumulating evidence base has revealed that it is possible to achieve remission without pharmacological intervention (Hallberg et al., 2019). There is an ongoing debate regarding the remits of remission (see Taheri, 2021). However, current guidelines within the United Kingdom (UK) consider remission to have been achieved if a recording of haemoglobin A1c (HbA1c) concentration less than 48 mmol/mol is obtained, which must be sustained for six months without any pharmacological input (Nagi et al., 2019). Whilst not everyone diagnosed with T2DM is of a higher weight, it is estimated that 90% of adults with T2DM are overweight or obese (Grant et al., 2021). Non-pharmacological treatment approaches specify weight loss as the necessary component to achieve remission for those of any size (Holman, 2014). Guidelines recommend between 5-10% as a weight loss goal through dietary modification and increased physical activity (National Institute for Health and Care Excellence (NICE) (2014).

Modifying diet in response to a diagnosis of T2DM has been well-documented across the literature as an effective way to maintain glycemic control, and to reduce comorbidities and side effects (Asif, 2014). A large body of quantitative research has been conducted to explore self-management interventions to support individuals to make lifestyle changes to reduce complications associated with unmanaged T2DM (Ernawati et al., 2021). In a systematic review and meta-synthesis García-Molina et al. (2020) revealed that greater weight loss efforts lead to greater intervention effects. International guidance on energy balance, as a form of nutritional therapy to prevent or manage T2DM recommend 'a nutritionally balanced, calorie-reduced diet to achieve and maintain a lower, healthier body weight' for individuals living in larger bodies (Ley et al., 2014, p.14). Whilst these recommendations have always been incorporated into self-management interventions, the shift in using weight loss as method to achieve T2DM remission has drawn increased attention to all dietary interventions which may be considered effective for long-term weight loss. In a consensus agreement by 131 experts in diabetes treatment, research, and remission, agreement was reached that diet should be considered as a primary intervention for T2DM which can result in remission for some, but not all adults. A variation of diets was suggested which ranged from low-fat, whole-food, plant-based diets, avoiding or minimizing refined foods, ultra-processed foods, and foods with added fats. Calorie reduction was suggested to be achieved

by reducing quantity of food intake by reducing portion sizes, or reducing energy density, by using liquid meal replacements or combining approaches (Rosenfeld et al., 2022).

Across the literature there have been advances in how diabetes care is being considered, studied, and delivered. There has been an important shift, underpinned by principles of health at every size, towards supporting individuals to engage in health promoting behaviours that acknowledges the complexity of making such lifestyle change (Penney & Kirk, 2015). An important part of the design and delivery of educational programmes on T2DM has prioritized helping individuals to build a healthy relationship with food, by promoting diets rich in nutritional value to nourish their physical health without excluding or eliminating food groups (Hou et al., 2023). There has also been an increased understanding of the emotional impact of living with and associated stress that can result from managing diabetes (Davis et al., 2022). With the most recent emphasis on the use of low-calorie diets to support individuals to achieve remission, psychosocial factors must continue to be prioritized alongside medical outcomes of success (Kalra et al., 2018).

In a qualitative meta-analysis on dietary modification for individuals with T2DM, Vanstone et al. (2017), outlined five inter-connected barriers to diet modification that are magnified by social marginalization. These included self-discipline, emotions, family and social support, the social significance of food and knowledge, and information. Whilst this review did not take a specific weight loss focused lens, it could be suggested that these challenges may be amplified if individuals are being asked to severely restrict their food intake. Being unable to follow such rules, can lead to self-blame, or self-criticism for not meeting self-imposed or healthcare imposed weight loss targets (Pedersen et al., 2018). Despite the diets being identified as unsustainable, individuals can internalize this as a personal failure (Tahreem et al., 2022).

We have learned from adjacent literature on dieting amongst those without T2DM, that following a period of restrictive caloric intake, individuals are more at risk for binge eating behaviours, which can result in feelings of guilt, shame, and low mood if one is aiming to follow a strict prescribed diet (Craven & Fekete, 2019). This can lead to a vicious cycle of restrictive eating, dieting and bingeing, which often results in short-term weight loss followed by longer-term weight gain (McCuen-Wurst et al., 2018). Patterns of disordered eating can unintentionally be learned, reinforced, or exacerbated in order to achieve or maintain weight loss (Ralph et al., 2022). Despite the multitude of risk factors that make this population vulnerable to developing disordered eating (Sachar et al., 2019; Salvia et al., 2022), this has been neglected and often overlooked in studies (Nieto-Martínez et al., 2017). The limited research

which has been conducted has primarily focused on binge eating behaviours (Salvia et al., 2022). However, it is becoming increasingly noted in clinical practice that transdiagnostic or sub-threshold disordered patterns of eating are prevalent among this population (Pekin et al., 2022).

Disordered eating includes behaviours that may be overtly identified as problematic such as restrictive eating, purging, overusing laxatives, and excessive exercise. Whilst these behaviours can result in greater physiological harm, they are more likely to be identified in a healthcare assessment. What can be more challenging for individuals to express, or for healthcare professionals to identify are the internal cognitive patterns, that are often hidden including strict food rules, preoccupation with weight and shape, labelling foods as 'good or bad', excessive calorie counting, increased anxiety around food, or feelings of loss of control when eating (Ralph et al., 2022). These behaviours are also often overlooked for individuals living in larger bodies. For example, while concern may be expressed for someone who is engaging in restrictive eating living in a smaller body, the same concern may not be afforded to someone in a larger body, who may be praised for engaging in unhealthy eating patterns (Ralph et al., 2022). Negative self-beliefs, poor emotion regulation, low self-esteem, and dietary restraint can all contribute to, and maintain disordered patterns of eating (Burton & Abbott, 2019). As healthcare professionals, it is fundamental to ensure that the design and implementation of interventions in services do not cause harm (NICE, 2023). Prior to an increase in healthcare services adopting weight loss focused interventions, we must consider what has been learned from research exploring participants' experiences of using low-calorie diets to manage glycemic control.

To date, there has been an emphasis on supporting individuals to follow developed programmes rather than questioning the impact dieting can have on their relationship with food and what additional benefits may be achieved from making significant lifestyle changes to manage diabetes, beyond weight loss. Whilst there is a body of literature outlining many of the challenges experienced by those using dietary approaches to achieve weight loss by caloric restriction without a diagnosis of T2DM, the same level of consideration has not been provided for those with T2DM (Hallberg et al., 2019). Those who are of a higher weight and diagnosed with T2DM may present with unique challenges when engaging with weight management interventions because of their additional healthcare needs. For example, they may experience additional pressure by healthcare teams to reduce or restrict foods in order to improve their health outcomes (Taylor, 2019). In a systematic review of the research focusing on the efficacy and acceptability of very low energy diets in overweight and obese people with Type 2 diabetes mellitus, there were four randomized, five non-randomized controlled trials (21 references, 9 studies, 346

participants) were identified. No qualitative studies were identified highlighting at this time the significant gap in the research (Rehackova et al., 2016). Acceptability was aligned with attrition rates, which raises the concern that assumptions are being drawn that programmes are acceptable if they are tolerable, rather than taking individuals lived experiences into account. This clearly highlighted the need to review the literature to date to better understand the healthcare trajectories and experiences of individuals making dietary modification from a qualitative perspective. The aim of this review is to thematically synthesise qualitative data that has been collected on those who have a diagnosis of T2DM and who have made efforts to make a dietary change in response to weight loss-focused advice to manage their diabetes. The objectives of this review are to:

1. Systematically review the literature conducted in this area in order to identify gaps, as well as assess the quality of research conducted to provide clinical and research recommendations.
2. To gain insight into the benefits and challenges that arise for individuals following dietary modification recommendations to manage T2DM.

Methodology

As the primary aim of this research sought to explore individuals' experiences making dietary change, a thematic synthesis was chosen as the most appropriate review methodology. This systematic review was prospectively registered on PROSPERO (CRD42022306989) on the 26/01/2022 and is reported according to the ENTREQ statement (Appendix B) (Tong et al., 2012).

Eligibility criteria

Inclusion criteria: (a) Patients with a diagnosis of Type 2 Diabetes Mellitus, (b) Adults 18 years and older, (c) Studies which focus on the experiences of individuals making dietary change, following weight loss-focused guidance to support the management of T2DM (d) Qualitative research studies and (e) Mixed method studies will be included with only the qualitative component of the research being extracted and analysed, (f) Published papers and grey literature. Exclusion criteria included: (a) A focus on treatment through medication, (b) Treatment through bariatric surgery, (c) Research that is not published in English, (d) Studies which include participants who have not made dietary modifications with weight loss focus, and (e) Quantitative research.

Information sources and search strategy

The following electronic databases were searched on 09/04/2023: Ovid MEDLINE, Ovid Embase, Ovid PsycINFO, EBSCO CINAHL and Web of Science and ProQuest (Appendix C). The author conducted hand searches of reference lists of relevant papers and studies identified in the initial searches.

Selection process

The database search results were downloaded into Zotero and transferred to Covidence (2023). Duplicates were removed, allowing for the screening of the remaining titles and abstracts against the predefined inclusion criteria. All abstracts and titles were reviewed by the first author (RMcDM), and a second reviewer (CP) independently reviewed 30% of the abstracts and titles. Covidence was used to calculate inter-rater reliability, but determining the level of agreement and conflict across two reviewers. All conflicts were discussed, and an agreement was reached on which studies to consider further. An agreement rating of selected studies was read in full, allowing the full text to be screened against the inclusion/exclusion criteria by one researcher RMcDM. An agreement rating of 99.8% was achieved following this review process. CP independently reviewed 30% of the full texts. All papers were agreed upon for inclusion. Discussions were held for agreed-upon included papers between RMcDM, CP and FD.

Data items

Study characteristics (study title, author information, country of study, year of publication, methodology, brief description of diet followed, and participant characteristics) were extracted manually and exported into a pre-designed table. On-going discussions between RMcDM and FD were held on the data extraction table and presentation. A reflexive log was kept throughout the selection and analysis process (See Appendix D).

Synthesis methods

Given there was a limited number of studies which had been conducted in this area, it was known that there would not be sufficiently thick or rich data to conduct a meta-ethnography. However, it wasn't so limited that a meta-aggregation was necessary. Therefore, a thematic synthesis was possible and an important first step in reviewing the literature, identifying gaps, making research recommendations and initiating the necessary next steps in order for future researchers to consider a theory or framework that could be derived from this research. Analysis was conducted as per Thomas & Harden (2008) guidelines taking a three-step approach; steps one and two included line-by-line coding to develop descriptive

themes; following the identification of similarities and differences between codes to group them into a hierarchical structure; finally, descriptive themes were reviewed to go beyond the data and generate analytical themes. Data from the ‘results’ section were considered participant quotes and author interpretations. Data were extracted to NVivo 11 Plus for analysis (Allsop et al., 2022)

The first author, who has experience in qualitative methodology currently working within a weight management service as a trainee clinical psychologist, read each full-text several times to become familiar with the data. Coding was conducted by the first author (RMcDM). Regular conversations were held with FD (background in Clinical Psychology with expert knowledge of qualitative methodology) and CP (a PhD student with a background in Psychology and Neuroscience) while the coding framework was being developed and when identifying analytical themes. Illustrative quotes were chosen for each analytical theme and sub-theme. Initial descriptive themes were presented at an Eating Disorders and Behaviors Research group to seek feedback, which includes a panel of researchers and individuals with lived experience. Example analysis is presented in Table 1 below.

Table 1
Example analysis

Codes	“I don’t have to explain, people understand” Acceptability and Cultural Relevance
‘Culturally tailored support’	<p>Over half (n=26, 57.8%) of the respondents stated that the culturally tailored support in terms of materials and staff enhanced their engagement. In order to increase effectiveness, PilAm Go4Health was culturally tailored for FA integrating unique cultural features and culturally relevant education materials promoting healthy lifestyle behaviors.⁴⁰ Table 1 presents an overview of the cultural adaptations that included culturally oriented education materials promoting healthy lifestyle behaviors facilitated by FA identified research staff and an interactive private Facebook group providing virtual social networking support with other participants and research staff.</p> <p>Many participants had positive comments on: the health education slideshows that were simple, colorful, visual, and interactive; helpful tools such as: “ChooseMyplate” (www.choosemyplate.gov/MyPlate); regular progress reports; and physical activity photos with FA. The interactive and culturally tailored education helped participants to: 1) better understand concepts such as healthy Filipino weight loss; 2) recall health messages; and 3) disseminate information to family, friends, and community. A 36-year old male said:</p> <p>“What I’ve learned through this study is that we have a different physiology...There’s not a one size fit-all weight-loss plan, but that it is has to be conducive specifically to certain people’s biology and cultural ways of doing.”</p> <p>Increased engagement, retention, and positive behavior change among participants can be attributed to the utilization of research staff who share cultural traditions and beliefs with the participants.⁴¹ For example, one participant reported that having to eat alone (to support healthy food selections) conflicted with the obligation to participate in family meals (a sign of respect in the Filipino culture).⁴²</p>
‘peer support’	
‘a tailored approach’	
‘feeling heard/understood’	
‘culturally tailored support’	

'family support'	Participants commented that intervention delivery by FA research staff increased not only their comprehension of educational material but also their comfort with sharing cultural challenges regarding diabetes management. Overall, participants noted that research staffs' encouragement, monitoring, technical support, and engagement of family were crucial to achieving their weightloss goals.
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Additional analysis, and coding framework development are presented in Appendix E and F respectively.

Certainty assessment

The Modified version of the Critical Appraisal Skills Programme (CASP) quality assessment tool was employed to review the quality of papers selected for inclusion (CASP, n.d; Long et al., 2020). As it was intended for the findings of this review to provide clinical and research recommendations to inform policy and best practice, the decision was made to use GRADE-CERQual. This tool is employed to review confidence in the evidence of findings from qualitative research (Munthe-Kaas et al., 2018). The first author (RMcDM) used the CASP tool to review all included papers. A second reviewer (CP) reviewed 20% of included papers. Discussions were held between reviewers on choices regarding the quality review.

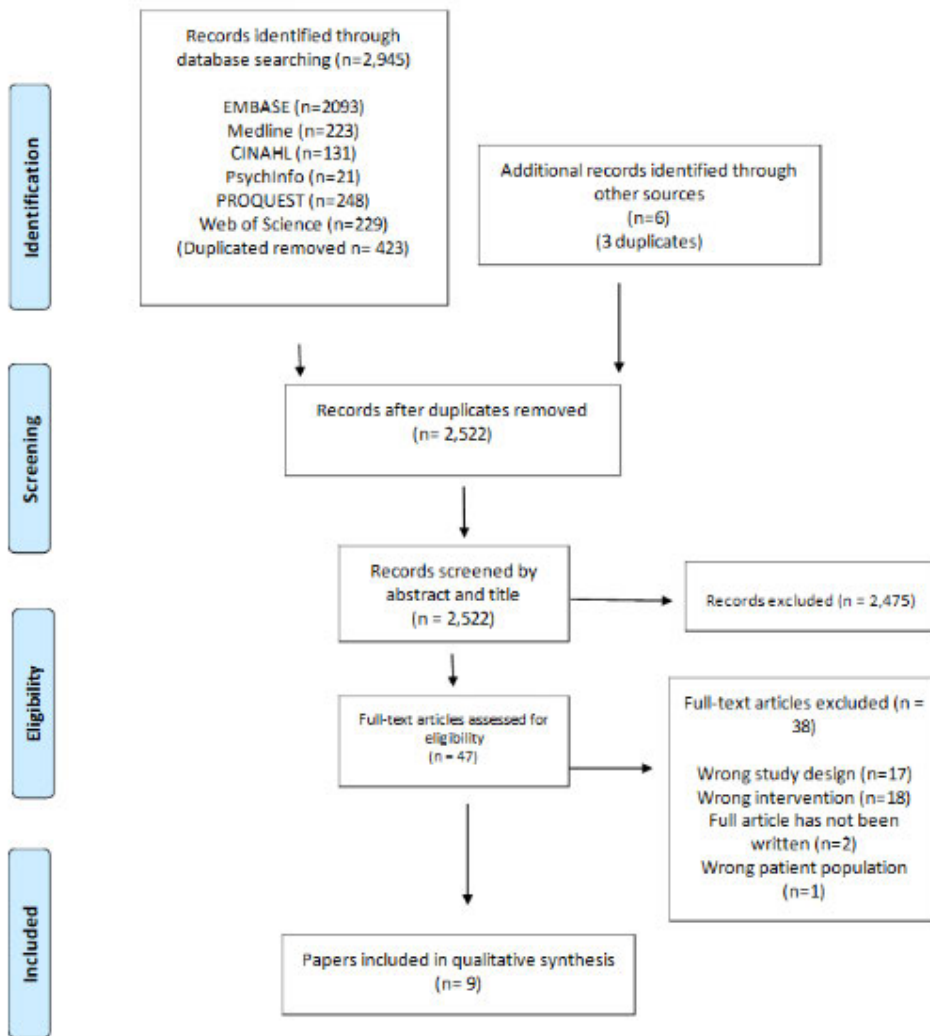
Results

Study selection

A PRISMA flowchart is presented in Figure 1, which illustrates the various stages of the review.

Figure 1.

PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses; Page et al., 2021) Flow Diagram



Study characteristics

Nine peer-reviewed papers were included for analysis in this review. Two of the papers drew from the same sample undertaking the same programme (Rehackova et al., 2017; Rehackova et al., 2020), one of which included a longitudinal follow-up time point. The intensity and frequency of support available varied significantly across studies. Most studies explored participants' experiences of a structured programme which included a prescribed diet (Bynoe et al., 2020; Rehackova, et al., 2017; Rehackova et al., 2020; Rehackova et al., 2022; Maglalang et al., 2017; Wycherley et al., 2012). There was a mix of dieticians (n=3), research staff (n=2), and a family practitioner (n=1) who delivered the interventions. For the remaining three studies, there was a variation in healthcare professionals who provided dietary guidance. The frequency and intensity of the programmes varied with some participants being asked to

log their food intake daily with 'ad hoc' virtual group discussions (Maglalang et al., 2017), to biweekly check-ins either by telephone or in clinic from 12 weeks to one year (Rehackova et al., 2017; Rehackova et al., 2020; Rehackova et al., 2022). Three studies were not associated with delivering a structured intervention. These studies explored participants modifying their diet in response to guidance offered by healthcare professionals. The support and advice offered across these studies varied (Vijan et al., 2005; Moore, et al., 2019), with the exception of Webster et al. (2019) where all participants followed the same diet. Blood glucose levels and weight loss was outlined as a measure of success in seven of the studies (Webster et al., 2019; Rehackova et al., 2022; Rehackova et al., 2017; Vijan et al., 2005; Rehackova et al., 2020; Maglalang et al., 2017; Bynoe et al., 2020), and described in one study (Moore et al., 2019). The characteristics of each study are presented in Table 2.

Table 2.*Study characteristics*

Authors	Conflict of interest	Country	Study design data collection points, and analysis	Programme	Sample size	Demographics
Bynoe et al. (2020)	No	Barbados	Mixed method study (semi-structured interviews at baseline, 8 weeks and 5 months) Thematic analysis	An 8-week total food replacement diet, consisting of 800 kcal a day. Followed by 4-week food re-introduced phase. Facilitated by a dietician.	25	Ten M and 15 women. Ethnicity = 88% classified themselves as black ethnicity, 8% as mixed, 4% as white.
Moore, et al. (2019)	No	United Kingdom	Qualitative study (focus groups, one time point). The COM-B framework	Variability of dietary recommendations being followed.	41	27 F and 14 M Ethnicity = 18 participants were Black African, 22 participants were Black Caribbean.
Maglalang et al. (2017)	No	United States of America	Mixed methods study (semi-structured interviews at baseline, 3-month and 6-months) Thematic analysis	Three-month weight-loss lifestyle intervention, self-report food/calorie intake and weight using the Fitbit diary app. Goals of the intervention include weight reduction of at least 7 percent through a healthy low-calorie, low-fat diet and to engage in at least 150 minutes per week. Followed by three-month maintenance phase. Facilitated by research staff.	45	62% F Ethnicity = all reported as Filipino.
Rehackova et al. (2017)	Yes	United Kingdom	Qualitative study (semi-structured interviews before and after completion	An 8-week total food replacement diet, consisting of 800 kcal a day. Facilitated by a healthcare team.	18	Seven F and 11 M Ethnicity = NR.

			of the programme). Thematic analysis			
Rehackova et al. (2020)	Yes	United Kingdom	Qualitative study (semi-structured interviews at three time points, longitudinal follow-up). Thematic analysis	A 12-week total food replacement diet, consisting of 800 kcal a day. Followed by food re-introduction and maintenance phase for up to 2 years. Facilitated by a healthcare team.	11	Seven M and Four F Ethnicity = NR.
Rehackova et al. (2022)	Yes	United Kingdom	Qualitative study (semi-structured interviews before, during the diet, 2 weeks into the food replacement phase and 1 year from the initial interview). Thematic analysis	A 12-week total food replacement diet, consisting of 825– 853 kcal/day for 12 weeks. Followed by food re-introduction phase and weight loss maintenance for up to 2 years. Facilitated by a healthcare team.	34	18 F and 16 M Ethnicity = all were of white ethnic background.
Vijan et al. (2005)	No	United States of America	Mixed methods study (focus groups, one time point). Q.S.R.NUD*ISTTM qualitative analysis software	A diet with sugar, fat, and calorie reduction aimed at weight loss. Varied dietary pattern across participants and prescriber.	36-72	97% = M Ethnicity: 88% white (sub-urban site); 92% African-American (urban site).
Webster et al. (2019)	No	South Africa	Mixed methods study (Semi-structured interviews time point not specified). Thematic analysis.	Self-selected, low carbohydrate, high fat diet. Average intake was 1,794kcal day. Carbohydrate intake was between 20 and 50 g/d (very low) for 10 participants, between 50 and 115 g/d (low) for 17 participants and was 142 g/day (moderate) for one participant.	28	14 M and 14 F Ethnicity = NR.
Wycherley et al. (2012)	No	Australia	Mixed methods (One year following completion of the programme). Content analysis.	A moderately energy-restricted prescriptive diet of 6000 kJ/ day 7000 kJ/ a day. Facilitated by a dietician.	30	22 M and 8 F Ethnicity = NR.

F= Female

M = Male

NR = Not reported

Quality appraisal

All studies were considered acceptable quality to be included in the analysis of findings, see Figure 2 (Full CASP review available in Appendix G). All themes were considered medium confidence or above based on a GRADE-CERQual assessment (See Appendix G). There were a number of methodological limitations that were pervasive across studies. Only one study discussed the ontological or epistemological position that was being taken. The relationship between the participants and the researchers was only considered in detail in three studies. A paragraph on reflexivity would have been helpful, particularly for studies where the authors were either being funded by or implementing the intervention. This would help to demonstrate purposeful reflexivity on the researcher's relationship with the data.

Figure 2.
Critical Appraisal Skills Programme (CASP)

Authors	Question									
	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
Bynoe et al. (2020)	Yes	Yes	Somewhat	Yes	Somewhat	No	Somewhat	Uncertain	Somewhat	No
Maglalang et al. (2017)	Yes	Yes	Uncertain	Yes	Yes	Somewhat	Somewhat	Uncertain	Yes	Somewhat
Moore et al. (2019)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Rehackova et al (2017)	Yes	Yes	Yes	Yes	Yes	Uncertain	Yes	Yes	Yes	Somewhat
Rehackova et al. (2020)	Yes	Yes	Yes	Somewhat	Yes	Somewhat	Somewhat	Yes	Yes	Uncertain
Rehackova et al. (2022)	Yes	Yes	Yes	Yes	Yes	Somewhat	Yes	Yes	Yes	Yes
Vijan et al. (2005)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Somewhat	No
Webster et al. (2019)	Yes	Yes	Yes	Yes	Yes	Uncertain	Yes	Yes	Yes	No
Wycherley et al. (2012)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No

Themes

There were four analytical themes; 1) variability of support, 2) choosing dietary change; 3) re-negotiating the food relationship, and 4) beyond weight loss, and seven subthemes that were identified from the analysis. Figure 2 illustrates the themes. Whilst some themes are more descriptive and reflect what has been reported previously in the literature, this review highlights a unique perspective on the importance of consistent, person-centered support and some of the underreported challenges that are arising for participants taking this approach to manage their T2DM.

Variability of support

This theme highlights the variability of support participants were provided when recommended to lose weight through dietary modification and how participants responded to this support. This theme underpins the following two themes, as the availability and quality of support had a central role in participants' choice to make change, and how they re-negotiated their relationship with food.

An opportunity for support

For those offered structured programmes, it was perceived as an opportunity for support. This is illustrated in the poignant quote below which evokes a feeling of uncertainty regarding the next steps towards change, if a programme had not been offered:

My parents both died because of complications of diabetes...I lost weight but then I gained it all back and I was starting to get afraid because...I was starting to be at my heaviest again. I said 'what will I do?'... I'm deeply grateful for this opportunity to be part of this study. I would want to see my granddaughter grow up and all my other grandchildren grow up and still be with them (Magalalang et al., 2017, P. 149).

Deep gratitude was expressed by participants who were offered guidance (Maglalang et al., 2017; Rehackova et al., 2017; Wycherley et al., 2012). They valued accountability, and frequency of contact as it became a space to problem solve, and overcome challenges experienced by participants. For some there was a recognition that the opportunity for support was not universally available clinically. This resulted in a pressure to do their best in order not to disappoint research staff/sponsors or "distort results of the study" (Rehackova et al., 2017, p.1560)

I do recognise the fact that this is a medical study so I'm one of a handful of people that are lucky to actually be on it so to not do as what I'm told would just be silly, stupid (Rehackova et al., 2017, p.1560).

Tailored guidance

The relationship participants had with those prescribing the diet, and their attunement to participants' nutritional literacy, ethnicity, culture or socio-economic status, appeared to play an important role in how supported or unsupported participants felt across all studies. This influenced participants' engagement with programmes, as highlighted in Maglalang et al. (2017)'s research which revealed that over half of the participants stated that the culturally tailored support in terms of materials and staff enhanced their engagement. Access to frequent support, providing the opportunity to build rapport was noted to be central in reducing barriers in implementing and sustaining healthcare recommendations regarding dietary choices:

The regular check-ups and the fact that you're being monitored and the fact it's part of a clinical trial, you can't just give in because you're letting other people down as well as yourself. That keeps you honest, and it makes it a lot easier. I would say my chances of being where I am just now without that help would be as much as half (Rehackova et al., 2021, p.9).

For participants offered continuous support to facilitate change, the transition following the end of the programme was noted to be the most significant challenge. Highlighting the loss of a relied upon source of support:

You go from intensive supervision to no supervision at all at the conclusion of the programme. You don't have regular weigh-ins or anything like that afterwards. The weigh-ins and that sort of thing are incentives during the study. Left to your own devices, you don't have that to look forward to and tend to let things slide (Wycherley et al., 2012, p. 636).

Those following a prescribed diet without intensive or frequent guided support experienced additional barriers to making dietary change. Healthcare professionals holding unrealistic expectations for participants without supportive follow-up, or disapproval of chosen dietary modifications, resulted in a rupture of the relationship between participants and their healthcare provider. Some participants felt there was a lack of understanding by those delivering dietary advice on the traditional foods that were central to their community, which also contributed to a distrust in the therapeutic dynamic. It seemed that not having the opportunity to develop rapport with their healthcare provider impacted on the quality of the support that met their individual needs.

See, that is where it comes down to these doctors again. They don't understand the community or your upbringing ... It ain't got nothing to do with black or white. I am a southerner man. They cook like this all the time (Vijan et al., 2005, p.35).

Neglecting to provide nutritional information on certain foods meant participants were unsure of how guidelines could be followed based on their food preferences (Vijan et al., 2005; Moore et al., 2019):

When I went to the course [diabetes education course] I was telling them about breadfruit, they didn't know what I was talking about. They didn't really give us anything on West Indian food...they just showed pictures of fish, bread and potatoes ... when I went home, I was thinking, well, what levels of sugar are there in yam? (Moore et al., 2019, p.5).

Following recommendations was also a significant financial challenge for some people who felt their healthcare provider failed to consider their socio-economic position:

My wife and I went down and did an inventory of what it would cost to get the dietetic food ... we spend about \$250 a month now for food for the wife and I It would have been \$450 the other way ... so we have to buy the cheap stuff (Vijan et al., 2005, p.36).

Socio-economic class, or availability of foods were not discussed in studies where the prescribed diet was provided free of charge (Rehackova, 2017; Rehackova et al., 2020; Rehackova et al., 2022; Bynoe et al., 2020).

Choosing dietary change

To improve health outcomes, by managing T2DM was the driving force for all participants making dietary change. For the five studies focused on remission, participants frequently equated weight loss as the method in which they would improve their health and manage their diabetes (Rehackova et al., 2017; Rehackova et al., 2020; Rehackova et al., 2022; Webster et al., 2012; Bynoe et al., 2020). For those wishing to increase physical activity, weight loss was also perceived as a necessary step that would allow them to participate in exercise. Dietary change was thus a method through which some participants felt they could lose weight, and in turn improve their health outcomes. This contrasted with the motivations voiced in the study by Moore et al. (2019), in which participants desired "a smaller waist whilst retaining a curvy shape" (p.8) rather than to lose weight.

Motivation for change

Increasing mobility, increasing energy levels, well-being, to manage their diabetes without the use of medication, and to prolong their life expectancy were motivations identified by participants (Rehackova et al., 2017; Rehackova 2020, Webster et al., 2019; Rehackova et al., 2022; Wycherley et al. 2012). The drive to prolong life is a powerful motivator for anyone being informed of the risks associated with unmanaged T2DM. Fear of extreme health consequences that may arise from untreated T2DM heightened the sense of urgency to engage with lifestyle change “We can see the complications, there are some people with amputated legs, some people with blindness” (Moore et al., 2019, p.6).

A preference for managing diabetes over pharmacological intervention was attributed to participants reluctance to rely on medication for the rest of their lives (Maglalang et al., 2017; Rehackova et al., 2017; Rehackova et al., 2022; Webster et al., 2012). For some participants, the side-effects of the medication were experienced as unpleasant. This evoked worry that medication would have a negative impact on their physical health:

When I was first diagnosed with diabetes it was like the end of the world, I had no way out. I’m gonna be living on medication for the rest of my life and all those medications are gonna destroy me from the inside out... (Maglalang et al., 2017, p. 149).

Many participants noted that they wished to increase their life expectancy in order to spend more time with their family (Maglalang et al., 2017; Rehackova et al., 2020; Moore et al., 2019; Wycherley et al., 2012; Rehackova et al., 2017). To live long enough to experience significant life events:

This is captured in one quote by a participant who stated: “My mom died of cancer and diabetes, it became personal to me...I want to live more...I have my own two kids now...I want to see their kids graduate high school, and college” (Maglalang et al., 2017, p.149).

Building a support network

Beyond the structure and support of healthcare professionals or research staff, perceived support from family members, friends, and colleagues played a central role in facilitating participants to make dietary change. A ripple effect occurred once they began to make changes, which influenced the diet and behaviour of those around them (Bynoe et al., 2019; Maglalang et al., 2017; Rehackova et al., 2022; Rehackova, 2017). This was a reciprocal process in which individuals felt supported in their journey by those around them, but also became the motivators and supporters of others making change:

It went from being lonely like you're doing it all by yourself... I got twenty to thirty people [to use a Fitbit and participate in weekly challenges]... We changed the whole lifestyle of our family cause everybody's eating healthy (Maglalang et al., 2017, p.149).

It was also noted by a number of authors that as participants began to lose weight, compliments received on physical appearance was perceived as support by some participants to continue with their weight loss efforts. For example, comments about weight loss were interpreted as a compliment for most: "receiving compliments on appearance was one of many ways participants felt supported during the very low-calorie diet" (Rehackova et al., 2017, 1560). In Bynoe et al. (2019)'s paper weight loss was perceived positively for women, and but negatively for men, "it's sad to hear things "man you looking small, you looking bony. What wrong with you?" (p. 1822).

Re-negotiating the food relationship

There was a re-negotiation process which occurred for most with regards to their relationship with food. There was an increased awareness and focus on exactly what participants were eating, the quantity, the frequency of meals and snacks, and the nutritional value. In addition to nutritional education, many participants also began to adopt behavioural strategies that influenced their eating patterns. There were a number of challenges experienced when following dietary guidance, particularly in relation to participants connecting socially, feelings of deprivation and continued hunger (Rehackova et al. 2017; Rehackova et al., 2022; Rehackova et al., 2020; Vijan et al., 2005).

Navigating the food environment

For those on total food replacement diets, navigating situations where food would be present was given significant consideration by participants. Strategies were employed to facilitate 'adherence', which included food removal, avoidance of a variety of situations, hunger management strategies, planning, weighing self and food, and accountability by telling others about their diet (Rehackova et al., 2017; Rehackova et al., 2020; Wycherley et al., 2012; Webster et al., 2019). Portion control was a challenge experienced across diets, particularly when feelings of hunger set in, "He told what I cannot eat, but if I followed the doctor's orders, I will be starving" (Moore et al., 2019, p.6).

For those on the liquid shake diets, portion control became a greater source of stress during the food re-introduction. Which evoked feelings of anxiety and uncertainty about getting it right, "I like regimented things, and being told you could only have soups and shakes and so much vegetables per day was spot

on for me but then it comes down to ‘you take control’. I’m not very good at that” (Rehackova et al., 2020, p.956).

This led to some participants adopting unhealthy compensatory behaviours to further restrict food, following the re-introduction of food. Research captured by follow-up interviews conducted after the programme had finished noted the continued use of highly restrictive calorie counting:

I’ll have to have periods of dieting extremely hard before and after each event to put it down, but I’m prepared for that. I’ve bought myself some Slimfast, which is what I’ve been using this last month. So, every second day I go on to basically consuming 800 calories, and then it means that I can perhaps go up to about 3000 on these events, and it shouldn’t affect me too much (Rehackova et al., 2022, p. 958).

Many participants made reference to how closely they felt they had to monitor their diet because of their diagnosis of T2DM. One participant’s quote captures this continuous effort, consideration, and in some cases preoccupation with controlling their eating behaviours that many participants shared: “It’s a lot of hard work being diabetic because you have to consciously think about what you’re putting in your body ... it’s every day you have to think consciously about what you’re eating” (Moore et al., 2019, p. 6).

Feelings of hunger were reported by participants in three of the research studies (Vijan et al., 2005; Moore et al., 2021; Rehackova et al., 2022). For some, hunger was notable during the initial stage of the diet as they began to significantly reduce calories whereas for others, feelings of hunger continued:

The hunger sort of came and went. It didn’t always stay, but the majority I was hungry for the first probably a couple of months. And I thought it would alleviate, and no. There are days I don’t think about food at all, and there are days I get really hungry (Rehackova et al., 2022, p.4).

There was also a thread of deprivation experienced by participants. The importance of enjoying food was described, which was phrased in ways that seemed to conflict with the dietary recommendations that they were provided: “I eat mostly our food and I enjoy it, I can’t leave it, no matter what the doctor says” (Moore et al., 2019). It’s interesting that participants hopes were to improve their health, and engage in meaningful lives, but as articulated by one participant, being able to enjoy food was an important part of their reason for living: “If I’m going to be alive today, I am going to eat what I want. Otherwise, there is no sense in being here if you can’t enjoy something about it” (Vijan 2005, p.36).

The challenges of socialising

Negotiating social situations for all those adopting dietary modifications was a notable challenge. In order to follow strict food rules according to prescribed guidelines, or caloric intake, participants struggled to engage socially in the way they had previously. There were a number of consequences that participants were confronted with. One example provided, which echoed the experience of many, was the choice of eating alone. Self-isolating during mealtimes conflicted with the participant's cultural Filipino values, in which participation in family meals was reported to be a sign of respect (Maglalang et al., 2017).

Challenges with socializing was common across all studies although the total food replacement diet presented unique challenges as participants were unable to share family dinners or eat in restaurants. Participants noted that refusing food offered by others led to feelings of guilt and discomfort "...you can't go in people's house and not take what they offer you, they feel that you think what they have is not good enough" (Bynoe et al., 2019, p.1822).

Speaking about their diet to others resulted for some in judgment or disapproval for some "You get the frowns, the 'Why are you not eating fruit anymore? Why are you not eating sugar anymore?' So, that has been my main battle" (Webster et al., 2019, p. 2578). This impacted the way in which participants could socialise in environments where food was available (Webster et al., 2019; Wycherley et al., 2012). For many, this resulted in limited attending social occasions; "We will no longer go out for meals during that period of time. Neither of us go out to pubs and clubs and things like that, we just don't do it" (Rehackova et al., 2020, p,965).

Being in restaurants where options within the dietary guidelines were not available, became a source of stress rather than a source of relaxation, comfort, or enjoyment: "Having supper in a restaurant is a problem in the majority of restaurants. It's just not enjoyable anymore" (Webster et al., 2019, p.2577).

Looking beyond weight loss

This theme pushes beyond the delivery and journey participants experienced along their healthcare trajectory to an understanding of the longer-term implications of engaging with a diet to manage their T2DM. It's worth considering the impact that having a weight loss focus has for participants of these studies. For example, a few studies captured valuable insights when participants began reflecting on themselves and their self-perception in the context of weight change. Participants' accounts reflected a critical stance towards their eating behaviors, or in some cases towards people living in a larger body.

It was described by Webster et al., (2019) that “several participants identified themselves as carbohydrate or sugar addicts”, and gave one illustrative quote of a participant who had tied their perception of themselves as an ‘addict’ to the need to eliminate carbs forever “I have come to understand with low carb, that I’m an addict. Carbs are something that I’m probably never going to be able to eat for the rest of my life” (p.2576).

Rehackova et al. (2020) detailed a shift in identity following participants lifestyle change and noted as participants began to lose weight that they began to think of themselves as “not fat anymore”. Participants “became more aware of other people’s weight or shape and were often critical of it, thinking they should get a little bit of weight off, just a little bit at a time” (p.958).

As participants began to gain insight into their own behaviours, they began to become equally aware of the weight, shape and lifestyle of those around them. Whilst this led to positive behaviour and lifestyle change for some, it is important to differentiate inspiring others to engage in health promoting activities, to the encouragement of weight loss efforts in unhelpful ways for others. For example, one participant noted, “she’s a bit overweight, my daughter. I’m trying to, I’m going to buy her a Fitbit for Christmas” (Rehackova et al., 2020). The challenges that may arise with the ripple effect of participants engagement with weight loss focused efforts, is the potential for fostering a ‘diet culture’ in a home, or among a social group.

Meaningful change did go beyond weight loss for many participants. Authors described the benefits of increased well-being, levels of energy, increased self-efficacy, and confidence in their ability to make lifestyle changes (Rehackova et al., 2017; Rehackova et al., 2020; Webster et al., 2019; Wycherley et al. (2012). There were a notable lack of participants’ quotes regarding these changes across the nine studies.

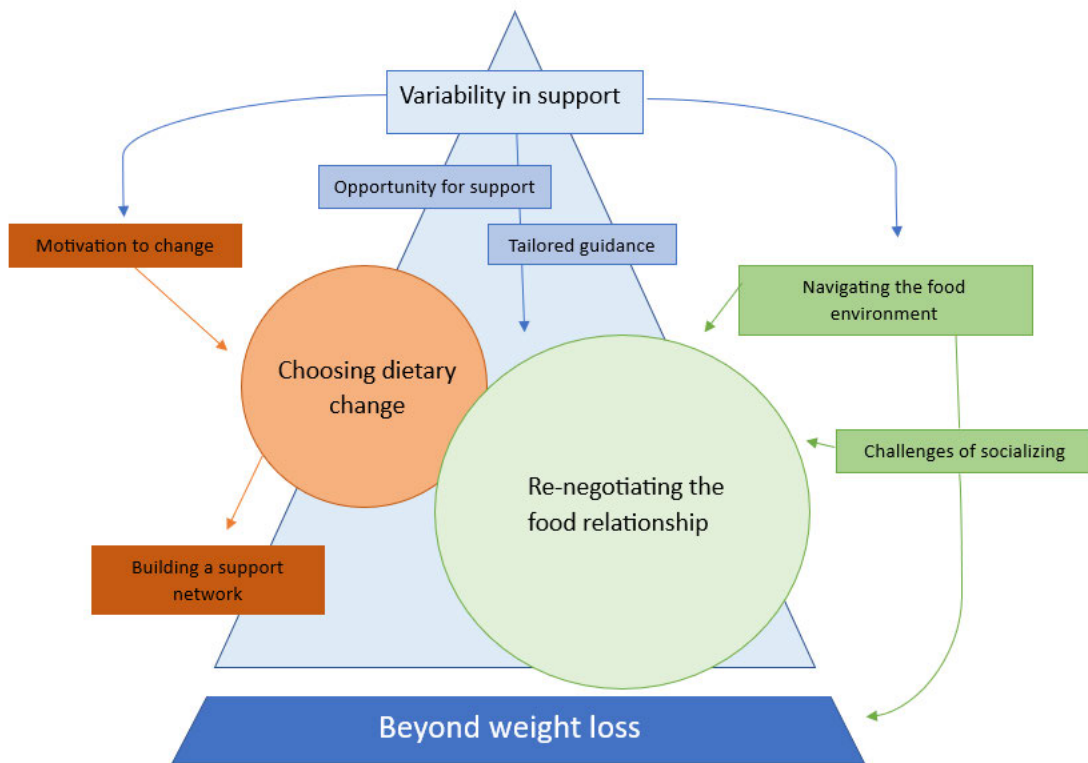
It feels like I’ve had a spring added into my step. I know that sounds really weird, but it’s just given us a lot more confidence, and I feel quite confident now, and I feel quite ... I feel more able to face things and more able to cope with things better, but I think it’s because my mind seems to be in a more focused frame of mind. (Rehackova et al., 2020, p.959).

Rehackova et al. (2017) provided insight into participants appreciation for increased time engaging in activities such as walking, climbing stairs, working in the garden, or playing with grandchildren. Becoming more in tune with patterns of comfort eating, or how they respond to stress was also voiced.

Presented in Figure 2 below is an illustration of the themes. It represents how interconnected and overlapping many of them are. Variability in support clearly underpinned the other two themes. Choosing to make dietary change, and the process of change appeared to be influenced by the frequency and quality of support which is represented in blue. Having an opportunity for support, and tailored guidance contributed to how motivated participants felt towards change, and how they began to navigate the food environment. 'Beyond weight loss' sits separately to the other figures, as it wasn't addressed explicitly in many of the studies, with its positioning reflecting how separately it sits to the other themes.

Figure 2.

Illustration of themes



Discussion

This is the first review to collate all qualitative research which has been conducted to explore individuals' experiences of dieting with a weight loss focus to manage their T2DM. There were four analytic themes developed that captured how participants responded to guidance offered. As depicted by Figure 2, the variability in support underpinned participants choice and motivation to make dietary

change, and how they re-negotiated their relationship with food. Being offered a structured programme provided participants with an opportunity for tailored support and guidance, which influenced participants engagement with dietary change. Re-negotiating the food relationship provided insights into how participants navigated life whilst on a diet. The final theme, beyond weight loss, sits separately to the other themes, which provides the space for the consideration of benefits or harms that may arise for participants beyond their weight loss journey. As the emerging evidence on remission has changed the landscape of diabetes care, it is crucial that we look towards the studies that have provided insight into what's helpful and what's harmful with weight loss approaches.

It was clear that there was a determination for all participants to improve their health outcomes, however, depending on the frequency, and type of support available, making significant changes was much more challenging for some participants than others. Participants were not afforded the same opportunities for support. Healthcare providers who neglected to acknowledge and tailor advice based on an individual's food preferences, cultural or traditional values, and socio-economic circumstances, resulted in an increased difficulty for participants to even make a start towards dietary change. All of these have previously been identified as barriers in making lifestyle changes (Cheng et al., 2016), reinforcing the critical need for all assessments, guidance and interventions to be delivered in a person-centred way. Researchers have shown person-centred care and length of time spent with patients, providing lifestyle guidance, is associated with increased efficacy for managing glycaemic control, increasing activity levels, improving eating patterns, and with longer lasting results (Asmat et al., 2022; Al Harbi et al., 2022).

Fears of a reduced quality of life and decreased life expectancy were extreme drivers for some participants to make dietary changes, in particular for those with family members who had a diagnosis of T2DM. These findings are similar to those identified by a systematic review conducted by Harper et al. (2018), who explored people's experiences of very low-calorie diets for weight loss purposes without T2DM. Participants interpreted being accepted on to an intervention as a 'last chance' for support and to make changes for health and well-being. This feeling of urgency may be more pronounced for those with T2DM, which provides context for the sincere gratitude and fear of failing, or disappointing staff expressed by participants provided a structured programme in this review. Individuals engaging in diet modification for weight loss purposes are a highly motivated group of individuals, powerfully expressed by some participants here. Despite this, a large body of literature continues to identify motivation being a significant barrier to change, rather than considering the wider systemic issues that play a central role

in individuals' ability to sustain such changes (Anderson-Steeves et al., 2014). Drastic public health measures must be taken through legislative and policy change in order to shift the responsibility from individual, to the food environment (Walls et al., 2011).

Some of the concerns raised here reflect the growing understanding of the harms dieting can have on an individual's self-perception, social network, and eating behaviours (Robinson et al., 2020). Bringing this awareness to all approaches aiming to support individuals with weight loss is essential to help rather than hinder the development of healthy eating patterns. Participants spoke of dietary recommendations excluding foods that were central to their culture, and their taste preferences. Smaller portion sizes led to feelings of hunger, and elimination of previously enjoyed foods which led to a sense of deprivation. Feelings of deprivation have been associated with the loss of pleasure in meals, which is often preceded by restrictive food intake (Cheng et al., 2016). Participants experiences of deprivation, pulls into question the recommendations of extending the liquid shake diet phase or introducing a 'rescue plan' (Marples et al., 2022), if individuals struggle to lose weight, or are beginning to re-gain weight. By encouraging further deprivation of food in response to increased weight, it may unintentionally increase individuals fear of weight re-gain and encourage the use of extreme calorie restriction to maintain weight loss as a method of managing diabetes.

Deprivation of social connection as a result of dietary choices was also identified from participant accounts. Navigating the food environment resulted in an oscillation of guilt for refusing food and declining social invitations, frustration for not being able to eat out, and an acceptance of needing to impose social isolation to follow dietary requirements. Vanstone et al., (2017) highlights the social significance of food being a barrier to individuals making dietary modification, which resonates with participants experiences presented here. It is noticeable that throughout every theme there is an interpersonal element, building a relationship with a healthcare provider, seeking support from friends and family, losing weight to engage in valued activities and prolonging life to be around for significant family life events. However, the imposed social isolation that dieting culture often creates, conflicts with many of the participants hopes to increase quality time with family and friends. As a diagnosis of T2DM has already been identified to have a negative impact on social connection, increased loneliness and isolation may only be exacerbated for individuals who are unable to join family meals, or social occasions because of the restraints of their diet (Woolley et al., 2020).

The final theme considers the necessary components that often underpin sustained health promoting behaviours over time. Looking beyond weight loss and supporting individuals to identify goals

that are aligned with what they value may support longer-term behavioural change (Greaves et al., 2017). In this review, limited data was available exploring people's individual goals or progress made towards achieving them. Rather than outcome measures of BMI being considered as success, perhaps a re-focus of building a healthy relationship with food, with oneself and engaging in valued activities may also facilitate a shift in attention towards sustainable health promoting behaviours over time, rather than restrictive eating strategies (Fink et al., 2019). Following weight management interventions weight-regain has been observed to begin at 36 weeks following intervention (Machado et al., 2022). What is missing is longitudinal research to explore what has been gained and sustained to support diabetes management and well-being, in addition to the long-term misuse of weight management strategies.

Strengths and Limitations

There are a number of strengths and limitations to this review that must be acknowledged. Firstly, it is clear there remains a significant gap in qualitative research for this approach for those diagnosed with T2DM. The search yielded only nine studies, which highlights the stark gap of research conducted in this field. As nearly half of the studies were of mixed methods, direct participant quotes were limited. Whilst this is a valuable finding in and of itself, analytical themes must be considered with this caveat in mind. GRADE-CERQual was a valuable tool to consider the confidence in each theme based on available data. There was a variability in weight loss efforts by participants and guidance provided. The decision was made to include all studies which asked participants about their experience of weight loss focused dietary modification, because of the limited available evidence for one specific diet. This has provided an interesting perspective on what researchers have been interested in and their purpose for carrying on qualitative methodology, which has mainly been to evaluate or contribute to the development of programmes. Finally, most studies were available because of research funded studies and were not routinely offered as part of clinical care. This was expressed by a number of participants in their appreciation for being offered an opportunity, which may have influenced a more favourable view of their experience.

Conclusion

To conclude, further research and clinical consideration is needed in order to ensure those living with T2DM are being provided with person-centered, safe care. This review has synthesized the experiences of participants who have engaged in dietary modifications to achieve weight loss and manage their T2DM. The review showcases the many challenges that arise which go beyond the effective use of

strategies to follow a prescribed diet. Emotional, social and cultural needs must be considered for those making such significant lifestyle changes and whether low calorie diets are conducive to individuals health and well-being. Longer-term qualitative research is critically needed to identify the sustainability of dietary change, and the long-term impact of weight loss focused goals.

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Chapter 2. Empirical Research

“Just do it by diet”: An Exploration of Individuals Experiences of a Weight Management Programme to Achieve Type 2 Diabetes Remission

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The Authors declare that there is no conflict of interest.

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6. Ethics approval

Ethical approval was sought and granted from the Integrated Research Application System (IRAS), South Central - Berkshire B Research Ethics Committee (REC reference: 22/SC/0007). Sponsorship and ethical approval were also sought and granted from the University of Edinburgh, through the School of Health in Social Science. The study was also reviewed and granted approval by the Academic and Clinical Office for Research and Development in Lothian, Scotland [See appendix X].

7. Pre-registration

N/A

8. Data availability statement

The current empirical research study is accompanied by the relevant raw data generated during and/or analysed during the review process, including the required files detailing the review process and the complete database of extracted data. These files are available in the Figshare repository and accessible

as Supplemental Material via the SAGE Journals platform. If there are any required ethics approvals, participant permissions, or other relevant approvals for the data sharing accompanying this systematic review then these have all been granted.

Word count: 11,867 (excluding references and references)

Abstract

Introduction: Efforts to support individuals diagnosed with Type 2 Diabetes Mellitus (T2DM) to achieve and remain in remission have been an on-going pursuit by researchers and clinicians. An accumulating body of research has suggested weight loss through very low-calorie diets to be the most effective non-surgical method to reach remission. Understanding the expectations, hopes, meaningful changes and challenges for those undertaking the programme must be considered to ensure programmes are sustainable and without harm.

Methodology: Participants were recruited from the Counterweight Plus programme, a two-year weight loss focused intervention designed to support individuals achieve remission. Five participants beginning the programme and five participants finishing the programme were interviewed. Transcripts were transcribed verbatim and subjected to multiperspectival interpretive phenomenological analysis (Larkin et al., 2021).

Results: There were five themes, identified following analysis; overwhelmed by the system, a life worth living, taking the wee steps, cutting food, cutting calories and not good enough. The results capture shared experiences across both groups engaging with the programme, in addition to the tensions which run across and within both groups.

Discussion: This study provided insight into the lived experiences of individuals engaging with a weight management intervention hoping to achieve remission. The findings provide a unique perspective on the potential harms of engaging with these programmes. A number of considerations that require further research exploration and clinical consideration are outlined.

Key words: Type 2 Diabetes Mellitus, Remission, Total food replacement diet, Lived experience, Sustainable change

Introduction

Type 2 Diabetes Mellitus (T2DM) is a complex metabolic disorder which results from insulin resistance, caused by a gradual decline of beta-cell function (Smushkin & Vella, 2010). A combination of both environmental and genetic factors can lead to the development of T2DM, whilst environmental factors may trigger the onset of the disorder, there is a strong genetic component, with heritability rates ranging from 20%-80% (Ali, 2013). The interaction between environmental and genetic components is complex, with many pre-disposing factors including lifestyle behaviours, that may make an individual vulnerable to developing the disorder (Wu et al., 2014). Whilst T2DM was considered historically to be progressive and life-long, there has been a significant shift in the past few years towards achieving 'remission' of the condition (Holman et al., 2022). There is continued discussion with regards to the definition of remission in the literature, and what is applied in practice. As an avenue towards unity, an expert group convened by the American Diabetes Association have proposed that remission may be considered to be achieved if a HbA1c reading of less than 6.5% (48mmol/mol) is recorded at three months following the cessation of pharmacological input. Remission over 'reversibility' or 'cure' was deemed the most appropriate descriptor (Riddle et al., 2021).

Evidence for achieving remission comes from studies which have shown that 5% of weight loss can improve β cell function, liver and muscle insulin sensitivity. A higher percentage of weight loss has been associated with improvements in adipose tissue disturbances (Magkos et al., 2017). Whilst not all those who are diagnosed with T2DM are of a higher weight, all non-pharmacological treatment approaches specify weight loss to be the necessary component to achieve remission for those of any size (Taylor, 2019). The Look AHEAD trial, conducted in 2003, set the foundation for investigating the achievement of diabetes remission using calorie restriction (Pi-Sunyer, 2014). Promising findings instigated the proliferation of non-surgically focused research, using dietary modifications to achieve weight loss outcomes, and in turn remission (for review see Brown et al., 2022). Guidelines and service delivery within the national health service (NHS) were changed to reflect the accumulating evidence. Guidance recommends bariatric surgery and diet interventions as first line of treatment for those who are of a higher weight newly diagnosed with T2DM, and hoping to achieve remission (Rosenfeld et al., 2022; Hallberg et al., 2019)

The most recent and influential trial within the UK has been the Diabetes Remission Clinical Trial (DiRECT) which included a low-calorie total food replacement diet (823-852 calories, 12-20 weeks), followed by food re-introduction (13-19 weeks), and structured weight lost maintenance phase (19-104

weeks). Of 146 participants who took part in the 2-year intervention, 46% of people achieved remission at 12 months and 35.6% at 24-month follow up (Lean et al., 2019). A three-year extension of the trial revealed that of the 48 out of 85 participants who were in remission following the two-year trial, only 11 (23%) remained in remission at the five-year follow-up (Diabetes UK, n.d). Notably 29% of participants withdrew from the trial within these 2 years. Although research has identified that programmes employing meal replacement interventions have a higher dropout rate compared to other dietary modification programmes (Cradock et al., 2017), no studies explored reasons for attrition, or interviewed individuals who did not complete the programme.

Despite the high attrition, low levels of sustained remission at longer term follow-up, and little exploration into the potential adverse effects of severe dietary restriction, the Counterweight Plus (CW+) has been rolled out across the United Kingdom. This is a commercial programme originally designed for weight loss, that was adopted for use within the DiRECT trial. Healthcare professionals who deliver the programme vary across practices, however, it is primarily delivered by practice nurses, or dieticians supported by general practitioners, with fewer services involving psychology (Rehackova et al., 2022; Rehackova et al., 2017). To date, the qualitative and mixed methods studies exploring individuals' experiences of the CW+ programme specifically have aimed to gather information on participants' motivations to engage with the programme, the benefits and challenges, and to provide recommendations on how best to support participants to follow liquid diets and maintain weight loss outcomes. For example, Rehackova et al. (2017) identified facilitators and barriers to the liquid shake diet, which resulted in drawing together a list of strategies suggested by participants that were helpful for their adherence to the very low-energy diet. Although adopting restrictive eating patterns or hunger management strategies often does result in short-term weight loss, long-term use of disordered eating patterns to maintain weight loss can be more harmful to an individual's psychological and physical well-being than living at a higher weight (da Luz et al., 2018).

Disordered patterns of eating are often overlooked and underdiagnosed for individual's living in larger bodies. Weight stigma is a known contributing factor that can often mask disordered eating patterns for individuals living in larger bodies (Ralph et al., 2022). With weight loss often being monitored as a measure of success, healthcare professionals may unintentionally reinforce the continued use of unhealthy behavioural approaches, without considering the potential consequences. Many of the studies conducted to date have neglected to take a broader perspective of individuals' relationship with food, the potential consequences of severe calorie restriction as a weight loss method,

or the lasting impact of such diets beyond engagement with the intervention (Rehackova et al., 2017; Taylor, 2019). With such a large emphasis across the literature and in clinical practice on using weight loss strategies to achieve T2DM remission, it is critical to consider the impact of this approach, and the potential harms that may arise for individuals during and following engaging with a highly calorie restrictive diet.

Drawing from adjacent literature on the harms of fad diets, and the impact of dieting on an individual's relationship with food, weight fluctuation, and preoccupation with weight and shape (e.g., Blomain et al., 2013; MacLean et al., 2004), it is clear that the current trajectory of T2DM treatment must be carefully considered. Limited empirical research has been conducted on the prevalence of disordered eating or eating disorders, among those with T2DM. It is estimated that 1 in 10 individuals with T2DM have an eating disorder, and 1 in 4 have disordered eating, which totals an estimated prevalence of 35% between both groups (Young-Hyman & Davis, 2010). Currently, no guidance has been published on supporting individuals who are sub-threshold meeting criteria for an eating disorder or presenting with patterns of disordered eating. As a diagnosis of T2DM in and of itself brings several additional challenges, research is needed to bridge the gap between what is known from the literature of challenges experienced by individuals engaging with very low-calorie diets, and what is yet to be learned from those seeking to achieve remission.

The historic and continued trajectory for most living with T2DM is pharmacological input, and on-going medical monitoring (Layani et al., 2023). Whilst on-going medical monitoring is a necessity for the care of those with T2DM, there appears to be a delayed shift in the research on the importance of psychosocial considerations when promoting such significant lifestyle changes. Using weight loss as a primary measure of success sets the precedence for weight loss to become the metric by which individuals will measure progress (Gutin, 2018). Measures of quality of life currently used within the literature for individuals seeking to achieve remission often fail to adequately capture potentially meaningful outcomes that participants may achieve by making significant lifestyle shifts. Interventions based on third wave cognitive behavioural therapies, have employed additional outcome measures such as self-acceptance, compassion, psychological flexibility, mindfulness, understanding and responding to cravings and emotional eating to measure the success of an intervention (Lawlor et al., 2020). There is a gap which exists between evidence available from weight management approaches which take a holistic perspective of an individual's relationship with food, health promoting behaviours, and psychological

well-being, and the design and delivery of such interventions for patients with diabetes seeking remission.

The qualitative research which has been conducted to date have primarily adopted thematic analysis to understand and explore participants accounts of their experience of the counterweight plus programme. Many of these studies which have included larger samples, or longitudinal components have involved researchers which have a vested interested in the programme, with conflict of interests and study funding clearly outlined (e.g., . Rehackova et al., 2017; Rehackova et al. 2020; Rehackova et al., 2022; Bynoe). Given the potential bias that may be presented in how favourably participant experiences are presented, additional research is needed to add to this growing qualitative research evidence base. Taking an IPA approach is also unique in exploring participant experiences on an individual basis, rather than as a group. Individuals' relationships with food, and the food environment are complex and depend on a multitude of factors, from cooking responsibilities in the home, cooking ability, access to cooking facilities, access to nutritious foods, income, work schedules, culture, individual taste preferences, experiences of dieting, and weight and shape concerns. Given how unique the trajectory of those diagnosed with T2DM can be, understanding participants experiences on a case-by-case basis, incorporating the multitude of contextual factors that impact on their ability to make change needs to be better understood (Bukhsh et al., 2020).

Qualitative research lends itself well to this form of exploration, as it can provide a wealth of information that cannot be captured by healthcare outcome measures. The endeavor with this research is to understand the personal trajectories of those engaged with a weight management programme focusing on supporting individuals to achieve remission. This understanding is crucial to critically consider the direction of diabetes care and provides an opportunity to learn from the lived experiences of individuals engaging with these programmes. This research is unique in its application of multiperspectival IPA design, to capture this experience from two pivotal vantage points, embarking upon and finishing the counterweight plus programme. The main objectives include:

1. To explore participants' journey to, expectations, and hopes for the programme.
2. To explore meaningful outcomes and perceived success following engagement with the programme.
3. To gain insight into concerns, and challenges arising for participants prior to or following engagement with the programme.

Methodology

Study design

Interpretive phenomenological analysis (IPA) is a qualitative methodological approach, based on phenomenology, a philosophical approach to the study of experience, and hermeneutics the theory and art of interpretation (Smith et al., 2021). It uses an idiographic approach to take a detailed and nuanced understanding of an individual's perspective on a phenomenon within a particular context (Boutillier et al., 2022). Multiperspectival design follows the same commitment to phenomenology, hermeneutics and idiography, adding a layer of complexity through the introduction of an additional group's experience of the same phenomena from a different perspective or vantage point (Larkin et al., 2022). From the emerging taxonomy of designs developed within this approach, this study aims to explore the experiences of two 'directly related groups' who are immersed in the same environment, involved with the same phenomena, but are likely to have distinct perspectives on it (Larkin et al., 2019). The shared phenomena of interest is a weight management programme designed to support remission of T2DM. By gaining insight of experiences from individuals diagnosed with T2DM, from two pivotal time points of transition, it allows us to gain a fuller understanding of the experiences of participants hoping to manage their diabetes using this approach.

Recruitment

Participants were recruited from the Counterweight Plus (CW+) programme as part of the weight management service in NHS Lothian, Scotland. A purposeful sampling approach was adopted in line with IPA principles, which recommends recruiting a homogenous sample who represent a perspective rather than a population (Smith et al., 2021) Given the multiperspectival nature of the design, two sub-samples of participants were recruited in this study; the first sample included those with a diagnosis of T2DM, who were in the initial stages of the programme, specifically 1 week to 3 months following initial dietician assessment. The second sample consisted of individuals within three months of finishing the programme. This recruitment strategy was chosen as it captures two periods of transition for people who are taking the first steps embarking upon or completing a programme to support the management of their T2DM. As IPA takes an idiographic approach it is recommended that sample sizes remain small to allow for depth of experience to be explored and considered by the researcher (Smith et al., 2021). Although sample size depends largely on the study design and question, within IPA smaller samples are valued as it allows for quality to be prioritised over quantity and enables a concentrated focus on each individual case (Smith et al., 2021). Therefore, a sample of five participants per group was considered

appropriate for this design. Recruitment was facilitated by dietitians working in the service. Those who voiced interest in participating were provided with a plain language statement by the dietitian which described the study in detail. They were then contacted by the lead researcher RMcDM if they expressed interest.

Setting

The CW+ programme is a commercial programme for weight loss that has been adopted by the NHS to support people to achieve remission. The programme begins with a 12-week total diet replacement (TDR) phase followed by an 18-month food reintroduction, and a structured support programme for long-term weight loss maintenance (Leslie et al., 2016). The programme is offered on a one-to-one, or group basis, delivered by a dietitian. Patients meet with the dietitian every two weeks, for the first two stages and then once a month for the maintenance stage. The programme is not ordinarily designed to have psychological input. However, in some NHS health boards in Scotland, including in Lothian where this research was conducted, the dietitians receive supervision sessions with a clinical psychologist. Patients are also referred to the psychologist to assess the suitability of the programme for patients needs, and where disordered eating has been highlighted at the assessment stage and at any later stage during the intervention.

Consent and interview process

Informed consent was sought by asking participants to complete a consent sheet, which they accessed through the online platform JISC (n.d) (See Appendix J). Following an opportunity to read the participant information sheet and having the opportunity to ask questions, participants were provided with a unique code to complete this form online. This was in line with information governance and to protect anonymity. Verbal informed consent was also sought at the beginning of each interview. Once written informed consent was obtained participants were interviewed either over the telephone or through an online video platform, NearMe. All interviews were conducted by RMcDM, without a prior relationship being formed between the researcher and the participant. Consent was also sought verbally at the beginning of each interview, to provide participants with the opportunity to withdraw if they wished at this point. It was acknowledged that participants may have considered the interviewer to be part of the Counterweight plus programme. A small description of who the researcher was and why they were conducting the research was provided at the beginning of each interview.

A semi-structured interview guide was employed to guide the interview. The guide was developed according to IPA methodology, to facilitate a comfortable interaction with the participant, enabling them to a more detailed a fluent account of their experience (Larkin et al., 2022). The interview guide was developed in collaboration with FD and DC. Questions were open-ended and focused on participants' journey to the programme, their experience so far, concerns and challenges they experienced as well as hopes and goals for the programme. Those finishing the programme, were asked about the programme in more depth, and about their personalized goals (See Appendix I for interview guide). As recommended within IPA research, the interview guide was designed to open with a question of relative ease to allow participants to become comfortable and more in-depth or analytical questions were held until the participant appeared to ease into the interview (Larkin et al., 2022). Follow up questions included asking participants about how they felt about certain interactions with healthcare professionals, uncovering their understanding of the changes they were in the process of making and purposes for making such changes.

Participant characteristics

There were 10 participants who took part in the research, which provided insight from both groups of participants, while also maintaining a manageable amount of data (Larkin et al. 2022). Table 1 includes participant demographic information. All participant names have been changed for anonymization and confidentiality purposes. Interviews ranged between 24 and 60 minutes, with a total interviewing time of 316 minutes.

Table 1.

Participant characteristics

Participant	Age	Time since diagnosis	Group
Patsy (P1)	61	Two years	1
Elsbeth (P2)	52	Two years	1
Bessie (P3)	49	Three months	1
Karl (P4)	49	Six months	1
Ross (P5)	52	Two years	1
Harley (P6)	53	Five years	2
Robert (P7)	56	Five years	2
Beryl (P8)	43	Six years	2

Charley (P9)	63	Two years 6 months	2
Ewan (P10)	51	Six years	2

Group 1 = participants who were within three months of beginning the group

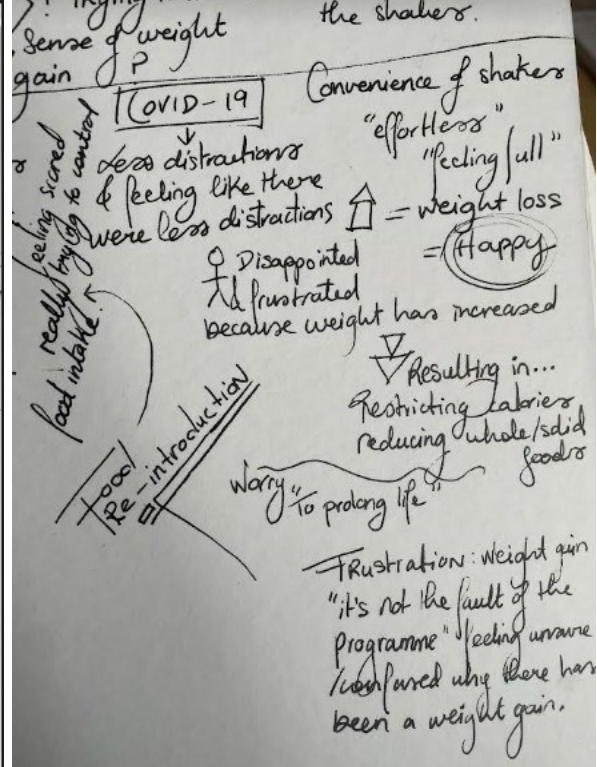
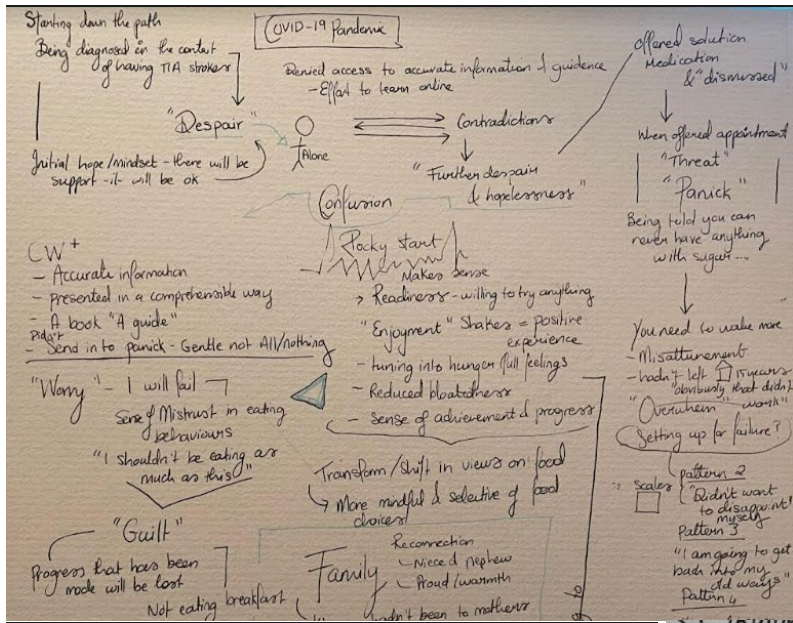
Group 2 = participants who were within three months of finishing the group

Analysis

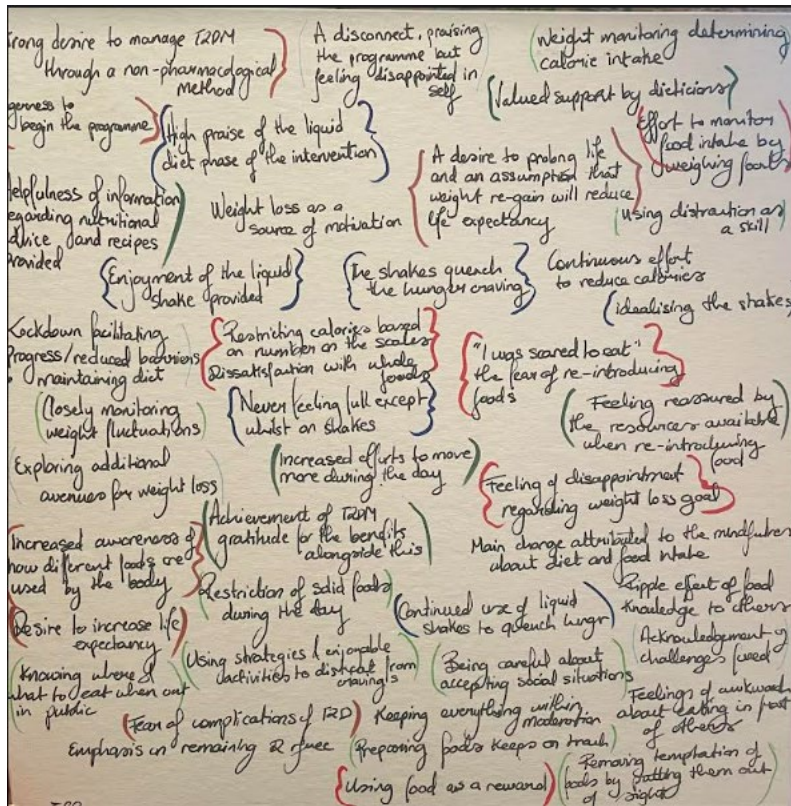
Interviews were transcribed verbatim by RMCDM. Traditional IPA was followed for individual cases, and multiperspectival guidance was followed to conduct a cross case and group analysis which required a number of additional steps and consideration (Larkin et al., 2019). Interpretative Phenomenological Analysis (IPA) was chosen over other qualitative methodologies, such as thematic analysis, to understand how participants made sense of their experience of being referred to, and engaging with the CW+ programme. The hope for this approach was to gain insight into the meaning participants derived from their individual trajectories, taking an idiosyncratic approach to explore each participant’s account in depth rather than generalizing from a large group of participants experiences.

As recommended by Larkin et al. (2021) the analytic process lends itself well to creative approaches for the researcher to make sense of the participant experiences, as this is a novel approach within IPA a detailed account of the analysis is outlined here. Step 1 involved initial reading and re-reading one transcript at a time, in order for RMCDM to become familiar with the language, context, narrative of each participant. Step 2 involved tentative note taking holding a phenomenological focus, staying close to the participant's explicit meaning, as the researcher became familiar with the participant, their way of speaking and understanding of their diagnosis. To add a layer of depth in understanding, the researcher considered the language that participants used, paying particular attention to the context of participants concerns, and identifying more abstract concepts to move from the descriptive to identifying patterns of meaning. An on-going analytical dialogue transitioned into the challenge of retaining the complexity of exploratory notes but articulating points of significance which led to step 3; constructing experiential statements. Using blank canvas cards illustrations, quotes, and interpretations by RMCDM were drawn up. For step 4, experiential statements were written out on the back, and were colour coordinated to identify connections, rooted closely to the analytical process on the flip side of the canvas. Step 5 consisted of drawing together experiential themes to name personal experiential themes (PET) (See below for example of analytic process, Appendix K includes full example of coding process).

Photographs representing use of canvas to make sense of individuals narrative



Example of experiential statements categorised using colour coordination to form Personal Experiential Themes (PETS)



Steps 1-5 were repeated for each individual interview. Step 6 involved returning to all PET's that were identified for group 1, these were drawn out on matching coloured post-it notes and laid out randomly. Paying particular attention to the convergence and divergences across participants' experiences, group experiential themes (GET)s were developed. PETs were grouped, taken apart and re-grouped in an iterative interpretive dance between each individual's narrative and the wider context of the research aim. Once GETs were developed for both groups, an overarching collective of GETs were identified using a jigsaw exercise of placing GETs from group 1 besides, above or on-top of GETs from group 2. This process tried to make sense of where participants' experiences complimented or fit with one another, and where conflict or tensions arose. There was an interpretive, reflexive and interrogative skill to step 7, as RMCDM aimed to identify meaningful patterns running through both groups, that represented meaningful perspectives voiced by the collective, while remaining grounded in the intricate and specific voice and context of each participant (See Appendix L for an overview of the transition from Step 6 to step 7). It must be noted that during this process it became apparent that whilst not all participants shared the same experience, neglecting to include certain aspects of the weight management programme would fail to represent significant points of the programme for participants.

As each transcript was subjected to traditional IPA, some themes or sub-themes presented the views and experiences of only one group, Table 2 notes this specifically.

Reflexivity

The researchers play a fundamental role within IPA, in which they are encouraged to become immersed in the data and engage in a continuous process of making meaning of the participant's process of making sense of their experiences (Larkin et al., 2021). Given the central role the researcher plays in this double hermeneutic process, researchers must engage in a reflexive process whilst undergoing qualitative research (Larkin et al., 2021). Reflexivity has been defined 'as a set of continuous, collaborative, and multifaceted practices through which researchers self-consciously critique, appraise, and evaluate how their subjectivity and context influence the research processes' (Olmos-Vega et al., 2023, p. 241). A reflexive journal was used to bring awareness to subjective elements that could impact interpretation of the data. RMcDM engaged with this process prior to conducting the interviews, following each interview, and whilst conducting the analysis. This was a method used to document thoughts, decision making, and meaning making that could then be shared with the team.

There is a psychological perspective taken within this paper, given that all authors are working or training as clinical psychologists. The authors do hold the view that the psychological well-being of participants must be held to the forefront in all healthcare treatments. RMcDM is a trainee clinical psychologist with experience of working within a weight management service and working with people with patterns of disordered eating and eating disorders. Her position has exposed her to the harms that results from diet culture and weight stigma, which she was aware could impact upon her interpretation of data. To limit bias and understand what may be evoked from personal experience or expressed by a participant RMcDM received regular supervision with FD an academic supervisor and DC, clinical field supervisor. FD works as a senior lecturer, and as a consultant clinical lead with the child and adolescent mental health service (CAMHS). DC works part-time within the weight management service and with a specific remit to support the T2DM remission pathway.

Credibility

Having confidence in research findings warrants close attention to the validity and quality of the research design. As it was intended for findings to contribute to the field in a meaningful way, principles for conducting high-quality qualitative research were followed throughout, the consolidated criteria for reporting qualitative studies (COREQ) (Tong et al., 2007), was followed throughout in the reporting of this article (See Appendix M). For IPA methodology specifically, guidance by Smith et al. (2021) on

markers of high quality in IPA studies were closely followed. FD coded 20% of interview transcripts independently to increase the trustworthiness of data, discussions were held between FD, DC, and RMcDM throughout this process. Ongoing consultation meetings were held during the analysis phase with a research panel including FD, a PhD candidate using IPA, and a researcher with lived experience of an eating disorder.

Ethical approval

Ethical approval was sought and granted from the Integrated Research Application System (IRAS), South Central - Berkshire B Research Ethics Committee (REC reference: 22/SC/0007). Sponsorship and ethical approval were also sought and granted from the University of Edinburgh, through the School of Health in Social Science. The study was also reviewed and granted approval by the Academic and Clinical Office for Research and Development in Lothian, Scotland (See appendices N, O, P). For study protocol see Appendix Q. Informal consent

Results

The final GETS developed across both participant groups are presented in Table 2 below.

Table 2.

Results

Theme	Sub-theme	Group
1. Overwhelmed by the system	1.1. Processing the diagnosis	1,2
	1.2 Searching for support	1,2
2. A life worth living	2.1 Insight	1
	2.2 Re-engaging with life	1,2
3. Taking the wee steps	3.1 Empowered	1,2
	3.2 The wee steps	1,2
4. Cutting food, calories	4.1 Preparing for the cut	1
	4.2 Navigating life whilst on shakes	1,2

	4.3 Transitioning	1,2
5. Not good enough	5.1 Undervaluing success	2
	5.2 Still trying	2

1. Overwhelmed by the system

This theme provides insight into the significant variability in support offered to participants. Whilst participants were processing being diagnosed, they were also having to navigate the system, searching for support. Learning of the diagnosis and making sense of the implications, underpinned by a questioning of self-blame, led to heightened distress following diagnosis. Searching for support to manage their condition became an additional source of distress with many participants expectations not being met, which led to overwhelm.

Processing the diagnosis

The way in which participants processed the diagnosis varied across both groups; there was a thread of shock that rippled through the experiences of those just beginning the programme as they made sense of being diagnosed. Bessie, Elspeth, Karl and Patsy were asymptomatic going for routine blood tests. Elspeth and Patsy voiced their confusion as they had not been informed by their GP they were being tested for T2DM.

Bessie swaps between past and present tense highlighting a grappling of acceptance as she attempts to connect with the reality of what the diagnosis means for her:

Well it was all a bit of a shock, I was diagnosed with diabetes, I had no idea that I had it em, it was kind of a routine blood test up at the GPs ...so I still don't have any symptoms and still find it a bit unbelievable really em (Bessie, G1)

The uncertainty and slight despair can be felt in Elsbeths account, the worry apparent in the thought 'am I on that road' as she repeats the guidance that she was provided with:

I just think that you just because you are low, you change your diet, and exercise more, you are just kind of left to it, rather than actually 'this is scary' because you read the horror stories, and what can happen, em and you just think, 'am I on that road?', you know they keep telling me I can put it into remission, but there is no really ... (Elsbeth, G1)

The underlying sense of worry and fear was present for those beginning the programme. Still trying to make sense of the diagnosis, there was clear uncertainty about their trajectory. From those finishing the programme there was a more cognitive re-telling of the events leading up to and following the diagnosis, the shock had subsided but a continued rumination on how they developed the condition ensued. For example, in Robert's case, he had been experiencing symptoms, until he was forced to go to the doctor because of how much he had suffered. He tried to endure for as long as he could, "I had let it go on for that long that it had really got a grip of me, where my readings were taken and they were sky high.." (Robert, G2)

Searching for support

There was significant variability within both groups, between those who were offered the programme immediately, and those whose expectations of healthcare support were not met. Some participants who were referred to the programme swiftly after diagnosis did not appear to experience the same levels of distress, or confusion in relation to their health care trajectory, as those with a more challenging path to support. For Ross 'things moved quite quickly' (Ross, G1) following diagnosis, being referred to the programme and speaking with the psychologist. Despite all participants being part of the same geographical region of care, it showcases the lottery participants experienced in being offered support.

Elsbeths quote carries through to this sub-theme as she begins her search for support.

The doctor just ran a diabetes test, didn't expect for it to come back as positive, so I went and had a quick chat, they said just to do it by diet, and then didn't hear anything for over a year, from the doctor (Elsbeth, G1)

Participants spoke of piecing together the limited guidance on how they could manage their T2DM. This resulted in increasing anxiety, and a feeling of isolation prevailed. This feeling is captured in Karl's articulation, as he described it was as if he had gone into the "abyss" (Karl, G1).

Whilst this was in the context of COVID-19, the irony of what Ross expresses mirrors Elsbeth's experience of being advised 'to just do it by diet' without supportive follow-up:

So everything was cancelled and he said you are going to get no information, the best thing to do is to look it up online and find out what you need to do and I was like ok, and he was like we have a nurse here in the practice that can give you information haha but he said you can't make an appointment for that because were not allowed to make any appointments due to the covid

and she won't call you because she's too busy, so just look online and see if you can find anything on diabetes (Ross, G2)

Ross's extract captures this feeling of being failed by the healthcare team. Being instructed to look resources up online was rightly deemed as inadequate as a form of support. For Patsy there was a "mixed up referral" resulting in a delay for support "I kept on chasing it up every few months" (Patsy, G1). A mistrust in the system ensued, resulting in a feeling of hopelessness that support was available. This is reflected in Charley's experience of a lack of tailored advice:

I did because the doctor had said you will have to change the way you do things, and I said what do you mean and he said you will have to start moving, and walking and doing things, before I hadn't done that I hadn't been out the door in 15 years, and it was just a lot to take on in one go, and it did it changed the way I ate, but it obviously didn't work (Charley, G2)

It is clear from Charley's expression that the GP had not taken his individual circumstances into account, and despite unrealistic expectations being set, there was a feeling of overwhelm and sense of disappointment that Charley suffered as a result.

Being on the programme and being offered accurate, comprehensible information that was specific to their diagnosis, and tailored to their individual needs, provided relief. Reaching the programme was reprieve and validation that their condition warranted attention and support.

The despair can be identified in Elspeth account as she sees the programme as a last resort:

I just need to look after myself, so that's' why when the dietician phoned about this programme, I was like I am just going to take it, you know because I just need to look after my health, because I kind of get the impression that the doctors aren't really fussed, you know, about it (Elspeth, G2)

Taking the steps to reach out and ask for help was difficult. Two participants reflected on the struggle they had with weight for years, which had led to beliefs about the absence of care. The urgency of the T2DM diagnosis offered them no choice but to battle harder for support.

2. A life worth living

This theme illustrates the hopes that participants have about how they can change their trajectory by making significant lifestyle change. There is a split across this theme, bringing attention to the different stages of the two groups of participants. Powerful expressions are captured by those beginning the

programme as they pull into question the value of making significant lifestyle changes at this life stage. Moments of clarity, leading to insight about what is fundamentally important to them in life come to the surface as they consider this path. The second sub-theme is inclusive of the values held by each participant, driving them to make change, reminding them of what they hope to achieve.

Insight

This subtheme illustrates the significant change in perspective that participants experienced following diagnosis of T2DM. Three participants poignantly convey this gained clarity and how it has given them a different perspective on the fragility of life and how they wish to change their healthcare trajectory. As they weighed up the benefits of making extreme dietary changes with some of their concerns, they began to consider what truly mattered. This existential unfolding seemed to be a turning point for Karl, Beryl and Bessie. The programme provided an opportunity to begin a new chapter:

I am coming up to my 50th birthday in October, so that's just something that, it feels like a kind of point in my life where I have to choose what I am going to do, if I am going to just carry on like this if I am just going to get sick, so it is an opportunity to change my life at 50 and still have a good few years ahead of me, you know (Bessie, G1)

Bessie uses a significant birthday as a frame of reference, it's like she is giving herself an ultimatum. You either choose life or ill health. Karl also considered his point in life, determined to see this as an opportunity to make a significant lifestyle shift to improve health outcomes:

I am not getting any younger I am not the young man I was before, so I think it will just get harder the older I get, so it's good that I have had the kick up the arse that came from this one, I know it is silly to say that about diabetes myself it was a good wakeup call (Karl, G2)

There is a temporal element to this process by participants. Although they are motivating themselves to make change to escape complications that result from unmanaged diabetes, there is a deeper reflection occurring. The choice has increased their awareness of their own morality. Ross spoke of wishing to prolong his life, evocatively expressing his wish to be around for his family for as long as he could:

I remind myself of what I am doing this for, and there is obviously the relationship with my kids, I want to be here for a long time, I want to see my daughter get married and I want to be here for them for as long as I possibly can be and that's the driving force for why I am really doing it, I want to see them grow up I want to see them become adults and have their own families (Ross, G2)

Re-engaging with life

Although all participants hoped to achieve T2DM remission and improve their health, there were nuanced reasons underlying their hopes, and individualised goals paving the way. Increasing life expectancy was naturally a powerful motivator for participants wanting to make change.

To avoid having to take daily medication, to improve physical fitness, and reduce cardiovascular risk factors were specified by participants when they spoke of improving their health outcomes: “that was the goal for me, get off the tablets and go into remission” (Harley, Group 2)

Whilst some didn’t identify weight loss as a goal, most equated a reduction in weight loss with improved health, as voiced by Patsy:

All of the cardiovascular risk factors that I have got will be improved if I lost 10% of my body weight, everything will improve a little bit, you know I have high cholesterol, I have got I eh ... I have just think that.. Being able to lose a significant amount of weight initially will improve all of my risk factors a little bit that will make me feel better ... (Patsy, G1)

Participants spoke about unfulfilled hopes, or valued activities that they had disengaged with because of their health conditions. For example, Bessie had always wanted to begin “tai chi” (Bessie, G1). This programme became a source of inspiration and confidence to take the step towards this activity. Following a conversation with the psychologist, she had begun practicing meditation, a small step towards her wish to practice martial arts.

Ross spoke of wanting to re-engage with cycling, to bring his children cycling, “I used to love it, when I was younger, em and it is something I want to get my children into, because they have their bikes but they never use them” (Ross, G1). Ross spoke at length of wanting to be a role model for his children. His role as a father was at the core for him making change. His noticing that his children never used their bikes was an opportunity seized by Ross to bring his past passion back to life, as an opportunity to spend quality time with his children and increase his physical activity.

Elsbeth described her favourite beach, a place she would seek solitude with her husband on weekends away in their beloved caravan. Her hope for engaging with the programme would help to increase her physical fitness, so she could “walk the length of the beach” (Elsbeth, G1). A cherished place.

3. The wee steps leading to sustainable change

This theme illustrates the changes participants began making in response to their diagnosis, and in response to engagement with the programme. Voiced by Robert, but experienced by many it was, “the wee things that I have seen make a big difference” (Robert, G2).

Empowered

Support from family, the psychologist and the dietician were voiced by different participants as a source of empowerment to make changes. Those who had developed the relationship with their dietician over the course of two years spoke of their continued determination to sustain change because of this consistent support. This is captured by Charley:

I think it was knowing you were going to have a call every two weeks and then a follow up call every month I think if I hadn't had that em two week you know to tell you and just say you had noticed the things that had changed or had happened in that two weeks ..I think if I have just been given the food and been told there's the food for three months, there you go, I probably would never have stuck to it (Charley, G2)

Charley is expressing the importance of his connection with the dietician. The way felt able to make change, went beyond simply the food. Similarly, Ewan's appreciation for the support is captured in his repetitive use of adjectives. It almost conveys a sense that he perceived the dietician doing more than he had expected.

[the dietician] was a very good listener em and it was absolutely fantastic as I said it was good to get to meet [the dietician] never judged, or anything like that, [the dietician] was always very very supportive which was great (Ewan, G2)

What is common across both groups is the non-judgmental, validating support they received that went beyond the mere guidance of what they 'should' be doing.

Ross who just began the programme, had received sessions with the psychologist prior to working with the dietician. He described having this space to speak about his difficulties as “a weight lifted off my shoulders” (Ross, G1). For Ross he had never been provided with the space to share how much he had been struggling before. Referred to the programme because of his diagnosis, it was somehow missed that he had frequent thoughts of wanting to end his life. He had engaged in several diets previously which he blamed himself for not having “the power to keep going”:

I had the first session I had I had my wife in there with me, by the time we finished the call she was quite surprised and shocked by some of the things that I was saying, because I didn't want to talk to her about certain aspects of the problems I was having (Ross, G1)

The difference this time was that there was a space provided in which Ross felt safe enough to say aloud what he had held within. There was a significant ripple impact of his behaviour on his relationships with his kids, family and co-workers.

There were a number of powerful moments during the interviews when participants had internalised this sense of empowerment that was expressed by Ross. Participants spoke about prioritizing their own health needs, and with increased awareness they began to understand their relationship with food.

The wee steps

Regardless of where participants were on the programme there were small and more profound steps of change participants had begun to make. There were common behavioural changes highlighted across participants including mindful choices at mealtimes, learning to identify and respond to their emotional needs, increasing variation of foods in their diet, trying to be more prepared for lunches and dinners, making healthy food swaps, and increasing movement. However, there were also significant differences across and within groups that lead to sustainable and meaningful differences for each participant.

For most participants the 'wee things' that worked, included creative and individualized strategies to incorporate behavioural change into their day, as described by Karl and Robert:

I am trying to insist I get half an hour for lunch, so I don't always do video meetings now at work, I often say to people phone me, and when someone phones me I walk the garden, while on the phone (Karl, G1)

I was getting off the bus one or two stops early, and things like that, where before I wouldn't have thought about it, I would have just stayed on the bus. So you know it opened my eyes to more regular exercise (Robert, G2)

For others there was a more profound shift in their understanding of the relationship they had developed with food. For example, there was a depth to the change that Ross made when he began practicing grounding skills throughout the day compared with previous dieting and exercise regimes. Ross had a number of physical health difficulties that meant he struggled to exercise for long periods of time. Ross had taken a new approach with this programme, and it is clear from the extract below that

noticing the cycle of turning to food for comfort, followed by a greater wave of guilt, was an important shift to how he made steps to break the cycle:

If you have had a bad day, all I wanted to do is go home and have cheese on toast, or something like that, so my way of getting through it is by just eating something... and then you feel guilty for eating all that... so there's a circle there, so [the psychologist] kind of helped me to come out of that circle, or if something bad happens to just take deep breaths and chill out a bit and this and that and not think about (Ross, G1)

Whilst Charley's small steps began as walks in the night, they became a way of re-connecting with his family. His increased confidence in taking these steps to improve his fitness, resulted in him re-connecting with his family, and meeting his nieces and nephews for the first time:

My mother moved house 10 years ago, I had never seen her house.. where as now I have been in and seen the house and have been a few times em but again it is early in the morning, but she is up at that time anyway, so it is ideal for me, and I have gone down, so things have changed that way, and also.. I have got nieces and a nephew, they have been up and I teach them how to make, the wrong things, cakes and scones, we do a baking session on a Saturday and they get to make things, they're only young, the oldest is 9 and the youngest is 5 (Charley, G2)

There was a significant part of Charley's life being put on hold because of the anxiety he felt about being in public places. He had led an isolated life for some time. Charley had never met his niece and nephew prior to the programme but his use of the phrase 'we do a baking session on a Saturday' indicates that this has become a regular occurrence.

4. Cutting food, cutting calories

This theme captures a spectrum of experiences, from preparing for the liquid shake diet, navigating the diet, to re-introducing food, and the lasting impact for those finishing the programme. The expressed turmoil of emotions from those about to start the liquid shake diet provides insight into their hesitancy, presented beside the reflections of those almost two years on is stark and insightful.

Preparing for the cut

There's an oscillation that was expressed for those beginning the programme. They voiced their concerns for the liquid shake diet, but the appeal of quick weight loss outweighs these thoughts. The

most common concern regarding the programme, was how drastic the liquid diet would be. Elsbeth acknowledges her uncertainty:

I know this programme is going to be hard, only 800 calories a day, so for me there is no real food if you get my meaning, there's no real chewing, or feeling that you have actually had a meal, em but I think I need to get my health under control, and maybe by doing this as well it will lower my iron, so maybe it will do both at once (Elsbeth, G2)

Elsbeth speaks fluidly, indicating confidence in the concerns she has about the diet. She wants to be understood, expressing what 'no real food' means for her. The hesitancy 'em' stops her on this line of speech. It's as if there is conflict in being able to enjoy a meal, the texture, chewing and experience as well as getting her health under control.

This oscillation is also present for Bessie as she queries the physical impact of cutting out solid food, "I know it is going to be very difficult, you know and I don't know how it's going to affect me physically, like my bodily fluids and that sort of thing, you know I don't know about that really" (Bessie, G1)

There seems to be an on-going reassurance as part of her is clearly eager to begin the programme to make change, whilst part of her expresses an uncertainty:

I am waiting to see how it is, it will be different for everybody, I really well, I don't know if looking forward is the right expression, but I am hoping to break this behaviour that got me into this situation, so three months I am not really looking beyond that, I am looking forward to getting started and then to see how I feel (Bessie, G1)

Patsy linked the diet with previous dieting experiences, where she struggled to maintain weight, she had lost. Her quote below illustrates her considerations for why this diet may be different given her children are older. However, it appears that her responsibility of caring has shifted, and she is now looking after her mother. There seems to be a hesitant determination to put her own needs first:

The psychologist said that a lot of people do lose weight with the soups and shakes programme and they don't always keep it off, and I certainly ...when I did the Cambridge diet before that it was a very similar experience to then, I am in a different place in my life now, my children are older, em I have got, I can make a few more things for myself, but I have got an elderly mother that I am helping looking after as well, but I think I can make a bit of time for me as a priority, at the moment (Patsy, G1)

Navigating life whilst on shakes

Participants preparing for and reflecting on the liquid shake diet identified ways to navigate life, whilst trying to follow the prescribed diet. There appeared to be a negotiation that occurred for participants with families when preparing for, or on the liquid shake diet. Ewan and Beryl who had finished the liquid phase, had described their avoidance of mealtimes, and a reduction in attending social occasions.

Finding ways to suppress the hunger arose, for example Robert spoke of going to bed early, and increasing his water intake:

It was very difficult, very difficult.. it's very hard to cut your whole lifestyle to four drinks a day... you know I call them drinks, eh on sachets it says 240ml.. But what I was doing, I was watering it right down to 500ml, because I thought it was more filling.. I was getting a constant constant hunger pang (Robert, G2)

Elsbeth's worry of the repetitiveness of the shake diet and lack of texture, was Ewan's reality as he described having the same flavoured shake across the three-month programme:

Was still tough just drinking shakes and my palette is not a very good one when it comes to different foods, I can't eat yogurts I can't eat all these sorts of cottage cheeses and these sorts of things, so I wasn't have all of the different flavours of these shakes, I was having chocolate four times a day haha (Ewan, G2)

He shared how he coped with the lack of solid food, by introducing low calorie snacks to substitute for one of the liquid shakes:

I used to get what was the sticks, the bread and what I used to do is have a bit of toast and a bit of ham I used to fill it up with tomatoes and I used to weigh it, where the shake was equal to 200 calories em that was similar to the bread which was 200-300 so it was slightly over but I think if I didn't do that I think I would have just decided not to do it (G2)

What's interesting with this subtheme is the fact that many of the concerns expressed by participants beginning the programme became the reality of those who had completed the programme. Despite it being over a year and a half since completing the liquid shake diet, participants gave specific details about how they coped whilst on shakes.

Transitioning to regular eating

Whilst the second phase of the intervention focused on re-introducing food and regular eating, this transition was difficult for many of the participants. Increasing calorie intake evoked anxiety and guilt as they began to re-introduce solid foods. There appeared to be underlying fear of weight re-gain in some participants' accounts. Beryl speaks of how challenging this shift was for her psychologically:

Initially I found it hard eating the 1,400 calories a day I still try to keep it to the 800 so I would have it maybe a piece of salmon, but I was scared to eat and so originally I would have three bits of salmon in the pan with maybe some carrot sticks eh peppers em not anything OTT (Beryl, G2)

Although over a year on from ending the liquid diet, it was evident that patterns of disordered eating were present. This fear of eating perpetuated a goal of 800 calories a day of food intake for Beryl. For Charley the guilt of eating solid foods also resulted in restrictive eating, and recurrent thoughts that he shouldn't be eating:

It was strange at the beginning and then I felt awkward, I thought oh god how much weight have I gained by eating that, and even though I knew it was vegetables I was eating, I was still like no, I shouldn't be eating as much as this, and I felt guilty, it was like for all of the work you have just done in the past couple of months by eating the liquid food, and then I am eating food again, and I am like no I need to cut down, and so it was quite difficult at the beginning, and that's why even now I don't have a breakfast, and I don't eat until after 1 o'clock in the afternoon, and it, I know it is all in the head (Charley, G2)

Here we get a glimpse into Charley's internal world. There's almost a thread of self-punishment weaved through as he berates himself for eating, threatening that he will undo 'all of the work' time and effort he had put into staying on the liquid shakes. These thoughts have maintained a pattern of restricting food before 1pm. What's difficult to make sense of is Charley's expression that it is 'all in the head'. The programme did outline, he had to severely restrict his eating, and yet it is a self-critical voice that he is left with.

5. Not good enough

This theme captures the dissonance and conflict of what participants considered success. It is exclusive to Harley, Robert, Beryl, Charley and Ewan who are nearing the end of the programme. As participants prepare to finish the programme, there is a prompt for all to consider what they felt they had achieved from the programme. Despite no participant speaking for the need to take medication to manage their

glucose levels and all noting they had gone into pre-diabetes range of HaB1c levels, there was an overarching sense of disappointment that ran through participant accounts. This disappointment was attributed to an internal failing for not achieving the goal weight they had set. Two participants were considering the possibility for bariatric surgery despite technically having met the goal they were referred to the service for.

Undervaluing success

All participants provided positive feedback as a whole for the structure and set-up of the intervention. However, there was a minimization of their personal achievements. The success of achieving remission and changing their perspective on lifestyle changes was attributed to the programme, but what they hadn't achieved was because of them personally not doing enough.

The importance of the relationship Ewan had with the dietician shone through. However, there is a pain that could be picked up from his account of not feeling like he had lived up to the expectations he perceived the dietician had for him:

As I said [the dietician] has done a great job, and you felt if you weren't doing well you were letting [the dietician] down, and I kept saying 'I am going to be your success story' haha but unfortunately have gone up a bit so I am not much of a success story just now (Ewan, G2)

He laughs halfway through, which may be an attempt to make the heaviness of what he is saying seem lighter.

This conflict is also present in Beryl's expression - "But it was a very worthwhile, and I am kind of frustrated with myself, because my weight has gone up over the last few months" (Beryl, G2), where she pauses following her consideration for how worthwhile the programme had been and becomes self-critical. There is an annoyance that is present. The dissonance is captured in the linking of 'and', both exist in unison.

What's interesting for Harley is that the excitement of achieving remission is present, but it is almost as if it was a surprise that his readings came down. He does not link this with the efforts he had made, "the best thing about it all, in the height of it all, I went into remission, the blood thing, I went down to 41 and I was way up in 58 or something, so that improved like mighty" (Harley, G2).

Harley goes on to speak in depth about needing to restrict his food intake further, as he had not lost enough weight:

I could have gone further if I could have gone on the shakes...I wish I could have just stayed on the shakes and had my meal at nighttime.... I think the way I had it in my head, and which wasn't going to be stupid or anything, I wasn't going to go down like 10 stone, or something like that, I mean I had it in the if I went down to 16 and a half stone or 16 4, I think that would have been perfect, but got down to 17 odd, and they wanted to re-introduce the food, that's what I found very difficult, because you get the taste of it and you just want it all again (Harley, G2)

The words 'I could have gone further' evoke this sense of disappointment Harley feels. This feeling that if he had stayed on the liquid diet, he wouldn't be where he was right now. A sense of frustration is

Still trying

It was clear that participants were hypervigilant of weight fluctuations, making efforts to continuously monitor their weight. Beryl described her weight measurements in detail and can relay her exact intake of calories the previous day. There is a sense that she is left with a feeling of hopelessness in not understanding what was contributing to her weight increasing on the scale:

Just as an example, I weighed in there yesterday morning, and I was 15.1 and a quarter, which 11.25 points, this morning I was 15.4 and a half.... now yesterday, I had eh three mini lattes at work, no sugar or aspartamines, I had em a cup of soup, that was for my main dinner, I had an oxford cube that was for later, I had a chocolate shake that's about 150 calories, so all in I was about 768 calories so unless it's the liquid from the .. I don't know... if I could pinpoint what it was I could eliminate it (Beryl, G2)

As the liquid shake diet was held in such high regard by participants, the temptation of substituting meals or shakes became part of a new routine. For Charley and Beryl there was an idealisation of the liquid shake diet, "I absolutely loved the liquid food, because I never had to think about what I was cooking, I never had to think about having the food" (Charley, G2). Similarly, Beryl expresses, "if I was to have shakes for ever more, I would be a happy happy person" (Beryl, G2).

Charley acknowledges the significant change that has occurred for him since beginning the programme. There was a sense of pride that he was making these changes for himself "it is a huge change for me, it is a massive change, I can see it but I don't know if anybody else can, I'm not really interested if anyone else can see it, but I know how I feel" (Charley, G2). His expression 'I know how I feel' reflects the confidence in what he is leaving this programme with. The change goes beyond the observable, something deeper has shifted for Charley, rooted in something more profound than weight loss. And

yet, there is an undervaluing of this success by his dissatisfaction of his weight loss. He has done so much, and still from a weight loss perspective, he has not done good enough.

Beryl and Harley spoke of their continued use of commercial liquid shakes, and Ewan spoke of wanting to order them online to continue to lose weight:

I managed to find some reasonably priced shakes, there are ones called fuel and ASDA had them on offer... I got a selection of those because I carry it in my handbag and this week I am working full time for my employer just to cover holiday leave and because I tend not to eat during the day, I rather than just fill up on the lattes, is to have the shake and a cup of tea it takes the edge off feeling hungry if that makes sense. And then after a wee while, most of those shakes they're not as good as the counterweight ones, but they do take the edge off any hunger feeling (Beryl, G2)

Changes in weight, resulted in an increased use of weight loss strategies, as described by Robert he would significantly restrict his food until he saw a change on the scales:

Well I get hunger pangs, because when I say radically cut out, that's me having my tea at night time and then I have absolutely nothing until the morning, and then I'll just have like two pieces of toast in the morning, and then fruit, and that's me right until 6pm at night, until my weight drops, if I have seen that my weight is back down to the level I was at.. then I will go back to having what I was having (Robert, G2)

It is clear for Robert, that he was continuing to use weight loss strategies to restrict his eating if he noticed his weight fluctuating. It seems to be an extreme approach by his use of the words 'radically cut out'.

Discussion

Five themes detail the experiences of individuals diagnosed with T2DM, illustrating the fears, the overwhelm, the challenges, as well as the hope, and empowerment experienced as participants reflected and made sense of their journey to, and engagement with the weight management programme. To the author's knowledge this is the first study to use a multiperspectival IPA methodology to gain insight into this path of support being offered to people diagnosed with T2DM. The interpretive endeavor of this approach was to identify poignant patterns within and across groups, who were at different stages of their healthcare journey. Being diagnosed was a shock for many participants, which

reflects the progressive and often asymptomatic nature of T2DM (Porta et al., 2014). Current estimates from diabetes onset to diagnosis can range from 6 to 10 years (Tuso, 2014). If left untreated during this pre-diabetic period there is an increased risk of micro and macrovascular complications (Porta et al., 2014). Whilst this awareness has resulted in increased prevention efforts, it highlights the importance of access to timely intervention following diagnosis. Managing T2DM requires continuous attention to lifestyle changes including dietary modification, exercise, monitoring of health changes, and on-going attention to blood sugar levels (Wareham, 2022). Those not provided with adequate support or tailored guidance may quickly become overwhelmed, as feelings of uncertainty about managing their condition arise, evoking anxiety and exacerbating their distress. The trajectory of those accessing the programme is reflective of the considerable variability in the delivery of diabetes care and content of diabetes education on a national scale (Barnard-Kelly & Cherňavsky, 2020; systematic review above).

This study was conducted during the COVID-19 pandemic when there was a decrease in services available for diabetes care (Seidu et al., 2022), but it reflects a wider systemic issue regarding equity of access to services (Tan et al., 2021). Across the UK the system of delivery of diabetes care is often fragmented involving a variety of health care professionals offering different interventions across primary, community and specialist services (Tan et al., 2021). A lack of communication and collaborative working across services, can impact the ability for healthcare professionals to provide timely referral to appropriate interventions, resulting in poorer healthcare outcomes for patients (Barnard-Kelly & Cherňavsky, 2020). Despite all participants within this study being from the same health board within Scotland, the lack of joined up care was apparent resulting in a challenging healthcare journey for some participants, as they felt dismissed, their healthcare needs neglected, and unsupported prior to finding the programme. Many were overwhelmed with having to navigate the system. There was a sense of relief and gratitude expressed as participants received accurate tailored information about the management of their condition following engagement with the CW+ programme. It provided a pathway of consistent tailored support (Stoop et al., 2019).

Feeling prioritized, heard, motivated by a sense of accountability, and receiving personalized care have all been identified as core facilitators to building a therapeutic relationship between patients and their dietician (Nagy et al., 2022). All of which was captured in participants' accounts as they spoke of their interactions with their dietician resulting in a sense of empowerment to begin or sustain lifestyle changes. In a review of health care professionals' experience of delivering the CW+, conversations regarding challenging emotions, life events, socializing or negative self-views, were perceived as

wearing (Rehackova et al., 2022). Participants from this study, and across the literature have voiced the value in having a space to problem solve, raise issues regarding self-criticism, dealing with blame or shame if they struggle to make change, interpersonal challenges and wider weight stigmatizing experiences (Rand et al., 2017). Individuals living in larger bodies with a diagnosis of T2DM are at increased risk for experiencing social anxiety, low mood, self-harm, and high levels of self-criticism and shame (Barnard-Kelly et al., 2020; Feng & Astell-Burt, 2017). Self-perception and self-worth go beyond an individual's physical appearance and losing weight may not address underlying beliefs an individual may hold. Losing weight may in and of itself bring a host of unanticipated challenges (Orbach, 2016). Therefore, it is likely that these challenges will arise as they begin to make significant dietary change. Healthcare professionals should have access to on-going supervision and have the option to refer patients with more complex mental health needs for psychological support, as a way to protect staff well-being and prevent burnout (Emsley et al., 2022).

Whilst all participants shared the hope for remission to improve health outcomes, determination to engage with the programme came from a pursuit to increase their life-expectancy, to spend time with family, and to improve overall health and well-being. Similar motivations have been noted across the literature (e.g., Rehackova et al., 2017). The nuances of change, and specific goals participants hoped to achieve such as re-engaging with tai-chi, walking a favourite beach and cycling with family, were valued activities that are not captured by outcome measures of weight loss. The things that participants spoke about making a real difference included responding to overwhelming emotions using breathing exercises, mindfulness and grounding skills. Food can often be used as a way to self-soothe when experiencing overwhelming emotions (Reichenberger et al., 2020). Therefore, learning additional strategies to regulate emotions can increase the likelihood that emotional needs can be met in alternative ways, and decrease the reliance on food (Kerin et al., 2018). Participants also spoke of integrating movement into their daily routine, and tuning into feelings of hunger, fullness and having a more mindful approach to food choices. Many of these strategies overlap with intuitive eating, which promotes building a healthy relationship with food. Research into intuitive eating has shown a more sustained increase in healthy eating behaviours and psychological well-being compared with other dietary methods (Van Dyke & Drinkwater, 2014)

Despite significant changes noted by some participants nearing the end of the programme, there was a prevailing sense of disappointment about not reaching weight loss targets. Given how embedded the focus of weight loss is within the literature for T2DM, and a primary outcome measure

currently used for interventions (Noronha et al., 2022), it makes sense that this becomes a metric of success, even when remission has been achieved. It raises the concern of potential adverse psychological effects that can result for individuals solely focusing on weight loss as an outcome measure of success, and stresses the critical need of considering a broader range of relevant outcomes to measure change (Guess, 2022). In this study, patterns of disordered eating were evident in some participants accounts, as they spoke of hypervigilance of calorie intake, restrictive eating, concern regarding weight and shape, and replacement of solid foods for liquid sachets, in a continued effort to lose weight. It is difficult to distinguish at what point an individual's weight loss strategies have transitioned into more harmful disordered eating territory, given the evidence base is sparse, with limited clinical guidance available. However, cognitive factors, such as strict rules around food, preoccupation with weight, shape, or calorie counting have been identified across the research as driving disordered eating behaviours (Ralph et al., 2022). Overtime, these patterns may have a significant impact on individuals perceived sense of self-worth, physical health and overall quality of life (Baceviciene et al., 2020 et al., 2020; Wu et al., 2014).

While the liquid shake diet has been praised across the literature (Rehackova et al., 2022), it is evident that there is an idealization of this phase of the intervention, which heightens feelings of anxiety prior to and following the re-introduction of food phase. Ways to adhere to low calorie diets have included avoiding social situations, eating out, or eating with family members (systematic review). It is unknown what longer-term harms may arise for individuals with T2DM who to navigate the food environment in this way. Or who are required to ignore natural hunger signals even if for a short period of time. Future research is needed to determine these risks, what impact they can have on an individual's psychological well-being, and long-term impact on an individual's goal of making healthy lifestyle behaviour changes.

Implications of the research

This research has highlighted a number of clinical and research implications. Clinical implications must be taken with the caveat that experiences of participants presented here are unique and should not be generalised to all those who undergo interventions to achieve remission. The study highlights a number of unique points that are worth considering from a clinical practice and academic standpoint. Firstly, integrated diabetes care, with psychology embedded within diabetes care pathways (Schmidt et al., 2018), should be prioritized, to provide support for the team, and one-to-one support for individuals with more complex mental health needs. This is not often implemented in practice (Sachar et al., 2019),

and must be a continued consideration for funding allocation. Secondly, to ensure services are not causing harm, all potential patients should be screened for disordered eating prior to engaging with the programme (McMaster et al., 2023). A reevaluation of inclusion criteria may consider the exclusion of those who are vulnerable to the exacerbation of disordered eating, such as having a history of an eating disorder. This should be supported by ensuring that programmes healthcare professionals delivering programmes have had an opportunity to receive training on eating disorders. Outcome measures capturing psychological well-being, and value-based changes made during the programme should be designed and used as a primary outcome measure rather than a tokenistic method to evaluate tolerability or adherence. This approach would lend itself in conjunction with research focusing on identifying weight-neutral approaches which aim to identify specific nutritional choices which can have a meaningful influence on blood glucose and T2DM management independent of their effect on body weight (Guess, 2022). The research is in its infancy in providing tailored nutritional advice but is an important avenue to explore going forward.

Strengths and limitations

There are a number of limitations to this study, which should be held in mind, and considered for future research studies. Firstly, demographic details such as ethnicity, area of residence, socio-economic background, or HBA1c measures were not collected. Given the intervention is one to one, and the service includes two dieticians and one psychologist, collecting additional demographic information may have compromised the anonymity of those beginning the programme. Given the importance of cultural considerations and availability of affordable foods when modifying dietary behaviours (systematic review), understanding the diversity of those accessing this programme would add an additional layer of understanding to how participants are perceiving it to fit with their individual circumstances. Secondly, this research only interviewed those who were involved with the programme or successfully completed it. Whilst interviewing those at the beginning of the programme provided an opportunity to gain insight from participants that may leave the programme, the second group of participants may have provided a more favourable view of the programme because they had completed it. Future research is needed to explore the experiences of those who have left the programme early to gain a balanced perspective of potential challenges that arise. Finally, whilst this research adopted a multiperspectival approach there were some aspects of the journey that participants did not share an experience on. For example, the last theme only captures the experiences of those who had completed the programme. Similarly, whilst some participants finishing the programme reflected on how they felt at the beginning of the

programme, it is likely that engaging in and completing the programme may have influenced their perspective on the initial concerns they held and their perceived readiness to make change.

Conclusion

This research has provided a unique perspective on the experiences of individuals undergoing a highly restrictive diet, with the hope of achieving remission. It was clear that participants benefitted greatly in several ways by being provided with a path of support, which was tailored to their specific needs and prioritized psychological well-being prior to the engagement with significant dietary modification. It is evident that participants' goals for change go beyond weight loss alone, highlighting a hope to re-engage with valued based activities and develop a healthy relationship with food. Whilst participants spoke highly of the programme, those nearing the end provided a valuable perspective on the perceived sense of failure which can arise for not reaching weight loss goals, despite reaching remission. Concerns regarding the liquid shake diet, and reality of the lasting impact that so severely restricting calories can have, was notable. This research has shed light on a number of avenues for further research and clinical consideration.

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Appendices

Appendix A – Journal of Health Psychology Guidelines

Please read the guidelines below then visit the Journal’s submission site <http://mc.manuscriptcentral.com/jhealthpsychology> to upload your manuscript. Please note that manuscripts not conforming to these guidelines may be returned.

Only manuscripts of sufficient quality that meet the aims and scope of Journal of Health Psychology will be reviewed.

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Useful websites to refer to for guidance

We recommend that authors consider looking at the below guidance:

- [APA guidelines on Bias Free Language](#)
- [Words Matter](#)

- Authors are encouraged to refer to and use any language guidelines that relate specifically to their research

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The Editorial Board of the Journal of Health Psychology considers for publication:

- (a) Full-length reports on empirical studies (up to 8,000 words counting 500 words per table and figure for all study types including intervention studies and qualitative studies).
- (b) Brief reports on empirical studies (up to 3,000 words counting 500 words per table and figure).

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(f) The abstract word limit is 150 words.

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All parties who have made a substantive contribution to the article should be listed as authors. Principal authorship, authorship order, and other publication credits should be based on the relative scientific or professional contributions of the individuals involved, regardless of their status. A student is usually listed as principal author on any multiple-authored publication that substantially derives from the student's dissertation or thesis.

Appendix B - Enhancing transparency in reporting the synthesis of qualitative research (ENTREQ) Statement

Item No.	Guide and Description	Report Location
1. Aim	State the research question the synthesis addresses	Page 14
2. Synthesis methodology	Identify the synthesis methodology or theoretical framework which underpins the synthesis, and describe the rationale for choice of methodology (e.g. meta-ethnography, thematic synthesis, critical interpretive synthesis, grounded theory synthesis, realist synthesis, meta-aggregation, meta-study, framework synthesis)	Page 15
3. Approach to searching	Indicate whether the search was pre-planned (comprehensive search strategies to seek all available studies) or iterative (to seek all available concepts until they theoretical saturation is achieved)	Page 15
4. Inclusion criteria	Specify the inclusion/exclusion criteria (e.g. in terms of population, language, year limits, type of publication, study type)	Page 15
5. Data sources	Describe the information sources used (e.g. electronic databases (MEDLINE, EMBASE, CINAHL, psycINFO), grey literature databases (digital thesis, policy reports), relevant organisational websites, experts, information specialists, generic web searches (Google Scholar) hand searching, reference lists) and when the searches conducted; provide the rationale for using the data sources	Page 15
6. Electronic Search strategy	Describe the literature search (e.g. provide electronic search strategies with population terms, clinical or health topic terms, experiential or social phenomena related terms, filters for qualitative research, and search limits)	Included in Appendix C
7. Study screening methods	Describe the process of study screening and sifting (e.g. title, abstract and full text review, number of independent reviewers who screened studies)	Page 15
8. Study characteristics	Present the characteristics of the included studies (e.g. year of publication, country, population, number of participants, data collection, methodology, analysis, research questions)	Page 17
9. Study selection results	Identify the number of studies screened and provide reasons for study exclusion (e.g. for comprehensive searching, provide numbers of studies screened and reasons for exclusion indicated in a figure/flowchart; for iterative searching describe reasons for study exclusion and inclusion based on modifications to the research question and/or contribution to theory development)	Page 17
10. Rationale for	Describe the rationale and approach used to appraise the	Page 16

appraisal	included studies or selected findings (e.g. assessment of conduct (validity and robustness), assessment of reporting (transparency), assessment of content and utility of the findings)	
11. Appraisal items	State the tools, frameworks and criteria used to appraise the studies or selected findings (e.g. Existing tools: CASP, QARI, COREQ, Mays and Pope [25]; reviewer developed tools; describe the domains assessed: research team, study design, data analysis and interpretations, reporting)	Page 16 CASP
12. Appraisal process	Indicate whether the appraisal was conducted independently by more than one reviewer and if consensus was required	Page 16
13. Appraisal results	Present results of the quality assessment and indicate which articles, if any, were weighted/excluded based on the assessment and give the rationale	Page 21 and 22 (Appendix G)
14. Data extraction	Indicate which sections of the primary studies were analysed and how were the data extracted from the primary studies? (e.g. all text under the headings “results /conclusions” were extracted electronically and entered into a computer software)	Page 20
15. Software	State the computer software used, if any	Page 16
16. Number of reviewers	Identify who was involved in coding and analysis	Page 16
17. Coding	Describe the process for coding of data (e.g. line by line coding to search for concepts)	Page 16 (Example in Appendix E)
18. Study comparison	Describe how were comparisons made within and across studies (e.g. subsequent studies were coded into pre-existing concepts, and new concepts were created when deemed necessary)	Page 16
19. Derivation of themes	Explain whether the process of deriving the themes or constructs was inductive or deductive	Page 16 (Inductive)
20. Quotations	Provide quotations from the primary studies to illustrate themes/constructs, and identify whether the quotations were participant quotations of the author’s interpretation	Page 23-19
21. Synthesis output	Present rich, compelling and useful results that go beyond a summary of the primary studies (e.g. new interpretation, models of evidence, conceptual models, analytical framework, development of a new theory or construct)	Page 23-29

Appendix C - Search strategy

PsychInfo

("Diabetes Mellitus, Type 2" or "type 2 diabet*" or "type ii diabet*" or "insulin resistant diabet*" or "noninsulin dependent diabet*" or "non insulin dependent diabet*" or "insulin independent diabet*" or "adult onset diabet*" or maturity onset diabet* or "Glycaemic control")

AND

("Diet modification*" or "Body weight loss" or "Weight reduction" or "Calor* restriction" or "Very low calor* diet" or "Low calor* diet" or "total food replacement" or "high-protein" or "low-carbohydrate" or "low energy diet" or "mild energy restriction").

AND

("Attitud*" OR "Experience*" OR "Lived" OR "Qualitative").

CINAHL PLUS

"Diet modification*" or "Body weight loss" or "Weight reduction" or "Calorie restriction" or "Very low calorie diet" or "Low calory diet" or "total food replacement" or "high-protein" or "low-carbohydrate" or "low energy diet" or "mild energy restriction"

Attitud* or Experience* or Lived or Qualitative

"Diabetes Mellitus, Type 2" or "type 2 diabet*" or "type ii diabet*" or "insulin resistant diabet*" or "noninsulin dependent diabet*" or "non insulin dependent diabet*" or "insulin independent diabet*" or "adult onset diabet*" or maturity onset diabet* or "Glycaemic control"

S1 AND S2 AND S3

EMBASE

1 ("Diabetes Mellitus, Type 2" or "type 2 diabet*" or "type ii diabet*" or "insulin resistant diabet*" or "noninsulin dependent diabet*" or "non insulin dependent diabet*" or "insulin independent diabet*" or "adult onset diabet*" or maturity onset diabet* or "Glycaemic control")

2 ("Diet modification*" or "Body weight loss" or "Weight reduction" or "Calor* restriction" or "Very low calor* diet" or "Low calor* diet" or "total food replacement" or "high-protein" or "low-carbohydrate" or "low energy diet" or "mild energy restriction").

3 ("Attitud*" or "Experience*" or "Lived" or "qualitative").

4 1 and 2 and 3

Proquest and Web of Science

noft(("Diabetes Mellitus, Type 2" or "type 2 diabet*" or "type ii diabet*" or "insulin resistant diabet*" or "noninsulin dependent diabet*" or "non insulin dependent diabet*" or "insulin independent diabet*" or "adult onset diabet*" or maturity onset diabet* or "Glycaemic control")

AND

("Diet modification*" or "Body weight loss" or "Weight reduction" or "Calor* restriction" or "Very low calor* diet" or "Low calor* diet" or "total food replacement" or "high-protein" or "low-carbohydrate" or "low energy diet" or "mild energy restriction")

AND

("Attitud*" or "Experience*" or "Lived" or "Qualitative"))

Medline

- 1 ("Diabetes Mellitus, Type 2" or "type 2 diabet*" or "type ii diabet*" or "insulin resistant diabet*" or "noninsulin dependent diabet*" or "non insulin dependent diabet*" or "insulin independent diabet*" or "adult onset diabet*" or maturity onset diabet*" or "Glycaemic control").
- 2 ("Diet modification*" or "Body weight loss" or "Weight reduction" or "Calor* restriction" or "Very low calor* diet" or "Low calor* diet" or "total food replacement" "high-protein" or "low-carbohydrate" or "low energy diet" or "mild energy restriction").
- 3 ("Attitud*" or "Experience*" or "Lived" or "Qualitative")
- 4 1 and 2 and 3

Appendix D - Example reflexive log

Why am I undertaking this review?

Individuals experiences?

What benefits do people notice who do make significant lifestyle changes? Do they achieve T2DM remission? What does this mean for them, their life, their well-being? Is there reduced anxiety over health complications of T2DM? Is there any discussion about managing T2DM through food/ following a prescribed diet compared with using medication? Do people talk about increased health promoting activities outside of losing weight through food alone (movement they enjoy?).

Significant weight discrimination and stigma among health care professionals – experiences of individuals undertaking VLCD? (Added pressure due to T2DM diagnosis?)

Harms / adverse effects of undergoing low calorie diets – trigger disordered eating behaviour – impact on mood/fatigue/quality of life/social life – are these described or included by researchers conducting the research – how are individuals supported?

Sustainability of such practices (major criticism among quantitative research – when are the interviews being conducted straight after the programme? Long term follow-up? Those who drop out of the programme?)

Initial coding

I'm picking up this template of time the before, during and after across all studies. I have initially created a template that matches this. What people are expecting before they begin, their motivations and concerns. What their initial experience is as they begin to make dietary changes, what is working, what are they finding difficult, are they able to adhere to changes recommended? Then there is this split, between programmes that are short term, total food replacement, and people transition to whole foods, and then the experiences of people who have made complete changes that have been recommended for much longer.

What am I hoping to achieve?

To go beyond 'what works' go beyond quantitative effectiveness outcomes and to get an understanding of what the patients describe as working for them. Having an understanding of how they perceive the low calorie interventions – how they impact on quality of life/ the challenges they face before, during and after/ the sustainability of consuming such low calories/ if there is any conversation regarding relationship with food/ the function of food/ what food means for them.

Going beyond the initial description

I have noticed, from conversations with a co-author and reading and re-reading participant quotes in random order, that my initial thoughts on the timeline have really been enforced by the authors. It is interesting that my initial descriptive codes are really in line with the authors' interpretations, I have really been taken in to how positively many of the findings are being presented and discussed. Going beyond the descriptive to reading what is actually being said and spoken by participants and then interpreted and presented by authors is an entirely different thing.

Generation of questions as I am reading

- What does an incredibly restrictive diet do for someone's relationship with food?
- Navigating social situations – resulted in some people avoiding the situation – inflexibility when out and about and increased stress associated with meal choices.
- The development of eating disorders as a result of diet culture? There is promotion here across all authors that weight loss is associated with improved psychological well-being, and a number of other positive outcomes. I wonder though about how many people are caught

in restrictive-binge eating patterns to try and sustain the recommended daily calorie intake count.

'One of the most anticipated barriers to adherence was negative emotions (e.g. during stressful situations), which could affect participants' ability to adhere to the VLED and potentially cause a spiral of lapses'. - Should relationship with food and managing difficult emotions then be focused upon as part of interventions? (i.e., negative emotions being, feelings of sadness, loneliness or stressful experiences affected the participants' willpower)

The prospect of support from the study staff also affected the participants' initial motivation to adhere to the diet (because of regular weighing and monitoring) - just by being in study and being monitored – how much of this drive is based on weight stigma? Has this been considered? There's something here about not wanting to disappoint the staff that I find interesting

Appendix E - Example of line-by-line coding

Codes	"I don't have to explain, people understand" Acceptability and Cultural Relevance
'Culturally tailored support'	<p>Over half (n=26, 57.8%) of the respondents stated that the culturally tailored support in terms of materials and staff enhanced their engagement. In order to increase effectiveness, PilAm Go4Health was culturally tailored for FA integrating unique cultural features and culturally relevant education materials promoting healthy lifestyle behaviors.⁴⁰ Table 1 presents an overview of the cultural adaptations that included culturally oriented education materials promoting healthy lifestyle behaviors facilitated by FA identified research staff and an interactive private Facebook group providing virtual social networking support with other participants and research staff.</p> <p>Many participants had positive comments on: the health education slideshows that were simple, colorful, visual, and interactive; helpful tools such as: "ChooseMyplate" (www.choosemyplate.gov/MyPlate); regular progress reports; and physical activity photos with FA. The interactive and culturally tailored education helped participants to: 1) better understand concepts such as healthy Filipino weight loss; 2) recall health messages; and 3) disseminate information to family, friends, and community.</p> <p>A 36-year old male said: "What I've learned through this study is that we have a different physiology...There's not a one size fit-all weight-loss plan, but that it is has to be conducive specifically to certain people's biology and cultural ways of doing."</p> <p>Increased engagement, retention, and positive behavior change among participants can be attributed to the utilization of research staff who share cultural traditions and beliefs with the participants.⁴¹ For example, one participant reported that having to eat alone (to support healthy food selections) conflicted with the obligation to participate in family meals (a sign of respect in the Filipino culture).⁴² Participants commented that intervention delivery by FA research staff increased not only their comprehension of educational material but also their comfort with sharing cultural challenges regarding diabetes management. Overall, participants noted that research staffs' encouragement, monitoring, technical support, and engagement of family were crucial to achieving their weightloss goals.</p>
'peer support'	
'a tailored approach'	
'feeling heard/understood'	
'culturally tailored support'	
'family support'	
	Motivation and initial expectations

<p>'diabetes remission'</p> <p>'weight loss'</p> <p>'boredom of det'</p> <p>'improving health'</p> <p>'increase life expectancy'</p> <p>'increase quality of life'</p> <p>'diabetes remission'</p> <p>'weight loss'</p> <p>'improving health'</p> <p>'proactive stance'</p> <p>'dislike or medication use'</p> <p>'motivation to reduce or stop medication use'</p>	<p>The prospect of diabetes remission and weight loss were the main motives for taking part in the Counterbalance study, in which the expected individual weight loss was ~15 kg. Prior to joining the Counterbalance study, many participants had tried to lose and maintain weight with various levels of success. Some of the main reasons for this were slow weight loss and boredom with the weight-loss regimen or dislike of it, which eventually resulted in weight regain. The appeal of large and quick weight loss was apparent through the participants' desire to be able to dress in more appealing clothing, become more confident, and feel better about their bodies as a consequence of the weight loss. The participants also anticipated improvements in their long-term health and regaining control over their health. Ageing and the will to increase the length and quality of life in the future were recognized as important drivers, and were often underlined by the desire to be healthy enough to take care of and spend time with their families later in life. The main thing that I'm after is trying to cut myself free from diabetes. That's a very strong motivation, because I am not getting any younger...It would be fantastic to come off the end of the study with a clean bill of health, in a situation where I can control my weight at a lower level knowing that any future illnesses might not be coming my way, because I've taken some action now. (man, aged 49 years, 9.5 years since diagnosis). Although the participants did not report that diabetes affected their day-to-day lives substantially, the practicalities of diabetes management, including taking tablets or experiencing side-effects associated with them, were the major sources of complaints among people treated with medication. I hate taking tablets, and I'm on six a day, so... I mean I'll try anything to get rid of it. If it goes, great. If it doesn't, well, at least it's helped. Well, it will have helped. I might come off the tablets, I don't know; just be a diet only.' (man, aged 44 years, 2.5 years since diagnosis)</p>
	<p>Diet, Diabetes Status, and Personal Experiences of</p>

<p>'Challenges with socializing' 'reduced enjoyment in socializing' 'feeling rude/guilty for not accepting what others offer' 'avoidance of social situation' 'criticism or perceived judgement from others' 'lack of support from others'</p>	<p>The main negative aspect of their LCHF diets was that socializing was difficult. Tom said: "Having supper in a restaurant is a problem in the majority of restaurants. It's just not enjoyable anymore." Lack of appropriate foods was identified as a problem; however, a bigger concern was that participants felt conflicted over being polite versus adhering to their diets when eating with friends. Juliet (52) said: "When people are going out for dinner and they are not aware of your [eating habits], occasionally you just need to put [your diet] aside and eat what they give you." Other participants held a firmer stance. George (62) said: The odds are, if we are going out to eat, then we've either eaten beforehand or we're not going to eat and basically have water, because it's pointless. You just can't get people to give you what you need. Some participants' social lives were impacted to the point where they said they no longer wanted to go out, even though socializing used to be a big part of their lives. Social situations were also made difficult for some participants who said that colleagues and acquaintances held a negative attitude towards low carbohydrate diets and were often judgmental. These participants were frustrated that they received "flak" and negative comments from people they felt did not understand the improvements that LCHF eating had made to their lives. Olivia (33) said: "You get the frowns, the 'Why are you not eating fruit anymore? Why are you not eating sugar anymore?' So, that has been my main battle." Gregory said: "People can't put two and two together to see it's benefited me. 'You can have a heart attack if you eat all that fat.' All of those stereotypical comments do come out on occasion." Several participants said that in certain social settings, such as casual work parties, people became irritated with them and often tried pressuring them into eating sugary foods. Andrea said: People don't understand that I am trying to [heal] without medication and I am trying to lower my sugars with diet. They will say things like, 'Oh just have a piece of cake, it won't kill you.' And inside I am saying, well actually it may just.</p>
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Appendix F - Example coding framework development

Step 1: Generating initial codes

This step was conducted by first author. Once a list was generated, this was reviewed by the third author. Discussions were held on direction being taken, and considering any bias that may be arising in the identification of codes and initial considerations for descriptive themes.

Descriptive theme ideas

1st – refers to direct patient quote

2nd – refers to authors interpretation

Motivation to engage with programme

- 'I want to live more' (1st): To increase life expectancy to be healthy to watch grandkids grow older/ regain control over their health
- To decrease medication use for diabetes control (1st)
- To lose weight (2nd)
- To achieve T2DM remission (2nd)

Adherence to the suggested dietary behaviour

Facilitators

- Tailored diet plan (1st)
- Collaborative support from staff (1st)
- Staff providing culturally relevant dietary advice (1st)
- Peer support from others on the programme (1st)2nd – sense that participants would have liked more
- Comparison between others on the programme
- Motivation as result of weight loss (1st)
- Support from family changing dietary behaviours (1st) - and also from family members who complete the cooking
- Social support (1st, 2nd)
- Support from friends changing dietary behaviour (1st)
- Receiving compliments for losing weight – motivation to continue going (1st)
- Regular check in's and monitoring progress (1st) - Incentive not to disappoint staff/ feeling grateful for the opportunity to be part of a study.
- Opportunity to take part in a study/programme (1st2nd)
- Specific strategies to change eating habits
- Strategies – tracking food intake (1st)2nd – found to be a tedious task
- Strategies – coping with cravings (1st) - distraction/avoidance of situations that would often be paired with snacking such as watching television.
- Strategies – self regulatory skills (1st)2nd – behaviour regulation skills
- Strategies – noticing eating habits (1st)

Challenges

- Navigating social engagement with friends (1st) - both in the sense of eating out for meals/navigating food at special occasions/responding to unhelpful comments from friends/ Change in behaviour at mealtimes with family
- How weight loss is perceived (1st)
- Staff not providing culturally relevant advice (1st)
- The cost of food (1st)
- Boredom with repetition of meals (1st) - also rigidity of the diet (this was both seen as a positive and a negative thing)

- Keeping track of calories/food intake (1st)
- Hunger (1st) 2nd
- Unclear dietary advice (1st)
- Fatigue (1st)

Following the intervention

Benefits/ positive aspects experienced by participants

- Self-confidence/self-belief (1st) - feeling in control of being able to manage their diabetes. Confidence that they can achieve a healthier way of living. (One negative example of an individual weighing every morning as a sense of control).
- Feeling healthier (1st) - Increased energy/ reduced pain
- T2DM remission (1st)
- Increased confidence
- Weight loss (Beyond?)
- Change in eating behaviours
- Change in relationship with food

Negative aspects following intervention

- Feeling it is not sustainable (1st) (and one example of a study where they felt it was unsustainable)
- Re-introducing food was perceived as most challenging aspect

Reflection: What we're not hearing

- Disappointment if participants did not achieve remission? How does this feel, what are they offered, what happens next?
- Well-being? Are individuals enjoying their food/ increased self-compassion/ emotional regulation – emotional eating?

Step 2

Initial codes and development of descriptive themes

Motivation to engage with the programme	Adherence to suggested dietary modification		Benefits experienced following changes in eating behaviours
	Facilitators	Challenges	
<ul style="list-style-type: none"> - 'I want to live more' increase life expectancy - experience of family member experiencing diabetes complications - failed past attempts to make change - live to see grandchildren grow up - diabetes remission - weight loss - increase quality of life - gratitude for being offered an opportunity - hope for increase mobility 	<ul style="list-style-type: none"> - Feeling healthier - simplicity of diet plan - enhanced engagement through culturally relevant material - tailored approach to diet changes - collaborative approach with staff - encouragement by staff, family, friends - feeling heard/understood by staff - use of technology to track and support diet change - sharing knowledge with friends/family - ripple effect of lifestyle change on others - involvement in research study - accountability - rapid weight loss - not wanting to disappoint others - employment of strategies to reduce cravings - avoidance of situations where food may be tempting - structured food plan - feedback on progress - avoidance of restaurants - compensation using shakes - building trust and 	<ul style="list-style-type: none"> - Navigating social situations - boredom of diet plan - comfort eating - situations with tempting food on display - the smell of tasty food - cost of the diet - feeling hungry - engagement at social occasions - communication with health care staff - rigid food plan - feeling rude/guilty for not accepting offers of food - reduce enjoyment of food - confusion about dietary advice - frustration at having to limit portion sizes or cut out foods - criticism from others about dietary changes - shame/awkwardness in social situations - challenges with socialising - judgement from others about diet - barriers in accessing certain foods - fatigue 	<ul style="list-style-type: none"> - Self-confidence/self-belief in ability to make lifestyle changes - taking a proactive stance - improvement in physical fitness - perceived increase of energy - tuning into hunger feelings - dig in the garden as a result of increased energy - feeling of control - accomplishment - Achieving T2DM remission <p>Benefits</p>

	rapport with healthcare provider		
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Step 3. Progression of codes and development of analytical themes

All authors participated in reviewing participant quotes and the development of analytical themes. This involved forward and back discussions over the course of a number of weeks over e-mail and verbally. Codes were used to identify sub-themes. Once sub-themes were identified, the framework below to review all manuscripts to identify relevant participant quotes.

Appendix G - CASP Full-text review

1. Inducing remission of Type 2 diabetes in the Caribbean: findings from a mixed methods feasibility study of a low-calorie liquid diet-based programme in Barbados

Bynoe et al. (2020)

Quality assessment grade: Medium

1. Was there a clear statement of the aims of the research?	
Yes	<ul style="list-style-type: none"> • ‘The aim of this study was to examine, in people with Type 2 diabetes in Barbados, the feasibility and metabolic outcomes of the approach employed in the UK to bringing about remission of Type 2 diabetes’.
2. Is a qualitative methodology appropriate?	
Yes	<ul style="list-style-type: none"> • The study is aiming to understand the ‘feasibility and metabolic outcome’ of a liquid diet in Barbados. One limitation, is that asking the participants about their experience, seems to be an addition rather than a focus of the research. The introduction does not review any literature of previous qualitative studies, and there is a limited amount of space provided for discussion of the qualitative data.
3. Was the research design appropriate to address the aims of the research?	
Somewhat	<ul style="list-style-type: none"> • The authors choice of quantitative research fits with the aims of the research, however this seems to have reduced the quality of the qualitative research.
4. Was the recruitment strategy appropriate to the aims of the research?	
Yes	<ul style="list-style-type: none"> • Recruitment appeared to range across a number of contexts (a combination of publicity and contacts with local government and private healthcare providers) Semi-structured interviews were conducted with the individuals who were undertaking the liquid diet.
5. Was the data collected in a way that addressed the research issue?	
Somewhat	<ul style="list-style-type: none"> • The explicit aims and objectives of the qualitative component of the research are not clearly outlined. One must assume that the use of their question on whether the liquid diet is ‘feasible’ includes patient’s perceived acceptability.
6. Has the relationship between researcher and participants been adequately considered?	
No	<ul style="list-style-type: none"> • The relationship between the researcher and participants or potential biases that may have been present during interpretation and write-up

have not been transparently reported.

- Solely asking participants on the challenges they faced and strategies they used to cope, already assumes a position of knowledge. This is not addressed by the researchers at any point in the paper.

7. Have ethical issues been taken into consideration?

Somewhat

- Ethical approval was sought by the University of the West Indies Institutional Review Board, and from the Ministry of Health of the Government of Barbados, indicating that consideration for ethical issues regarding the study commenced prior to the beginning of the study.
- However, the ethical processes have not been described. For example, informed consent, information sheet, anonymisation of participant data.

8. Was the data analysis sufficiently rigorous?

Uncertain

- The authors report that interviews were analysed ‘thematically’ using ATLAS.ti v7 qualitative software (ATLAS.ti Scientific Software Development GmbH, Berlin Germany) and data were coded and then reviewed to extract any emerging themes – exactly how these codes were organised into themes is unclear.
- It is unknown what analytical approach they took. How many researchers were involved in the analysis is not reported.
- There seems to have been a great deal of qualitative data collected but there are notable concerns regarding the analysis, for example it is uncertain if data was analysed across the different times point merged as one, or whether change over time was considered.

9. Is there a clear statement of findings?

Somewhat

- There are only two patient quotes presented in the results section. For so much qualitative data collected across 24 interviews, at three different stages of the programme, it feels that it doesn’t represent patient experiences in depth.
- I also notice that there is only one line which makes reference to participants ‘who did less’ well who seemed to have had a difficult experience – ‘participants who did less well reported very different experiences, including being ridiculed at times by family members for their new food choices’ it would be interesting to know if it was only the final food introduction phase that they found difficult? Or if the researchers are making the claim that the challenging experiences they faced resulted in them doing ‘less well’.

10. How valuable is the research?

- The total food replacement diet, and particular programme that is being investigated in this study, has primarily been studied with individuals who are white, living in the United Kingdom. Therefore, investigating its efficacy for individuals living in Barbados, with a varied food, and with participants who are predominantly of black ethnicity does contribute to our understanding of the generalisability of this intervention.
- Unlike some of the studies in which this programme was delivered in the UK, the intervention was delivered by a family practitioner (KB). This is helpful as it differs from some of the programmes offered in the UK, in which it is specialist dieticians offering the programme. However, the

relationship between patients and their family practitioner is not explored in any detail, or the impact this might have on how participants might voice uncertainty, or dissatisfaction with the programme if there are concerns it might impact other aspects of their healthcare with their family practitioner.

11. Are the study's theoretical underpinnings (e.g. ontological and epistemological assumptions; guiding theoretical framework(s)) clear, consistent and conceptually coherent?

No

- This has not been reported in the article.

2. "I don't have to explain, people understand": Acceptability and Cultural Relevance of a Mobile Health Lifestyle Programme for Filipinos with Type 2 Diabetes
Maglalang et al. (2017) 2.

Quality assessment grade: High

1. Was there a clear statement of the aims of the research?

Yes

- To assess the acceptability and cultural relevance of the PilAm Go4Health program - a culturally adapted mobile health weight-loss lifestyle programme including virtual social networking for Filipino Americans with type 2 diabetes.

2. Is a qualitative methodology appropriate?

Yes

- The research aimed to explore participants' perceptions of an app 'acceptability and cultural relevance' therefore semi-structured interviews lend themselves quite well to this research aim.

3. Was the research design appropriate to address the aims of the research?

Uncertain

- The authors describe that qualitative data is collected at baseline, at 3 months and at 6 months, but it is described that semi-structured interviews are only conducted at 3 and 6 months.

4. Was the recruitment strategy appropriate to the aims of the research?

Yes

- Recruitment to the programme was wide and varied occurring through Filipino community events, shopping centers, faith-based and civic organization meetings, community flyers, medical clinics, and select mailings. Everyone who took part in the programme was eligible to take part in the research, and so the recruitment strategy

5. Was the data collected in a way that addressed the research issue?

Yes	<ul style="list-style-type: none"> The data collection was quite thorough and recruited participants from a number of settings. Interviews lasted between 10-40minutes, and the interview guide is included.
6. Has the relationship between researcher and participants been adequately considered?	
Somewhat	<ul style="list-style-type: none"> There is one reference to a 'bicultural research team' and that the principal investigator was a member of the Filipino community. However, a paragraph on the researcher's reflexivity would have been helpful to gain an understanding of how their cultural background, or ontological or epistemological position played a role in the research design, recruitment, interviews and data analysis.
7. Have ethical issues been taken into consideration?	
Somewhat	<ul style="list-style-type: none"> Ethical approval was sought and granted by the University of California San Francisco, Committee for Human Subject Research, which indicates that the researchers took ethical considerations into account prior to beginning the study. However, some key ethical considerations are not clearly presented. The authors did note that written informed consent was obtained prior to study participation. However, how the confidentiality and anonymity of participants were protected has not been described, or the process of informed consent (were participants provided with an information sheet, how many people chose to do the intervention but not engage with the research.
8. Was the data analysis sufficiently rigorous?	
Somewhat	<ul style="list-style-type: none"> In the abstract it is noted that the data was 'thematically analysed' – however results are presented and summarised as percentages. There is no rationale provided for the decision and process of this. It is unknown how these percentages were collected – for example, did participants note the word 'despair' so many times and were then categorised together?
9. Is there a clear statement of findings?	
Yes	<ul style="list-style-type: none"> The findings are presented clearly in the results section, with participant quotes presented appropriately to illustrate themes.
10. How valuable is the research?	
	<ul style="list-style-type: none"> The research is valuable. It provides a good understanding of the importance of designing a programme that holds a cultural awareness at the core of its development. It is also helpful to gain insight from the participants on the importance of social support, in maintaining change. There seemed to be a great ripple effect on the changes they made to the behaviours of their family. It's interesting that remission is not discussed despite it being an article from 2017, it is clear that this is not something that was monitored, with the aim of the app focusing on the management of T2DM.
11. Are the study's theoretical underpinnings (e.g. ontological and epistemological assumptions; guiding theoretical framework(s)) clear, consistent and conceptually coherent?	

Somewhat

- The position of the researchers is unknown. However, the two theoretical frameworks (social cognitive theory and stages of change model), which underpin the development of the app are discussed and it is described that grounded theory has been used to guide data analysis.

3. Acceptability of a very-low-energy diet in Type 2 diabetes: patient experiences and behaviour regulation

Rehackova et al. (2017)

Quality assessment: Medium

1. Was there a clear statement of the aims of the research?
Yes <ul style="list-style-type: none">The aim is clearly presented 'To evaluate the acceptability of an 8-week very-low-energy diet for remission of Type 2 diabetes, and to identify barriers and facilitators of adherence and behaviour-regulation strategies used by participants in the Counterbalance study'.
2. Is a qualitative methodology appropriate?
Yes <ul style="list-style-type: none">This is a qualitative designed study to understand patients experiences of the very low energy diet. This was the most appropriate methodology to employ.
3. Was the research design appropriate to address the aims of the research?
Yes <ul style="list-style-type: none">Interviews were held at two time points, which is helpful to gain an understanding of participants experiences prior to and following the programme.
4. Was the recruitment strategy appropriate to the aims of the research?
Yes <ul style="list-style-type: none">Individual semi-structured interviews were completed at two time points before and after the programme. However, the authors do note that one person was excluded from the programme as they did not meet the prespecified weight loss. Given it was a study to explore barriers to adherence, interviews with those who did not complete the programme may have been insightful.
5. Was the data collected in a way that addressed the research issue?
Yes <ul style="list-style-type: none">The interviews were semi-structured, conducted face-to-face and audio-recorded. Field notes were taken during and after the interviews.The topic guide is reported.
6. Has the relationship between researcher and participants been adequately considered?
No <ul style="list-style-type: none">There is no mention in the paper on reflections from the researchers on their potential biases of the aims, objectives, methodology or data analysis of the research.This is significant as the authors declare a conflict of interest: L. R., A.A., F.F.S. and R.T. are currently engaged on a research project using VLEDs for diabetes remission (DiRECT) funded by Diabetes UK. Authors of the research evaluating the acceptability of the VLED are employed and working on the programme that is delivering the DiRECT trial.

7. Have ethical issues been taken into consideration?	
Yes	<ul style="list-style-type: none"> Ethical approval was sought and approved, meaning that ethical issues were considered by the researchers prior to beginning the research.
8. Was the data analysis sufficiently rigorous?	
Yes	<ul style="list-style-type: none"> There is a good description of how the data was analysed and what tool was employed to analyse the data. The authors describe how they formed codes based on predefined theory-based themes, as well as their use of additional themes identified in the data to form remaining codes. Some of the interview scripts were double-coded by two coders to ensure consistent coding and data interpretation, any differences were resolved through discussion. It does raise concerns that the one participant who was excluded, was a result of them not meeting the prespecified weight loss goal from the Counterbalance. The aim of the research is to investigate the acceptability of the VLED, if inclusion criteria was specific to those who successfully completed the 8 week programme, it puts the findings at risk of producing favourable results which may not be representative of each patients experience.
9. Is there a clear statement of findings?	
Yes	<ul style="list-style-type: none"> The findings are presented well and use to inform the design of a model.
10. How valuable is the research?	
	<ul style="list-style-type: none"> The research is valuable, the authors discuss the findings with reference to relevant research articles. For example, it is clinically helpful to know that social influence was central to the participants narratives, and how this could be facilitated in programmes which are individually focused. Included in the article is a table outlining behaviours by other people engaged around the participants, that they found helpful. There is a slight concerns that some of these strategies are promoting diet culture and weight loss focused approaches for others. The model of psychological, behavioural and environmental determinants of adherence with the very-low-energy diet also helps to provide an understanding of the multiple facets that should be considered by health professionals supporting patients undergoing these diets. The focus cannot solely be on providing the nutritional advice but must also include their emotional well-being and external pressures they face. It is important to note however, that consideration should also be given to behaviours that are learned during this phase that may not be helpful during the maintenance phase. For example, it is presented that a helpful adherence strategy is to avoid situations where there may be tempting food
11. Are the study's theoretical underpinnings (e.g. ontological and epistemological assumptions; guiding theoretical framework(s)) clear, consistent and conceptually coherent?	
Somewhat	<ul style="list-style-type: none"> Although the research codes are drawn from Theory Domains Framework, ontological and epistemological assumptions have not been

clearly stated in the paper, therefore it is unknown whether they guided the development of the methodology or not.

4. Behaviour change during dietary Type 2 diabetes remission: a longitudinal qualitative evaluation of an programme using a very low energy diet

Rehackova et al. (2020)

Quality assessment grade: High

1. Was there a clear statement of the aims of the research?
Yes <ul style="list-style-type: none">The aim of the research is clearly stated in the introduction 'to understand the developments and changes in experiences in the process of dietary diabetes remission'. It may have been helpful to outline specific objectives of the research.
2. Is a qualitative methodology appropriate?
Yes <ul style="list-style-type: none">The researchers aim to understand the patient's perspective of undergoing the eight-week programme as part of the Counterweight plus programme. Therefore, qualitative methodology was appropriate.
3. Was the research design appropriate to address the aims of the research?
Yes <ul style="list-style-type: none">Interviewing participants at three time points, pre and post interview, and at follow up, is an appropriate research design for what the researchers hope to achieve.
4. Was the recruitment strategy appropriate to the aims of the research?
Somewhat <ul style="list-style-type: none">This study was part of a larger ongoing study as part of the DiRECT trial.The authors note that 'of the 18 participants who consented to be interviewed in the qualitative evaluation, 11 participants had complete longitudinal interview' which they analysed in this study. Findings presented are therefore based on the experiences of participants who were successful in completing the VLCD phase and 6month programme. Whilst the authors acknowledge this as a limitation and noted the reasons provided were mostly attributed to 'lack of time', a helpful recommendation for future studies, may have been to gain an understanding of why participants withdraw from this study and follow-up on if there were any challenges the participants faced after withdrawing from the study following the VLCD.
5. Was the data collected in a way that addressed the research issue?
Yes <ul style="list-style-type: none">Semi-structured interviews were chosen as the data collection method. This is appropriate for the aims of the research. It would have been helpful to have included exactly how the semi-structured interviews were conducted (online/telephone/in person), and the average length of each interview.

6. Has the relationship between researcher and participants been adequately considered?	
Somewhat	<ul style="list-style-type: none"> The authors report the qualification of the interview, experience in qualitative research and a brief sentence that ‘interviewer–participant relationship was established at the beginning of the qualitative evaluation study and the researcher had no other contact with the participants during the study’. Whilst it is reported in the conflict of interest section, there is no reference to reflexivity by authors who are also employed and funded by the research grant (Diabetes UK), that is evaluating the programme and delivering the programme.
7. Have ethical issues been taken into consideration?	
Somewhat	<ul style="list-style-type: none"> Researchers sought and received ethical approval by the NHS Research Ethics Committee. A reference is provided on how consent was provided, however in the article referenced, the informed consent procedure is not outlined. Considerations of confidentiality or anonymity of participants are also not described in either article. Although this may be published elsewhere, it is not easily accessible for the reader.
8. Was the data analysis sufficiently rigorous?	
Yes	<ul style="list-style-type: none"> The authors describe the process of data analysis, and what researchers were involved with each step in good detail.
9. Is there a clear statement of findings?	
Yes	<ul style="list-style-type: none"> The findings are presented clearly in the results section, with participant quotes presented appropriately to illustrate themes.
10. How valuable is the research?	
	<ul style="list-style-type: none"> The findings are valuable. There is a limited number of studies which use qualitative measures to explore the patients experience of diet modification as part of T2DM programmes, and this study provides an important way to incorporate patient experiences within the larger quantitative study of the programme. Although caution must be taken when reading the findings, as the sample are those who successfully completed the VLCD and 6month follow up programme, it is helpful that the researchers have followed the patients journey to gain an understanding of how their experiences, or view may have changed over time. More longitudinal research such as this is needed to understand the sustainability changes made and T2DM remission.
11. Are the study’s theoretical underpinnings (e.g. ontological and epistemological assumptions; guiding theoretical framework(s)) clear, consistent and conceptually coherent?	
Uncertain	<ul style="list-style-type: none"> This is not reported in the study.

5. Participant experiences in the Diabetes Remission Clinical Trial (DiRECT trial)

Rehackova et al. (2022)

Quality assessment grade: Medium

1. Was there a clear statement of the aims of the research?
Yes <ul style="list-style-type: none">The authors described the 'aims of this report were to (1) Understand participant experiences of the DiRECT programme delivered in primary care; (2) Derive information which HCPs can adopt and share during implementation of behavioural weight-loss induced remissions of type 2 diabetes; and (3) Understand and define the process of change throughout the programme, with a view of future programme improvement'
2. Is a qualitative methodology appropriate?
Yes <ul style="list-style-type: none">As it was an exploration of patient experiences, semi-structured interviews were the best approach to collect data.
3. Was the research design appropriate to address the aims of the research?
Yes <ul style="list-style-type: none">Collecting qualitative data across four time points makes sense with the aims and objectives of what the researchers were hoping to achieve.
4. Was the recruitment strategy appropriate to the aims of the research?
Yes <ul style="list-style-type: none">Participants were recruited from the sample of Counterweight Plus participants across multiple sites across England and Scotland. However, the specific multidisciplinary teams, or whether any differences exist in the delivery of these programmes across England and Scotland has not been discussed.
5. Was the data collected in a way that addressed the research issue?
Yes <ul style="list-style-type: none">Data was collected from patients before starting the total food replacement diet (T1), during week 6–8 of programme (T2); 2 weeks into the food replacement phase (T3); and 1 year from T1 (T4) using semi-structured interviews.One limitation was that the authors make a note of reporting out of 6 participants who were unavailable for interview or who withdrew from the study, two had gained weight. Whilst the focus is intended to be on TDRM, weight loss is still the outcome measure of adherence and success.
6. Has the relationship between researcher and participants been adequately considered?
Somewhat <ul style="list-style-type: none">Reflexivity by researchers is not reported. As authors from this study have previously received funding to work on the programme being implemented, it is a significant limitation for their position was not described in detail.

7. Have ethical issues been taken into consideration?	
Yes	<ul style="list-style-type: none"> Ethical approval was sought and obtained from the West of Scotland Research Ethics Committee. How informed consent was sought from patients has been outlined. However, there are a number of key ethical procedures which are not clearly outlined, for example confidentiality of patient data, anonymised of text excerpts.
8. Was the data analysis sufficiently rigorous?	
Yes	<ul style="list-style-type: none"> Thematic analysis was employed. The process of analysis and role of each researcher in the analysis process is considered and presented in detail.
9. Is there a clear statement of findings?	
Yes	<ul style="list-style-type: none"> The findings are stated clearly under each theme heading and discussed with reference to the research.
10. How valuable is the research?	
	<ul style="list-style-type: none"> The findings are valuable as it is one of the few studies that collects and analysis data at multiple time points across multiple services for the duration of the intervention. Although caution must be taken when reading the findings, as the sample are those who successfully completed Counterweight Plus programme.
11. Are the study's theoretical underpinnings (e.g. ontological and epistemological assumptions; guiding theoretical framework(s)) clear, consistent and conceptually coherent?	
Yes	<ul style="list-style-type: none"> The researchers do state their epistemological assumption and the theoretical framework that guides the research. 'It is theoretically positioned in a relativist ontology, proposing that emotions, social norms, and experiences form how reality is constructed subjectively. Our epistemological position is constructionist, seeking to generate contextual understanding of peoples' experiences with the DiRECT programme through their engagement with it and interpretations of their experiences'.

**6. Diet, Diabetes Status, and Personal Experiences of Individuals with Type 2 diabetes Who Self-Selected and Followed a Low Carbohydrate High Fat diet
Webster et al. (2019)**

Quality assessment grade: High

1. Was there a clear statement of the aims of the research?	
Yes	<ul style="list-style-type: none"> The authors describe the aim of this study in detail 'the aim of the study was to characterize the diet, eating patterns, T2D status, and personal experiences of individuals with a confirmed history of T2D who claimed to have followed a carbohydrate restricted diet for at least the previous 6 months'.
2. Is a qualitative methodology appropriate?	
Yes	<ul style="list-style-type: none"> The authors chose to do a mixed methods study in order to collect the following information (Blood draw for HbA1c, Body weight, Medications history, Food frequency questionnaire, 1-day diet recall, 3-day diet logbook).
3. Was the research design appropriate to address the aims of the research?	
Yes	<ul style="list-style-type: none"> Assessing at baseline and 15 months follow up, facilitated the researchers to make comparisons between participants initial assessment and following engagement with the LFHC diet at a follow up point.
4. Was the recruitment strategy appropriate to the aims of the research?	
Yes	<ul style="list-style-type: none"> As the researchers were not implementing a programme it makes sense that they recruited participants from multiple sources (social media adverts, a press release, or posters placed at local clinics).
5. Was the data collected in a way that addressed the research issue?	
Yes	<ul style="list-style-type: none"> For the qualitative component of the research, semi-structured interviews were an appropriate method of collecting data in a way that addressed the researchers aims.
6. Has the relationship between researcher and participants been adequately considered?	
No	<ul style="list-style-type: none"> The relationship between the researcher and the participants has not been reported.
7. Have ethical issues been taken into consideration?	
Yes	

<ul style="list-style-type: none"> The researchers dedicate a paragraph to ‘compliance with ethical standards’. The study was approved by the University of Cape Town, Faculty of Health Sciences, Human Research Ethics Committee (REF: 608/2016). All participants were informed of the nature of the study and written informed consent was obtained before participants were enrolled in the study.
8. Was the data analysis sufficiently rigorous?
<p>Yes</p> <ul style="list-style-type: none"> The researchers chose to employ Braun and Clarke’s (2008) thematic analysis, describing each step in detail. The role of each researcher in each stage of the analysis is described.
9. Is there a clear statement of findings?
<p>Yes</p> <ul style="list-style-type: none"> The findings are presented clearly in the results section, with participant quotes presented appropriately to illustrate themes.
10. How valuable is the research?
<ul style="list-style-type: none"> This research is valuable as it adds to the mounting quantitative studies on the use of low carbohydrate diets prescribed for people with T2DM. It’s interesting to read about the participants experiences of the response from medical professionals. The conflicting responses are highly reflective of the current literature that is in existence on the use of LCHF diets.
11. Are the study’s theoretical underpinnings (e.g. ontological and epistemological assumptions; guiding theoretical framework(s)) clear, consistent and conceptually coherent?
<p>No</p> <ul style="list-style-type: none"> This has not been reported.

7. Self-reported facilitators of, and impediments to maintenance of healthy lifestyle behaviours following a supervised research-based lifestyle programme in patients with type 2 diabetes

Wycherley et al. (2012)

Quality assessment grade: High

1. Was there a clear statement of the aims of the research?
Yes <ul style="list-style-type: none">This is stated clearly in the introduction 'The objective of the present study was to identify factors reported by participants as enhancing or impeding the sustainability of lifestyle behaviours in overweight individuals with Type 2 diabetes following completion of a research-based programme incorporating an energy-restricted diet with or without a resistance-exercise training programme'.
2. Is a qualitative methodology appropriate?
Yes <ul style="list-style-type: none">The aim of the study is to explore patient's perspectives, understanding their personal journeys following an energy restricted diet as part of a research-based programme.
3. Was the research design appropriate to address the aims of the research?
Yes <ul style="list-style-type: none">This was conducted as a one year follow up from the 16 week programme. Incorporating a long-term follow up design is helpful in understanding the sustainability of what the programme hoped for participants to achieve. Taking additional measurements such as blood samples are appropriate for a one year follow up assessment.
4. Was the recruitment strategy appropriate to the aims of the research?
Yes <ul style="list-style-type: none">Participants were recruited through public advertisement.
5. Was the data collected in a way that addressed the research issue?
Yes <ul style="list-style-type: none">Semi-structured interview were employed to collect data. This is an appropriate choice of data collection, in line with the aim and objectives of the research question.
6. Has the relationship between researcher and participants been adequately considered?
Yes <ul style="list-style-type: none">The researchers chose for the interviews to be conducted by an investigator external to the original research team that had conducted the research-based programme.

7. Have ethical issues been taken into consideration?	
Yes	<ul style="list-style-type: none"> The study was approved by the Human Research Ethics Committees of the CSIRO and the University of Adelaide. The process of informed consent was also described. Methods of confidentiality and anonymity would have been helpful to report on.
8. Was the data analysis sufficiently rigorous?	
Yes	<ul style="list-style-type: none"> Content analysis was chosen to analysis the data. It is described clearly by the authors. The role of each author in analysis process is described well.
9. Is there a clear statement of findings?	
Yes	<ul style="list-style-type: none"> The themes are presented well. The percentages of participant responses are presented clearly.
10. How valuable is the research?	
	<ul style="list-style-type: none"> This research is valuable as it explores patients experience of a structured energy restricted diet alongside a supervised/unsupervised exercise programme. It was really helpful that participants were contacted one year following the programme to gain insight on what changes were sustained and what challenges they faced once the programme had finished.
11. Are the study's theoretical underpinnings (e.g. ontological and epistemological assumptions; guiding theoretical framework(s)) clear, consistent and conceptually coherent?	
No	<ul style="list-style-type: none"> This has not been discussed.

8. Barriers to following dietary recommendations in Type 2 Diabetes

Vijan et al. (2005)

Quality grade: High

1. Was there a clear statement of the aims of the research?
Yes <ul style="list-style-type: none">This is stated clearly in the introduction 'The objective of the present study was to identify factors reported by participants as enhancing or impeding the sustainability of lifestyle behaviours in overweight individuals with Type 2 diabetes following completion of a research-based programme incorporating an energy-restricted diet with or without a resistance-exercise training programme'.
2. Is a qualitative methodology appropriate?
Yes <ul style="list-style-type: none">The aim of the study is to explore patient's perspectives, understanding their personal journeys following an energy restricted diet as part of a research-based programme, therefore qualitative methodology is appropriate.
3. Was the research design appropriate to address the aims of the research?
Yes <ul style="list-style-type: none">This was conducted as a one year follow up from the 16 week programme. Incorporating a long-term follow up design is helpful in understanding the sustainability of what the programme hoped for participants to achieve. Taking additional measurements such as blood samples are appropriate for a one year follow up assessment.
4. Was the recruitment strategy appropriate to the aims of the research?
Yes <ul style="list-style-type: none">Participants were recruited from urban and suburban sites via flyers. Appropriate method of data collection for focus groups.
5. Was the data collected in a way that addressed the research issue?
Yes <ul style="list-style-type: none">Semi-structured interviews were employed to collect data. This is an appropriate choice of data collection, in line with the aim and objectives of the research question.
6. Has the relationship between researcher and participants been adequately considered?
Yes <ul style="list-style-type: none">The researchers chose to for the interviews to be conducted by an investigator external to the original research team that had conducted the research-based programme.

7. Have ethical issues been taken into consideration?	
Yes	<ul style="list-style-type: none"> The study was approved by the Human Research Ethics Committees of the CSIRO and the University of Adelaide. The process of informed consent was also described. Methods of confidentiality and anonymity would have been helpful to report on.
8. Was the data analysis sufficiently rigorous?	
Yes	<ul style="list-style-type: none"> Content analysis was chosen to analysis the data. It is described clearly by the authors. The role of each author in analysis process is described well.
9. Is there a clear statement of findings?	
Yes	<ul style="list-style-type: none"> The themes are presented well. The percentages of participant responses are presented clearly.
10. How valuable is the research?	
	<ul style="list-style-type: none"> This research is valuable, as it highlights socio-economic pressures that arise for people being recommended foods, which may not be easily accessible to them. It is also unique in how it compares and contrasts different T2DM management approaches but provides a more detailed account of the dietary approach for this paper. While it differs slightly to the other studies included in this review, I think the qualitative data collected offers a lot of insight on the challenges faced by those not being supported with making change and the barriers they are faced with.
11. Are the study's theoretical underpinnings (e.g. ontological and epistemological assumptions; guiding theoretical framework(s)) clear, consistent and conceptually coherent?	
No	<ul style="list-style-type: none"> This has not been discussed.

9. Designing the Healthy Eating and Active Lifestyles for Diabetes (HEAL-D) self-management and support programme for UK African and Caribbean communities: a culturally tailored, complex programme under-pinned by behaviour change theory

Moore et al. (2019)

Quality assessment grade: High

<p>1. Was there a clear statement of the aims of the research?</p>
<p>Yes</p> <ul style="list-style-type: none"> The authors state the ‘aim of this study was to apply the BCW and associated COM-B methodological framework to identify relevant behaviour change techniques (BCTs) and intervention components as part of the development of the HEAL-D culturally sensitive T2D self-management and support programme for people of AfC ethnicity’.
<p>2. Is a qualitative methodology appropriate?</p>
<p>Yes</p> <ul style="list-style-type: none"> The authors state their rationale clearly ‘focus group methodology was chosen, as our objective was programme design, so we were interested in the convergent views of the communities taking part’.
<p>3. Was the research design appropriate to address the aims of the research?</p>
<p>Yes</p> <ul style="list-style-type: none"> This research is part of a larger study which has incorporated co-design methods. The research plan of designing an programme has been well considered, the protocol published elsewhere, and this study fits well for the aims and objectives of the overarching project.
<p>4. Was the recruitment strategy appropriate to the aims of the research?</p>
<p>Yes</p> <ul style="list-style-type: none"> The researchers made an effort to recruit participants from different contexts including: GP surgeries, face to face via local Black majority church networks and mosques, face to face through Diabetes UK Community Champions and via advertisements and researcher presence at local cultural events
<p>5. Was the data collected in a way that addressed the research issue?</p>
<p>Yes</p> <ul style="list-style-type: none"> Focus groups were chosen as the data collection method.
<p>6. Has the relationship between researcher and participants been adequately considered?</p>
<p>Yes</p> <ul style="list-style-type: none"> The relationship was considered 'we recognise that the focus group facilitators being of White European ethnicity may influence the data collection and analysis and have addressed this where possible with active involvement of members of the communities in the analysis and interpretation of the findings’.

<ul style="list-style-type: none"> The background and experience of the researchers who facilitated the focus groups were also discussed in detail.
7. Have ethical issues been taken into consideration?
<p>Yes</p> <ul style="list-style-type: none"> Ethical approval was obtained. Informed consent procedures were described. Information was provided at initial screening appointments. Anonymisation of data was described.
8. Was the data analysis sufficiently rigorous?
<p>Yes</p> <ul style="list-style-type: none"> A priori framework approach was adopted by the researchers to assist analysis of the data, with deductive codes based on COM-B and the associated Theoretical Domains Framework (TDF). In order to improve validity 20% of data was independently coded by two researchers.
9. Is there a clear statement of findings?
<p>Yes</p> <ul style="list-style-type: none"> Findings are described clearly, in an organised fashion within the framework described and discussed with reference to relevant literature.
10. How valuable is the research?
<ul style="list-style-type: none"> The research is valuable, the researchers have designed a project to inform the development of a programme that is tailored for the unique needs of UK African and Caribbean communities. While this study also slightly differs to others included in this review, the qualitative information gathered is incredibly insightful, on how the NICE guidelines, focusing on 5-10% weight loss through food modification and exercise, are being implemented in clinical practice.
11. Are the study's theoretical underpinnings (e.g. ontological and epistemological assumptions; guiding theoretical framework(s)) clear, consistent and conceptually coherent?
<p>Yes</p> <ul style="list-style-type: none"> The researchers discuss their epistemological approach at the beginning. The theoretical framework they choose to analysis the data is clear, consistent and conceptually coherent.

Appendix H - GRADE CERQual

GRADE-CERQual

Review finding	Contributing papers	Methodological limitations	Coherence	Adequacy	Relevance	CERQual assessment
Theme 1.						
Variability in support	Maglalang et al. (2017) Ermakova et al. (2017) Vijan et al. (2005) Rehackova et al. (2020) Rehackova et al. (2022) Wycherley et al. (2012) Webster et al. (2019) Moore et al. (2019) Bynoe et al. (2020)	Minor concerns	No or very minor concerns	No or very minor concerns	No or very minor concerns	High confidence
Opportunity for support	Maglalang et al. (2017) Rehackova et al. (2020) Rehackova et al. (2017) Rehackova et al. (2022) Wycherley et	Minor concerns	Minor concerns	Moderate concerns	No or very minor concerns	Moderate confidence

	al. (2012)					
Tailored guidance	Maglalang et al. (2017) Rehackova et al. (2017) Rehackova et al. (2022) Webster et al. (2012) Moore et al. (2019) Vijan et al. (2005) Wycherley et al. (2012)	Minor concerns.	No or very minor concerns	Minor concerns	No or very minor concerns regarding relevance	High confidence
Theme 2.						
Choosing dietary change	Rehackova et al. (2017) Rehackova et al. (2020) Maglalang et al. (2017) Wycherley et al. (2012) Bynoe et al. (2020) Webster et al. (2019)	Minor concern regarding two studies.	Minor concerns	Minor concerns	No or very minor concerns	Moderate confidence
Motivation to change	Rehackova et al. (2020) Moore et al.	Minor concerns.	No or very minor concerns	Minor concerns	Minor concerns	High confidence

	(2019) Rehackova et al. (2017) Maglalang et al. (2017) Bynoe et al. (2020) Webster et al. (2019)					
Building a support network	Wycherley et al. (2012). Rehackova et al. (2022) Rehackova et al. (2020) Rehackova et al. (2017) Maglalang et al. (2017) Vijan et al. (2005) Bynoe et al. (2020)	Minor concerns	No or very minor concerns	Minor concerns	No or very minor concerns	High confidence
Theme 3.						
Re-negotiating the food relationship	Maglalang et al. (2017) Vijan et al. (2005) Rehackova et al. (2017) Rehackova et al. (2020)	Minor concerns.	Minor concerns	Minor concerns	No or very minor concerns	High confidence

	Rehackova et al. (2022) Wycherley et al. (2011) Webster et al. (2019)					
Challenges of socialising	Vijan et al. (2005) Rehackova et al. (2020) Rehackova et al. (2017) Webster et al. (2019) Moore et al. (2019) Bynoe et al. (2020)	Minor concerns.	Minor concerns	No or very minor concerns	No or very minor concerns	High confidence
Navigating the food environment	Rehackova et al. (2017) Vijan et al. (2005) Moore et al. (2019) Webster et al. (2019) Rehackova et al. (2022) Bynoe et al. (2020) Wycherley et al. (2012).	Minor concerns	Minor concerns	Minor concerns of adequacy of data.	No or very minor concerns regarding relevance	High confidence

Theme 4.						
Beyond weight loss	Rehackova et al. (2017) Rehackova et al. (2020) Webster et al. (2019) Wycherley et al. (2012)	Minor concerns.	Minor concerns. (some concerns about the fit between the data from primary studies and the review finding)	Moderate concerns	Minor concerns	Moderate confidence (concerns regarding the coherence of the review finding, and

Appendix I - Participant Information Sheet

An exploration into the experiences and personalised goals of individuals engaging in a Weight Management Programme for Type 2 Diabetes Remission.

You are being invited to take part in research on exploring patient's experiences of a weight management programme. Rachael McDonnell Murray, Chief Investigator and Trainee Clinical Psychologist at the University of Edinburgh is leading this research. Before you decide whether to take part it is important you understand why the research is being conducted and what it will involve. Please take time to read the following information carefully.

What is the purpose of the study?

The aim of this research is to explore the experiences of people with a diagnosis of Type 2 Diabetes, who are currently beginning the Counterweight plus programme or who are nearly finishing the program.

Type 2 Diabetes can have a significant impact on patients' quality of life. Recent research has found that calorie deficit weight management programmes has shown effectiveness in helping patients to achieve Type 2 Diabetes remission. Therefore, there have been many of these programs designed and carried out across Europe and the UK which focuses on this. To date, most of the research that has been done measuring programmes focusing on Type 2 diabetes remission, have measured successful outcomes of such programmes on symptom reduction. Although this can be an important part of the patients healthcare journey, it is only one side. What might be seen as important for healthcare professionals could be different to what the patients themselves value from such programs. Across the literature, the patient voice is missing and so we feel it's important to explore patient experiences before and after a weight management program focusing on Type 2 Diabetes to understand what the journey is like for them and what they find important from the programme.

Why have I been invited to take part?

You are invited to participate in this study because you are just beginning or are currently near the end of the Counterweight Plus programme. As described above we are hoping to hear about your experiences of your weight management journey, before beginning the programme, and near the completion of the programme.

Do I have to take part?

No – it is entirely up to you. If you do decide to take part, you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect your healthcare in the weight management service. Please note that your data may be used in the production of formal research outputs (e.g. journal articles, conference papers, theses and reports) prior to your withdrawal and so you are advised to contact the research team at the earliest opportunity should you wish to withdraw from the study. If you are unhappy about disclosing certain information in the interview please do not hesitate to contact the researcher and the interview recording can be destroyed and will not be used in the final write up of the data. This must be done within one month of participating in the interview, after this your data will be anonymised and it will no longer be possible for your information to be retracted.

What will happen if I decide to take part?

If you do decide to take part, please keep this Information Sheet. You will be asked to complete an Informed Consent Form to show that you understand your rights in relation to the research, and that you are happy to

participate. This will be sent to you via e-mail. You will have the opportunity to ask the chief investigator any questions before signing this..

Once you have completed your informed consent form, you will be invited to an online interview with the chief investigator. If you have just been enrolled onto the Counterweight plus programme, you will be asked a number of questions regarding your goals for the programme, what to hope to gain from the programme, and what your journey has been like until this point. If you are near the completion of the programme, you will be asked about what you valued from the programme, if you achieved the goals you had set and what the important parts of the programme were for you. The interview will take place online at a time that is convenient to you. Ideally, we would like to audio record your responses (and will require your consent for this), so we would appreciate if the place you did the interview is in a fairly quiet area. The interview should take around 45-60 minutes to complete.

If you would like to read about the research findings, you will be asked to contact the dietician who will have a summary of the results that they can send to you.

What are the possible benefits of taking part?

There are no direct benefits, but by sharing your experiences with us, you will be helping Rachael and the University to better patients' experiences going through a weight management programme for Type 2 diabetes.

Are there any risks or disadvantages associated with taking part?

There are no significant risks associated with participation. You can ask to pause or stop the interview at any point or chose not to answer a question. Due to the nature of this research direct quotes will be included in the final write up and therefore, although the researcher will go to every effort to anonymise every participant, there is a slight risk of being identified. However, this will be greatly minimised by the researcher providing pseudonyms for each participant and by removing any identifiable information from audio-recordings. You will also be sent a copy of your transcript to review, if you feel certain quotes are too identifiable they can contact the researcher to exclude this information or withdraw from the study (please note this must be done within two weeks of being sent the transcript as your data will be anonymised after this point).

If you would like to speak about issues which arose in the interview which has caused you distressed feel free to contact Dr. Davina Chauhan who is the Clinical Psychologist on the Counterweight plus team.

Will my taking part be confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name, e-mail address, gender and age. People will use this information to do the research or to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

If you consent to being audio recorded, all recordings will be destroyed once they have been transcribed. Your data will only be viewed by the researcher. All electronic data will be stored on a shared University of Edinburgh Drive. Your consent information will be kept separately from your responses in order to minimise risk.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, and without giving a reason. Your data can be withdrawn up until the research is being analysed, at which point your information will have been anonymised.

Where can you find out more about how your information is used?

You can find out more about how we use your information at <https://www.ed.ac.uk/records-management/privacy-notice-research>

- our leaflet available from Rachael
- by asking one of the research team
- by sending an email to the chief investigator

The University of Edinburgh and NHS Lothian are the co-sponsors for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Edinburgh will keep identifiable information about you for 6 months after the study has been completed and your anonymised data for a minimum of 5 years. Your anonymised data may be used in future ethically approved research.

What will happen with the results of this study?

The results of this study may be summarised in published articles, reports and presentations. You will not be identifiable from any published results. Quotes or key findings will always be made anonymous in any formal outputs unless we have your prior and explicit written permission to attribute them to you by name.

Who is organising and funding the research?

This study has been organised by Rachael McDonnell Murray, Dr. Fiona Duffy from the University of Edinburgh and Dr. Davina Chauhan from NHS Lothian.

Who has reviewed the study?

The study proposal has been reviewed by the School of Health in Social Science Ethics Committee at the University of Edinburgh.

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from <insert REC name>. NHS Management Approval has also been given.

Who can I contact?

If you have any further questions about the study, please contact the lead researcher, Rachael McDonnell Murray,
el: 07929784420.

If you would like to discuss this study with someone independent of the study please contact Dr. David Gillanders
(Head of Clinical Psychology),

If you wish to make a complaint about the study please contact NHS Lothian:

Patient Experience Team, NHS Lothian 2nd Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, Tel:
0131 536 3370. Email: feedback@nhslothian.scot.nhs.uk

Appendix J - Interview Guide

Group 1 and 2: Introduction

1. Ensure participant has had time to ask any questions prior to commencing interview.
2. Remind the participant that the interview will be recorded.
3. Ensure that the participant has completed and signed the informed consent form and reconfirm consent to continue.
4. Remind the participant how long the interview may last, but note that they can take a break at any point and do not have to answer any questions that they wish to and that they ask to stop at any time.

Main questions

Group 1:

Getting to know the person

So can you tell me a little bit about your journey up until this point of beginning the programme?

Follow up questions based on participant's answer to this question..

More specific questions

How do you feel about beginning the Counterweight Plus Programme?

What are you hoping to achieve by the end of the programme?

Do you have any goals for the programme? (If these are related only to weight loss as if there are any goals outside of weight loss the participant might have)

Is there anything that you are not looking forward to about the programme?

What is your main motivation for undertaking the programme now?

Group 2:

Getting to know the person

Can you tell me a little bit about your journey before beginning the programme?

What were your hopes before beginning the programme?

What did you value most about the programme?

Did you feel your goals shifted while on the programme?

Do you feel you reached the goals that you had made at the beginning of the programme?

Has anything changed in your life as a result of the programme (e.g., are there things you can do now that you couldn't before the programme).

In your experience, was there anything missing from the programme?

Follow up questions – learning about the person's social context and experiences to date.

More specific questions

Closing question

Is there anything else you would like to discuss that has not already been covered?

Ending

Thank the participant for being part of the study.

Let the participant know that they can contact you at any point should they wish ask any further questions about the study.

Let the participants know that they can contact Dr. Davina Chauhan if they feel in any way distressed from partaking in the interview

Appendix K - Example of IPA analytic process

Step 1: Development of experiential statements and exploratory notes

Example transcript		
Experiential themes	Transcript	Exploratory notes
<p>From a place of confusion and despair to a place of relief that support was available</p> <p>Paving a path to remission alone</p>	<p>How were you feeling about it? (the programme)</p> <p>008: em I was quite relieved actually, because the doctor told me when you have diabetes you go to someone who tells you all about diabetes, but that got all cancelled because of em the covid, so everything was cancelled and he said you are going to get no information, the best thing to do is to look it up online and find out what you need to do and I was like ok, and he was like we have a nurse here in the practice that can give you information hahah but he said you can't make an appointment for that because were not allowed to make any appointments due to the covid and she won't call you because she's too busy, so just look online and see if you can find anything on diabetes</p>	<p>Feelings of relief that support was available</p> <p>From a place feeling unsupported – alone on the journey (Due to COVID-19 – service/support was unavailable)</p> <p>The irony that there was someone who had specialist knowledge, but couldn't access the support (laughs)</p> <p>Being directed to online resources</p>
	<p>I: mm</p>	
<p>Guidance resulting feelings of panic, never to eat sugar again</p> <p>A conflict in information being provided</p>	<p>008: an so at the beginning he was like you're on these drugs now and you will need to take care, and the drugs were metforman and that was it, and so nobody I got no information, and it wasn't until even when the counter plus and that's when I was given all of the information, and I still have more information from [the dietician] that I have ever had from the doctors surgery and I have been in to see the nurse a couple of times now who is the specialist on diabetes, and everything she has told me about diabetes, the [dietician] had contradicted, and it was just silly things, because the nurse told me that I would never be able to have anything with sugar or fruit, like potatoes she was like you will never ever have that again In your life, and I was thought oh right, and that quite panicked me, to think oh what happens if I have something with sugar in it, and when I was talking to the [dietician] she was like no no you can, in moderation and she explained everything in great detail and if it wasn't for the counter plus properly I would have been totally confused</p>	<p>Participant maybe feeling shock, this is the diagnosis and here are the drugs a sense of 'off you go now' feeling healthcare needs dismissed</p> <p>Absence of information from GP</p> <p>Provided information with CW+- this feeling of trust in the information being offered</p> <p>Information of cutting foods out resulted in feelings of panic about management of diabetes and confusion about management of diabetes</p>

		Relief was re-introduced when he was given information that he understood, that made sense to him, and didn't result worry
	I: and that makes a lot of sense, it sounds like for those first six months you were really trying to well manage it yourself based on some of the reading on the internet?	
	008: but even what you're reading on the internet it can depend on what you're reading and who you are reading it from	Variability of online sources of information about diabetes
Overwhelmed by trying to make change alone	I: course 008: you know it can be totally different from em you know it can be totally different from one to the next and eventually I got to the stage where I was thinking ok that's it.. And it was quite difficult at the time.. So but	Variability of sources of information on management of T2DM leading to a 'I give up' 'quite difficult' Feeling of exacerbation
Setting up for failure -	I: it sounds it, did you make lifestyle changes before starting the programme? 008: I did because the doctor had said you will have to change the way you do things, and I said what do you mean and he said you will have to start moving, and walking and doing things, before I hadn't done that I hadn't been out the door in 15 years, and it was just a lot to take on in one go, and it did it changed the way I ate, but it obviously didn't work, and the reason was portion size, because I make my own food and I never made for one, I always made whatever I had I just used..	Being told you need to change – you need to move Lack of consideration for the fact that he hadn't left the house in 15years.... sending him into a state of 'overwhelm?' =- 'obviously it didn't work' - setting up for failure – mis attunement about what he understood, his particular circumstances/barriers to change/ specific challenges to him – portion size

Example of collating participants quotations into Group Experiential Themes

Development of GETS	Notes	Participant quotes
<p>A ripple of shock and upset following diagnosis</p>	<p>Overwhelmed/ Failed by the healthcare system</p> <p>Participants reflecting upon the trajectory of being diagnosed and accessing the programme – frustration expressed by two participants in how they felt failed by their health care team because of lack of follow-up care for both. A misdiagnosis for one woman, and a delay in referral for another woman. All of which contributed to distress in knowing how to best management their recent diagnosis.</p> <p>A turmoil of emotions at finding out about diagnosis</p> <p>“They said just do it by diet” confusion of how to manage T2DM</p> <p>“It’s like you go into the abyss” feeling unsupported by healthcare staff</p>	<p>“I was diagnosed two years ago, just before Covid – it has taken a long time before I got to speak with a dietician, I was actually referred to a dietician long covid, before I discovered I was diabetic, because I was struggling to ..i could lose weight but I couldn't keep it off, and that has been an on-going struggle through out my life, and due to health factors I felt that I needed help with losing weight, and I think I was referred to the weight management service five years ago, and then it wasn't until I became diabetic, well gave is the wrong word, but made my place on the list a bit more.. Gave me more criteria to be able to see some” (P1)</p> <p>“then when she said this is just over the borderline you can reverse this I felt better, but then I thought well the more that time has gone on I have thought well who is helping me to reverse this, no one is monitoring so I don't know if what I am doing it right or if it is wrong, you know so..” (P1)</p> <p>“em just one thing as it's not really related to the counterweight plus programme, but I was becoming quite frustrated after the em first ask the GP to refer me for weight management everything took so long, and although I had significant medical conditions I wasn't a clinical priority and the other thing that frustrated me when I first spoke to the dietician, she sent me out information on exercises classes and things like that and different kind of support everything was targeted towards people that don't work because everything was during the week and it was during office hours and that kind of thing, and I couldn't go to any of them, so I was frustrated about that that is nothing to do with the counterweight plus programme but just in general em I know ...” (P1)</p> <p>“no I found out about the counterweight plus programme myself” (P1)</p>

		<p>“so I went and had a quick chat, they said just to do it by diet, and then didn’t hear anything for over a year, from the doctor” (P2)</p> <p>“then I was back at the doctor for something else, and I said well how will that be for my diabetes, and she said well you’re not diabetic, ha, so I said, yea you diagnosed me then and she said, oh we’re going to have to re-do all of this, she says, cause we don’t have you down as being diabetic, and she then read my notes and was like oh.. So they had to re-do everything, adn then they diagnosed me again so” (P2)</p> <p>“I think ultimately I was a bit pissed off to be fair, because I know I have been working doubly hard during covid, and I know the nhs has been stretched, for me me I was like it’s fundamental, its for my health and you’ve not followed through you know” (P2)</p> <p>“so when they're diagnosed me I went in and I got I went and spoke to a nurse and I got a load of tests done on my feet and things, and then I've not heard anything again, you know, it's like you just go into the abyss” (P2)</p> <p>“that kind of stuff because my neighbor was diagnosed at the same time as me, and we often talk, and you know hes at the doctors every three months getting checked, I now have had my eyes tested, but he got that straight away, he was referred to the paediatrist straight away, you know I just seem to be sitting on waiting lists, em so I have only been on the foot thing, for about a year, waiting to see a paediatrist” (P2)</p> <p>“ well it was all a bit of a shock, I was diagnosed with diabetes, I had no idea that I had it em, it was kind of a routine blood test up at the GPs so this has all been in the last three months or so, so I still don’t have any symptoms and still find it a bit unbelievable really” (P3)</p>
	<p>Worry of health complications associated with T2DM</p>	<p>“when I first got the diagnosis I was really upset, because being a nurse I was really aware of all of the implications of diabetes and I was upset and anxiety about the diagnosis” (P1)</p> <p>“I know I am very low you know on the spectrum of diabetes, I am about two or three points about the level of where I should be, so I know I am</p>

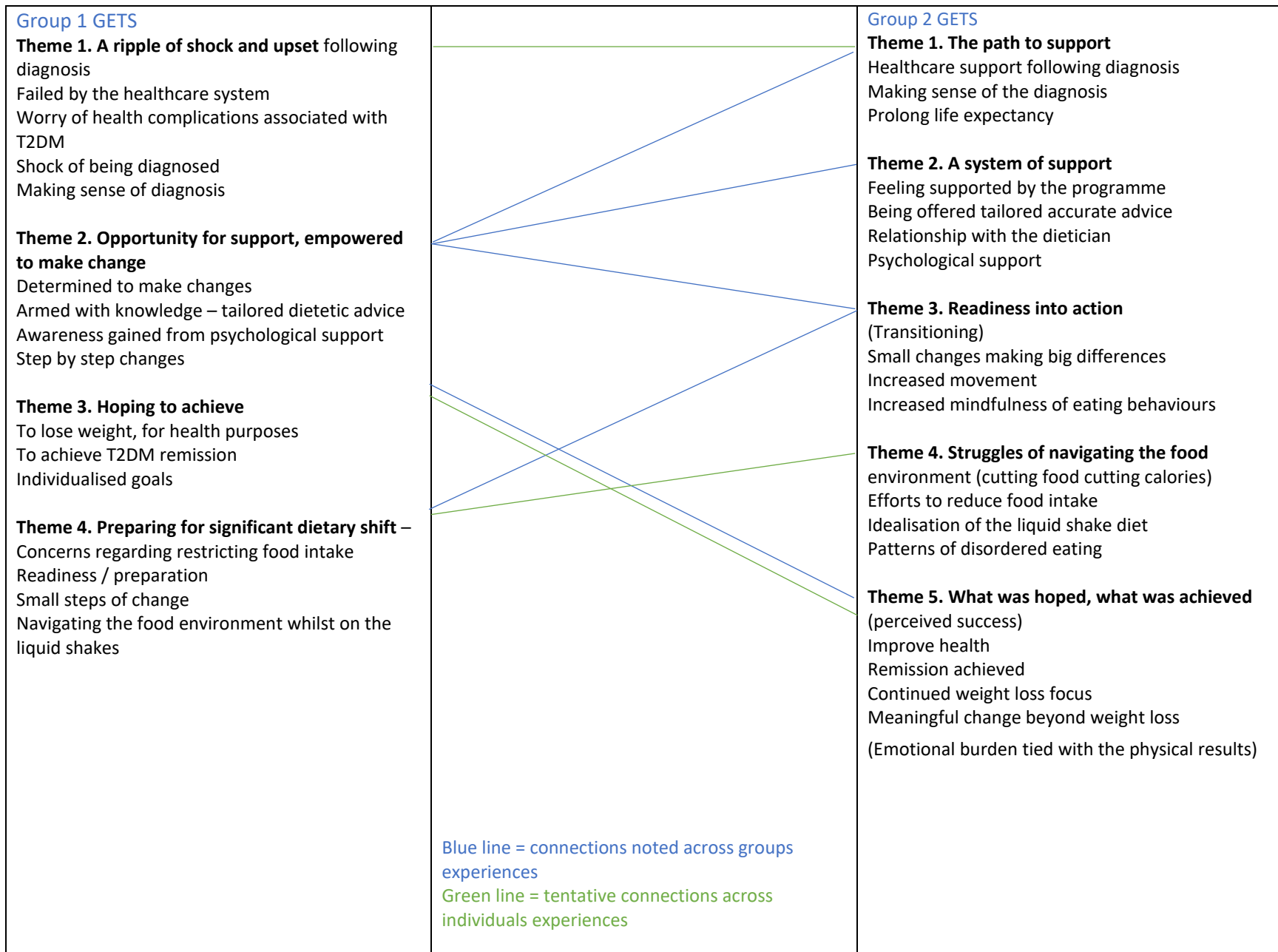
		<p>really low, but my concern is because nothing has been checked, you know am I climbing” (P2)</p> <p>“I just think that you just because you are low, you change your diet, and exercise more, you are just kind of left to it, rather than actually this is scary because you read the horror stories, and what can happen, em and you just think, am I on that road, you know they keep telling me I can put it into remission, but there is no really ...” (P2)</p> <p>“I don’t want to be suffering from complications that are caused by diabetes” (P3)</p> <p>“I don’t feel any symptoms whatsoever, I feel the same way I have always felt. But obviously that is not going to last for much longer if I keep carrying on like this so.. It may be easier if I was starting to feel ill, or you know thinking you know.. If I could see this is going to get worse, but because I cannot see anything, it is much more a psychological thing that I understand my health will suffer if I don’t go on this programme” (P3)</p>
	Shock of being diagnosed	<p>“I was shocked when I found out from the doctor for the very first time, I wasn’t expecting that and I didn’t know I was being tested for that, so I was quite shocked when she phoned me about that em quite taken aback, and then when she said this is just over the borderline you can reverse this I felt better, but then I thought well the more that time has gone on I have thought well who is helping me to reverse this, no one is monitoring so I don’t know if what I am doing it right or if it is wrong, you know so..” (P1)</p> <p>“so I was diagnosed during lockdown, originally, em, they were running tests for something else, and the doctor just ran a diabetes test, didn’t expect for it to come back as positive, em ..” (P2)</p> <p>“well it was all a bit of a shock, I was diagnosed with diabetes, I had no idea that I had it em, it was kind of a routine blood test up at the GPs so this has all been in the last three months or so, so I still don’t have any symptoms and still find it a bit unbelievable really em” (P3)</p> <p>“like I say I had no idea I had this condition” (P3)</p>

		<p>"I guess I went to the doctors, I had some other issues, they did blood tests and they came back and said some of the issues could be caused by diabetes so they were going to test for it, eh and obviously I am type two diabetic so I was told there" (P4)</p>
	<p>Making sense of diagnosis</p> <p>Making sense of path towards being diagnosed</p> <p>An immediate commitment to the programme</p> <p>Processing the role food played in the development of T2DM</p>	<p>"I also wondered if that has also triggered some of this because of the amount of fruit that you're eating, and the amount of carbs, you're eating, so the amount your body is getting used to on that compared to normal I guess you get the benefit of eating veg and you're cutting out fat, em , and I find hat I cant really tolerate that, and I wonder if it because I haven't really had it in the two years" (P2)</p> <p>"I have no family history of it so no not really. just maybe what you see in the news papers or what you see on TV, nothing that I thought could effect me directly. Em I realise my weight had been going up quite steadily over the last, 10 or 15 years really I really didn't think I was that bad. But clearly I was" (P3)</p> <p>"yea it is yea, cause as I said to you, I didn't have any symptoms, I don't have any symptoms, so it was a bit of a shocker obviously I hadn't been paying attention to what I was eating because I had a misconception about diabetes because of sugar, which I don't eat, really, I don't take it in coffee, I don't eat sweeties or anything like that, it is absolutely been too much carbohydrate in my case" (P3)</p> <p>"I might feel a lot lot better, because of the gradual decent into diabetes, is something you don't notice over long periods of time, I said I don't have symptoms, maybe I have but I have just never noticed because they have been so slow to come on, so I don't know I have not got a clue how it all works really" (P3)</p> <p>"during covid I felt I wasn't eating unhealthily especially during the day and at work, but that was really stressful because I was moved from my normal place of working to the covid ICU and obviously this was at the beginning before the vaccine and things like, so I was turning to a glass of red wine to help me to wind down and go to sleep, which obviously not a healthy behaviour either, if you are doing that several nights a</p>

		<p>week, so at some point I had to .. say this was a enough I need to stop.. stop drinking this red time and over the course of the past 2 years, I have lost about a stone, but you know it has taken me over two years to lose a stone (P1)</p> <p>“I think that in combination with all of the other risk factors that is really worrying me, I think I kind of you know used to say to myself, well I don’t smoke and I am not diabetic, yea I am a bit overweight but in the last couple of years, at the same time that I discovered I was diabetic, I discovered that my cholesterol has jumped up, from being normal to being I think it was over 7 at one point, and that gave me a huge fright as well” (P1)</p>
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Appendix L - Development of 'Overall' Group Experiential Themes

Group 1 GETS	Stage 1	Group 2 GETS
<p>Theme 1. A ripple of shock and upset following diagnosis Failed by the healthcare system Worry of health complications associated with T2DM Shock of being diagnosed Making sense of diagnosis</p> <p>Theme 2. Opportunity for support, empowered to make change Determined to make changes Armed with knowledge – tailored dietetic advice Awareness gained from psychological support</p> <p>Theme 3. Goals for the programme, weight loss and beyond To lose weight, for health purposes To achieve T2DM remission Individualised goals</p> <p>Theme 4. Preparing for significant dietary shift Small steps of change Concerns regarding restricting food intake Navigating the food environment whilst on the liquid shakes</p>	<p>Commonalities shared within each group, detailing the differences, tensions and nuances of each individual's experience.</p>	<p>Theme 1. The path to support Healthcare support following diagnosis Making sense of the diagnosis Prolong life expectancy</p> <p>Theme 2. A system of support Feeling supported by the programme Being offered tailored accurate advice Relationship with the dietician Psychological support</p> <p>Theme 3. What was hoped, what was achieved Improve health Remission achieved Continued weight loss focus Meaningful change beyond weight loss</p> <p>Theme 4. Small changes making big differences Increased movement Increased mindfulness of eating behaviours</p> <p>Theme 5. Struggles of navigating the food environment Efforts to reduce food intake Idealisation of the liquid shake diet Patterns of disordered eating</p>



Theme	Sub-theme	Group
Overwhelmed by the system	Processing the diagnosis	1,2
	Searching for support	1,2
A life worth living	Insight	1
	Re-engaging with life	1,2
Taking the wee steps	Empowered	1,2
Cutting food, cutting calories	The wee steps	1,2
	Preparing for the cut	1
	Navigating life whilst on shakes	1,2
	Transitioning	1,2
Not good enough	Undervaluing success	2
	Still trying	2

Appendix M - Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
<i>Personal Characteristics</i>		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	54
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	57
3. Occupation	What was their occupation at the time of the study?	57
4. Gender	Was the researcher male or female?	Lead authors gender reported
5. Experience and training	What experience or training did the researcher have?	57
<i>Relationship with participants</i>		
6. Relationship established	Was a relationship established prior to study commencement?	57
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Participants were briefed on the purpose of the study and understood it. Ethics had been granted, participants reviewed the participant information documentation prior to giving their written informed consent to be involved.
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	57 and 8

Domain 2: study design		
<i>Theoretical framework</i>		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	52
<i>Participant selection</i>		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	53
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	53 and 54
12. Sample size	How many participants were in the study?	53
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Two participants did not respond to follow-up telephone calls with the researcher for unknown reasons. No one dropped out of the study.
<i>Setting</i>		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	53
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	55
<i>Data collection</i>		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Appendix J
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	No
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Yes 53
20. Field notes	Were field notes made during and/or after the interview or focus group?	Yes

21. Duration	What was the duration of the interviews or focus group?	55
22. Data saturation	Was data saturation discussed?	No
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No
Domain 3: analysis and findings		
<i>Data analysis</i>		
24. Number of data coders	How many data coders coded the data?	53
25. Description of the coding tree	Did authors provide a description of the coding tree?	No
26. Derivation of themes	Were themes identified in advance or derived from the data?	Themes were derived from the data
27. Software	What software, if applicable, was used to manage the data?	Microsoft Word and paper
28. Participant checking	Did participants provide feedback on the findings?	No
<i>Reporting</i>		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	58-72
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Some similarities some differences
31. Clarity of major themes	Were major themes clearly presented in the findings?	Table 2 page 58
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Somewhat

Appendix N – Berkshire Research Ethics Committee Approval letter



Health Research
Authority

South Central - Berkshire B Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

21 January 2022

Ms Rachael McDonnell Murray

Dear Ms McDonnell Murray

Study title: An exploration into the experiences and personalised goals of individuals engaging in a Weight Management Programme for Type 2 Diabetes Remission.
REC reference: 22/SC/0007
Protocol number: CAHSS2111/05
IRAS project ID: 303025

Thank you for your submission on 18 January 2022. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 18 January 2022

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Participant information sheet (PIS) [Participant information sheet]	V2	18 January 2022

Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Contract/Study Agreement template		03 December 2021
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		03 December 2021
Interview schedules or topic guides for participants	V1	03 December 2021

IRAS Application Form [IRAS_Form_16122021]		16 December 2021
Letters of invitation to participant	V1	03 December 2021
Non-validated questionnaire [Participant demographics]	V1	03 December 2021
Participant consent form [Participant Consent Form]	V1	03 December 2021
Participant information sheet (PIS) [Participant information sheet]	V2	18 January 2022
Research protocol or project proposal [Protocol]	V1	03 December 2021
Response to Additional Conditions Met		
Schedule of Events or SoECAT	V1	03 December 2021
Summary CV for Chief Investigator (CI)		03 December 2021
Summary CV for student		03 December 2021
Summary CV for supervisor (student research)		03 December 2021
Summary, synopsis or diagram (flowchart) of protocol in non technical language		

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

IRAS Project ID: 303025	Please quote this number on all correspondence
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Yours sincerely

Katie Arnold
Approvals Officer

E-mail: berkshireb.rec@hra.nhs.uk

Copy to: Ms Rachael McDonnell Murray

Lead Nation Scotland: gram.nrspcc@nhs.scot

Appendix O - Research and Development approval letter

Lothian NHS Board



Queen's Medical Research Institute
47 Little France Crescent, Edinburgh, EH16
4TJ

DY/LS/approval

18 May 2022

Ms Rachael McDonnell Murray
Astley Ainslie Hospital
133 Grange Loan
Edinburgh
EH9 2HL

Research & Development
Room E1.16
Tel: 0131 242 3330

Email:
accord@nhslothian.scot.nhs.uk

Director: Professor Alasdair Gray

Dear Ms McDonnell Murray

Lothian R&D Project No: 2022/0019	REC No: 22/SC/0007
Title of Research: An exploration into the experiences and personalised goals of individuals engaging in a Weight Management Programme for Type 2 Diabetes Remission.	
Sponsor Reference: CAHSS2111/05	
Participant Information Sheet: Version 2.0, dated 18 January 2022	Consent Form: Version 2.0, dated 16 May 2022
Protocol: Version 1.0, 3 December 2021	
Approved Location within NHS Lothian: Astley Ainslie Hospital	

I am pleased to inform you this letter provides Site Specific approval for NHS Lothian for the above study and you may proceed with your research, subject to the conditions below.

We note that this study has obtained approval from NHS Lothian Information Governance for those aspects of the study that involve audio recording. You are responsible for informing the NHS Lothian R&D Office if there are any changes to the study that impact the terms of this approval.

Please be aware that ACCORD has issued COVID-19 Clinical Research Plan and Guidance that includes instructions for restarting/commencing non-COVID-19 clinical research, and also advice on what to do if there is a requirement to halt recruitment of new participants to an active study, what to do if the study design needs to be amended or if there is a resource issue within the study team in light of the ongoing COVID-19 pandemic.

*The ACCORD guidance is available on the ACCORD website:
<http://www.accord.scot/about-accord/accord-news/covid19-planning-and-guidance-research-0>*

The guidance detailed here applies to research projects Sponsored by NHS Lothian and/or the University of Edinburgh and to NHS Lothian hosted studies until further notice.

Please note that the NHS Lothian R&D Office must be informed of any changes to the study such as amendments to the protocol, funding, recruitment, personnel or resource input required of NHS Lothian.

Substantial amendments to the protocol will require approval from the ethics committee which approved your study and the MHRA where applicable.

Data controllers and processors have a legal obligation to hold a register of all its information assets (e.g. personal information (data) and/or special categories of personal data held in paper or electronic format for the purpose of clinical research). This R&D management approval is given on the understanding that you, as a potential information asset owner, will register any information assets associated with this research project with your employing organisation (where the data is held) in accordance the Data Protection Act 2018.

Please keep this office informed of the following study information, **which is a condition of NHS Lothian R&D Management Approval:**

1. Date you are ready to begin recruitment, date of the recruitment of the first participant and the monthly recruitment figures thereafter.
2. Date the final participant is recruited and the final recruitment figures.
3. Date your study / trial is completed within NHS Lothian.

I wish you every success with your study.

Yours sincerely

Dr Douglas Young
Principal R&D Manager

CC: Ms Sheena Muir, Hospital & Hosted Services Manager, Astley Ainslie Hospital

Appendix P - The University of Edinburgh - Ethical approval letter

Dear Rachael,

Thank you for your email and for providing us with all the relevant documents. We have now checked that your project adheres to any University governance concerns and your application has been logged. As your project has been reviewed and received a favourable opinion by IRAS it does not require further review by the Clinical Psychology Ethics Committee database if you need to make any changes to the protocol these would go through the REC, but I would appreciate if you could also copy University ethics into any correspondence.

Wishing you all the best with your project.

Best wishes,
Ingrid

Ingrid Obsuth, PhD
Lecturer in Clinical Psychology
Ethics &

Appendix Q - Study Protocol (as submitted for ethical approval)

School of Health in Social Science Research Ethics Application

The supervisor or primary investigator must complete and sign this form after checking that all relevant sections are completed, and relevant documents are attached. For all undergraduate (UG) and MSc student projects, it is the supervisor's responsibility to submit this form and all attachments. **Please note that failure to do this will result in the application being returned (and not processed) causing your research to be delayed.**



Supervisor (name and UUN): Dr. Fiona Duffy	
Primary Investigator (name and UUN): Rachael McDonnell Murray	
List of all collaborators (with affiliated institutions in brackets): Dr. Davina Chauhan	
Student's programme of study (if applicable): Doctorate in Clinical Psychology	
Project Title: Exploring outcome measures employed by weight management interventions	
Case Number (if known – assigned by Administrator at time of 1st submission):	
Proposed Project Start Date: February 22 nd 2022	Proposed Project End Date: May 2023

Please indicate whether the primary investigator on this project is staff or student and select your subject area:

- Staff UG or MSc Student DClin Student PhD Student
 CPASS Clinical Psychology Nursing Studies

This is a:

- New application for ethical review – first submission
 Resubmission following reviewer comments
 Resubmission with requested amendments

Has been reviewed by an external ethical board, such as NHS IRAS or a UK HEI (multi-site studies only) with a favourable opinion? Level 1 *

- RAS (NHS research ethics) Other: _____

Please tick one option that best describes your application:

- Collecting or generating new data involving other people: Level 2
 Extracting, re-coding and analysing existing data that contains sensitive information (i.e. identifiable information): Level 2
 Analysing secondary (archival) data that is routinely collected or is an existing anonymised dataset: Level 1

**If your project has been reviewed and generated an opinion by an external agency with a full ethics board, for example IRAS approval from the NHS, you only need to complete the questions related to university regulations covered in the Level 1 section of this form to ensure you are following University policies and guidelines. Please also attach the externally reviewed application and decision letter. Please note that your project will not undergo a full additional ethical review by the School of Health in Social Sciences REC, however we need to ensure your project is adhering to university regulations before you begin collecting data.*

- Collecting new data BUT an external ethical review board (such as NHS IRAS; UK HEI – for multi-site studies; etc) has fully reviewed this project and generated a favourable opinion:
Level 1

This application is complete with the following attachments (tick all that apply):

Advert/flyer <input type="checkbox"/>	Caldicott application stating what data was requested <input type="checkbox"/>	Caldicott signed approval <input type="checkbox"/>		Consent form/s <input checked="" type="checkbox"/>
Data collection tools (e.g. interview guides) <input checked="" type="checkbox"/>	Debrief with signposting <input type="checkbox"/>	IRAS application <input checked="" type="checkbox"/>	IRAS opinion letter <input checked="" type="checkbox"/>	NGO or local authority letters <input type="checkbox"/>
Participant Information Sheet/s <input checked="" type="checkbox"/>	Participant Information Sheet (young person version) <input checked="" type="checkbox"/>	R&D application (submitted pending approval) <input checked="" type="checkbox"/>	R&D approval <input type="checkbox"/>	Researcher Checklist (C-19) <input checked="" type="checkbox"/>
Risk assessment <input type="checkbox"/>	Standardised recruitment email <input checked="" type="checkbox"/>	Sponsorship Letter OR Email to confirm no sponsorship needed / statement explaining why sponsorship is not needed. <input checked="" type="checkbox"/>		

Other attachments (please specify):
Favourable outcome from the IRAS review (REC meeting).

To be completed by primary investigator or project supervisor

By signing this front sheet, I confirm that I have prepared and/or reviewed this ethics application and related documents in accordance with ethical guidelines. I also confirm I have checked that all relevant sections of the application form are completed and relevant documents are attached.

Supervisor or/PI Signature: Fiona Duffy

Student signature: Rachael McDonnell Murray

Date: 24/01/22

On completion, this Word document along with the relevant attachments should be submitted to ethics.hiss@ed.ac.uk. Note: **Please note all undergraduate and MSc applications MUST be signed and submitted by the project supervisor**

LEVEL 1 and 2 – Confidentiality and Handling of Data

Section 1: Introduction

External Research Ethics Approval:

Does your research project require the approval of any other institution and/or ethics committee, nationally or internationally?

Note: It is each researcher's responsibility to check whether their project requires Sponsorship, Caldicott Approval, R&D approval, and/or IRAS (see <https://www.ed.ac.uk/health/research/ethics/sponsorship-and-governance>). The principal investigator is responsible for ensuring compliance with any additional ethical requirements that might apply, and/or for compliance with any additional requirements for review by external bodies.

This research project does not require external ethics approval.

OR

If you require external approval, please state the name of the review body:

IRAS (NHS research ethics)

Local Authority

Other:

NB: If you require external approval from IRAS/NHS/Caldicott, **you must have external approval before submitting your application for School of Health in Social Science Research Ethics approval.** You can only submit your application to us once external approval has been obtained, and you must include all documentation including your application to and approval of external approval as an attachment.

If you require approval from a **local authority**, you must first receive ethics approval from the School of Health in Social Science Research Ethics Committee, before submitting your application to the local authority.

Q1. Project summary

Please provide a brief summary of your proposed study. Do not exceed 1500 words. Our interest is in areas of your methodology where ethical issues may arise so please focus your detail on areas such as recruitment, consent, describing your participants and the nature of their involvement, and data handling.

Study design

This will be an exploratory, cross sectional study. The study will be qualitative in nature, and in-depth semi-structured interviews will be used as a data collection strategy. Participants will be invited to a virtual interview with the researcher.

Study population

Patients will be recruited from the Counterweight plus program as part of the weight management service in NHS Lothian. The Counterweight+ programme is a commercial programme that is not ordinarily designed to have psychology input. However, in Lothian the dieticians receive supervision sessions with a clinical psychologist, patients are also referred to the psychologist to assess the suitability of the programme for the patients, and also for psychological intervention when helpful, before or during the commencement of the programme.

Recruitment

Recruitment will consist of convenience sampling facilitated by the dieticians. Once patients have been assessed and it has been agreed that they will begin the program, the dieticians will describe the study and ask if they would be interested in taking part. If the patient is interested, they will be provided with a plain language statement describing the study in detail by the dietician and asked to contact the researcher. The participants will also be given the option to be contacted by the researcher if they wish to ask further questions about the study. Recruitment in stages of the program - Group one consists of recruiting participants 1 week to 3 months following dietician assessment for the program. The aim is to recruit up to 12 participants. - Group two consists of recruiting participants near the end of their program 18-24 months. The aim is to recruit up to 12 participants or more.

Procedure

All interviews will be conducted without a prior relationship being formed between the researcher and participants. Once informed consent has been signed and participants are happy to engage with the research, they will be invited by the researcher to attend a meeting on Microsoft Teams (or other platform that may be more secure as recommended by IT team at time of recruitment) at a time that is convenient for them. The participants will be able to choose from a range of times and days provided by the researcher. Once they have selected, a link to the meeting will be sent to their e-mail address. Open ended research questions, and a colloquial style will be employed to encourage participants to speak more fluently on different aspects of the weight management program, without being limited to certain questions that quantitative research would require and provide rich data on the experiences of participants.

Interview guide

Group 1

Focus of interview: 1. Expectations of the program, fears, barriers, goals? Approximate time: 45-60minutes in accordance with recommendations made by Moser & Korstjens (2018).

Group 2:

Focus of interview: Participant expectations at the beginning of the program, what participants focused on to see if the program was meeting their expectations, experience with dieticians, experience with psychology (if seen by psychologists), dealing with setbacks and challenges and how they measured their progress. Approximate time: 45-60minutes in accordance with recommendations made by Moser & Korstjens (2018).

Additional information collected from participants Demographics/ psychological history/ seen by dietician only/ seen by psychologist/ (collect information from study completers including – activity levels/ did they achieve T2DM remission?).

Ethics

Ethics approval will be sought from the Integrated Research Application System (IRAS). Ethics will also be sought from the University of Edinburgh, through the School of Health in Social Science.

Informed consent

Several measures will be taken in order to ensure that the participants are fully informed and fully comprehend the potential risks of the research, the purpose of the research and the potential implications of the research (Nusbaum, Douglas, Damus, Paasche Orlow & Estrella-Luna, 2017). Consent will be obtained through an online platform (Qualtrics). Participants will also be asked to fill in a demographic questionnaire on Qualtrics and given an e-mail address to contact the researcher. Participants will be informed that it will be possible to withdraw from the research up to the point of anonymous data characterization, as all qualitative data will be completely anonymous once the audio files are deleted post-transcript.

Confidentiality

The plain language statement and informed consent form will specify that identifying information will be removed from transcripts to preserve client confidentiality, and that audio-recordings will be destroyed / deleted when transcripts have been made. All participants will be given the option to be contacted by the researcher using a pseudonym, and an e-mail that they have created for the purpose of the study, or one they are happy to use to be contacted. This will be essential to ensure that patients have the opportunity to be completely anonymous when taking part in the research. Participants who agree to take part in a follow-up interview, will be given pseudonyms if they have not chosen to themselves by that stage.

How data will be managed and stored

Data on individual patients excluding patient identifiable information will be stored securely and aggregated with data from other patients on a computer programme stored on encrypted device. Patients will be identified by their identification numbers on this computer data base. E-mail addresses that were used to communicate with participants will be deleted three months following the completion of their interview.

Benefits indirect/not for taking part in the research

Although there may not be any direct benefit for taking part in the research the participants may appreciate being part of research that will contribute to continuous improvement of weight management services. It will enable the participants to identify areas of the program offer the most benefits, what additional supports may be necessary, and how best to understand successful and more important meaningful outcomes for patients on weight management programs.

Q2. Will you collect or use NHS data?

Yes No

If "yes" – what NHS data will you collect or use?

Interviews will be carried out with Patients with Type 2 Diabetes

Q3. What information about participants/data subjects will you collect and/or use?

Information will be collected on participants experience of the counterweight plus programme, prior to and after engagement. The interview guide is outlined below:

Interview guide

Group 1 Focus of interview: 1. Expectations of the program, fears, barriers, goals? Approximate time: 45-60minutes in accordance with recommendations made by Moser & Korstjens (2018).

Group 2: Focus of interview: Participant expectations at the beginning of the program, what participants focused on to see if the program was meeting their expectations, experience with dieticians, experience with psychology (if seen by psychologists), dealing with setbacks and challenges and how they

measured their progress. Approximate time: 45-60minutes in accordance with recommendations made by Moser & Korstjens (2018)

Q4. What training will staff who have access to the data receive on their responsibilities for its safe handling? Have all staff and students who have access completed the mandatory data protection training on the self-enrolment page of Learn?

Yes, all staff and students who have access to the data, have completed the mandatory data protection training on the self-enrolment page of learn.

Q5. Will the information include special categories of personal data (health data, data relating to race or ethnicity, to political opinions or religious beliefs, trade union membership, criminal convictions, sexual orientations, genetic data and biometric data)?

Yes No

If "yes" – Explain what safeguards e.g. technical or organisational you have in place; including any detailed protocols if this requires special and/or external processing, storage, and analysis.

Q6. Please indicate how your research is in the public interest:

- Your research is proportionate
- Your research is subject to a governance framework
- Research Ethics Committee (REC) review (does not have to be a European REC)
- Peer review from a funder
- Confidentiality Advisory Group (CAG) recommendation for support in England and Wales or support by the Public Benefit and Privacy Panel (PBPP) for Health and Social Care in Scotland
- Other

Q7. It is essential that you identify, and list all risks to the privacy of research participants. You will then need to consider the likelihood of the risks actually manifesting and the severity of harm if the risks actually manifest.

Risk	Likelihood of risk manifesting			Severity of harm		
	Remote	Possible	Probable	Minimal	Significant	Severe
identifiable due to data linkage	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
identifiable due to low participant numbers	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
identifiable due to geographical location	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
identifiable due to transfer of data	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
identifiable due to access of data	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Insert more rows as appropriate</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please use this text box to record any other risks and the likelihood of them occurring, along with the severity of harm. Please also use this when dealing with secondary data.

1. Internet connectivity – it may be the case that individuals who wish to participate in the study are unable due to limited internet connectivity or difficulty accessing Microsoft teams. Risk: low – it is not foreseen that this will be a major issue as many of the regular appointments in the service due to Covid-19 have been over NearMe (an internetbased platform). Response: where necessary and appropriate the researcher will send the participant a step by step guide showing how they can access Microsoft teams/ how to audio into a call on Microsoft teams.

2. Causing participant distress - Questioning may trigger issues that may cause an emotional response. In the unlikely event that a participant becomes upset during the interview, they will be asked if they are ok and would like to continue. Risk level: low – as participants will be speaking about a program they are currently enrolled in and questions will not specifically be focused on traumatic or adverse experiences, it is not foreseen that the interviews will cause any more distress than encountered by participants in daily life. Response: Participants can take a break from the interview or terminate it at any stage if they wish. If participants do experience any upset as a result of the interview they will be advised to contact the psychologist who is working on the team and other supports where necessary.

3. Risk of breach of anonymity - Due to the nature of qualitative interviews and the small sample size, participants may be at risk of being identified through direct quotes. Risk level – low. Response - Participants will be fully informed that there is a possibility of being identified in the plain language statement and this will be reiterated once the interview is over. In order to minimize the risk of participants being identified, they will be provided with the option, by the dietician, to contact the researcher using a pseudonym, and an e-mail of their choosing (this could be one that has been developed based on their pseudonym for the purposes of the research). Even those participants who do not opt for a pseudonym will be given one once the interviews are being transcribed, the researcher will extract any identifiable information (such as any names, place names or any personal information).

Despite this slight risk, as the researcher will be able to identify each interviewee it allows participants the right to withdraw from research right up until the research is transcribed, this will allow participants time after taking part in the research to re-consider whether they wish to participate in the research.

4. Low sample size/ difficulties with recruitment – The most commonly identified limitation in any research study is often ‘small sample size’ with recommendations to repeat the research with a larger and more diverse sample. Having low uptake during the recruitment phase is something that is very difficult to predict. However, based on the number of patients who are currently engaged in the programme, and the number of participants on the waiting list, it is not foreseen that any major difficulties will arise. Therefore, this would be rated as a low risk. With that said, insufficient participant numbers can cause major difficulties at the analysis phase, and lead to poor research with little practical applications. Therefore, if the expected sample size numbers are too low following recruitment in NHS Lothian, it is planned to recruit from the same Counterweight+ programme that is also being carried out in the Borders and Fife, who also have a similar psychology pathway as part of the tier 3 weight management service.

Please identify measures you could take to reduce or eliminate risks identified as possible/significant or probable/severe.

As described above.

Q8. Will information containing personal, identifiable data be transferred to, shared with, supported by, or otherwise available to third parties outside the University?

Yes No

If “yes” - Please explain why this necessary and how the transfer of the information will be made secure. If the third party is based outside the European Economic Area please obtain guidance from the Data Protection Officer.

Q9. Other than the use by third parties, will the data be used, accessed or stored away from University premises?

Yes No

If “yes” - Describe the arrangements you have put in place to safeguard the data from accidental or deliberate access, amendment or deletion when it is not on University premises, including when it is in transit, and (where applicable) it is transferred outside the EEA.

Once data has been anonymised it will be saved securely on a University of Edinburgh shared drive.

All personal identifiable data will be stored on an NHS Shared drive, in a folder that will be password protected. Personal information will include; consent forms, demographic information and e-mail addresses. Completed consent forms will be kept in a separate password protected folder to other personal information. Interviews will be recorded using an NHS recording device which will be kept in a locked cabinet while transcription is being completed. Once transcription has been finalised, anonymised and saved in a shared university drive, recordings will be deleted from the recording device. Such e-mails that were used to communicate with participants will be deleted once the transcript has been sent to them and sufficient time (3months) has passed to allow them time to respond. All correspondence with participants will be done through the Chief-Investigators NHS e-mail account. Normal information governance guidelines and informed consent will be sought and followed. Informed consent sheets will be stored on the shared NHS drive, these will be deleted after 6 months.

Q10. Will feedback of findings be given to your research project participants or data subjects?

Yes No

If "yes" - How and when will this feedback be provided?

This will be provided to participants indirectly through the dieticians if still on the programme. For those who have completed the programme they will be informed that they can access a summary of the research if they make contact with the service.

If "no" - Please provide rationale for this.

Q11. How do you intend to use/disseminate the results of your research project?

The results will be published in a peer-reviewed journal and may be presented at national and international conferences.

Section 2: Security-sensitive material

The Terrorism Act (2006) outlaws the dissemination of records, statements and other documents that can be interpreted as promoting or endorsing terrorist acts.

Q12. Does your research involve the storage on a computer of any such records, statements or other documents?

- Yes No (if you answered no to this question please jump to section 3)

If “yes” - Please type ‘Yes’ to indicate that you agree to store all documents on that file store

Q13. Might your research involve the electronic transmission (for example, as an email attachment) of such records or statements?

- Yes No

If “yes” - Please type ‘Yes’ to indicate that you agree not to transmit electronically to any third party documents stored in the file store

Q14. Will your research involve visits to websites that might be associated with extremist, or terrorist, organisations?

- Yes No

If “no”, please proceed to Question 15.

If “yes” - You are advised that such sites may be subject to surveillance by the police. Accessing those sites from University IP addresses might lead to police enquiries. Please type ‘Yes’ to acknowledge that you understand this risk

By submitting to the ethics process, you accept that your School Research Ethics Officer and the convener of the University’s Compliance Group will have access to a list of titles of documents (but not the contents of documents) in your document store. *Please type ‘Yes’ to acknowledge that you accept this.*

Please confirm that you have contacted your School Research Ethics Officer to discuss security-sensitive material by ticking 'Yes'

- Yes, I have contacted my School's Research Ethics Officer
- No, I have not contacted my School's Research Ethics Officer

Section 3: Copyright

Q15. Does your project require use of copyrighted material?

Yes

No

If "yes" please give further details

Section 4: Good conduct in collaborative research

Q16. Does your project involve working collaboratively with other academic partners?

- Yes No (if you answered no to this question please jump to section 5)

If "yes" - Is there a formal agreement in place regarding a collaborative relationship with the academic partner(s)?

Yes, the chief investigator will be supervised by an academic supervisor from the University of Edinburgh (Dr. Fiona Duffy).

If "no" - Please explain why there is no formal agreement in place

Q17. Does your project involve working collaboratively with other non-academic partners?

- Yes No

If "yes" - Is there a formal agreement in place regarding a collaborative relationship with the non-academic partner(s)?

Yes, the chief investigator will be supervised by a clinical supervisor from NHS Lothian (Dr. Davina Chauhan)

If "no" - Please explain why there is no formal agreement in place.

Q18. Does your project involve employing local field assistants (including guides/translators)?

- Yes No

If "yes" - Is there a formal agreement in place regarding the employment of local field assistants (including guides and translators)?

If "no" - Please explain why there is no formal agreement in place

This is not necessary as part of this research.

Q19. Will care be taken to ensure that all individuals involved in implementing the research adhere to the ethical and research integrity standards set by the University of Edinburgh?

Yes

No

If "no" - Please explain why care will not be taken

Q20. Have you reached agreement relating to intellectual property?

Yes

No

If "no" - Please explain why you have not reached agreement

Section 5: Good conduct in publication practice

In publication and authorship, as in all other aspects of research, researchers are expected to follow the University's guidance on [integrity](https://www.ed.ac.uk/governance-strategic-planning/content-to-be-removed/research-integrity). <https://www.ed.ac.uk/governance-strategic-planning/content-to-be-removed/research-integrity>. By ticking yes, you confirm that full consideration of the items described in this Section will be addressed as applicable

Yes

No

If you intend to collect new data, please continue completing the Level 2 application in the next page.

If you are NOT collecting any new data, you have now completed the Level 1 application. Please submit this document alongside all attachments to

LEVEL 2 ONLY – Participant Risk and Information

**The following Sections are to be completed if you are collecting new data.
Please do not complete it if you are using existing data.**

Section 6: Potential risks to participants and researchers

Q21. Is your research project likely or possible to induce any psychological stress or discomfort in the participants or others, indirectly associated with the research?

Yes

No

If “yes” state the types of risk and what measures will be taken to deal with such problems

It is not anticipated that participants will experience any adverse effects from engaging with the research compared with risks encountered in everyday life.

It has been considered that questioning may trigger participants which could result in an emotional response. In the unlikely event that a participant becomes upset during the interview, they will be asked if they are ok and would like to continue. Risk level: low – as participants will be speaking about a programme they are currently enrolled in and questions will not specifically be focused on traumatic or adverse experiences, it is not foreseen that the interviews will cause any more distress than encountered by participants in daily life. Response: Participants can take a break from the interview or terminate it at any stage if they wish. If participants do experience any upset as a result of the interview they will be advised to contact the psychologist who is working on the team and other supports where necessary.

As outlined elsewhere, due to the nature of qualitative interviews and the small sample size, participants may be at risk of being identified through direct quotes. Risk level – low. Response - Participants will be fully informed that there is a possibility of being identified in the plain language statement and this will be reiterated once the interview is over. In order to minimize the risk of participants being identified, they will be provided with the option, by the dietician, to contact the researcher using a pseudonym, and an e-mail of their choosing (this could be one that has been developed based on their pseudonym for the purposes of the research). Even those participants who do not opt for a pseudonym will be given one once the interviews are being transcribed, the researcher will extract any identifiable information (such as any names, place names or any personal information). Despite this slight risk, as the researcher will be able to identify each interviewee it allows participants the right to withdraw from research right up until the research is transcribed, this will allow participants time after taking part in the research to re-consider whether they wish to participate in the research.

Q22. Does your research project require any physically-invasive or potentially physically harmful procedures?

Yes

No

If "yes" give details and outline procedures to be put in place to deal with potential problems.

Q23. Does your research project require the use of privacy-invasive technology, such as CCTV, biometrics, facial recognition, vehicle tracking software?

Yes

No

If "yes" - Give details and outline procedures to be put in place to deal with potential problems.

Q24. Does your research project involve the investigation of any illegal behaviour or activities?

Yes

No

If "yes" - Give details of any illegal behavior or activities you may investigate

Q25. Is it possible that your research project will lead to awareness or the disclosure of information about child abuse or neglect?

Yes

No

If “yes” - Indicate the likelihood of disclosure and the procedures to be followed if you become aware that a child has been or may be at risk of harm

Q26. Is it likely that dissemination of research findings or data could adversely affect participants or others indirectly associated with the research?

Yes

No

If “yes” - Describe the potential risk for participants/data subjects of this use of the data. Outline any steps that will be taken to protect participants.

Q27. Could participation in this research adversely affect participants and others associated with the research in any other way?

Yes

No

If “yes” - Describe the possible adverse effects and the procedures to be put in place to protect against them.

Q28. Is this research expected to benefit the participants, directly or indirectly?

Yes

No

If “yes” - Give details of how this research is expected to benefit the participants.

There are no direct benefits but participants may derive some satisfaction from their inclusion in research intended to improve future patient care

Q29. Will the true purpose of the research be concealed from the participants/data subjects?

Yes No

If “yes” - Explain what information will be concealed and why.

Q30. Will participants/data subjects be debriefed at the conclusion of the study?

Yes No

If “no” – Why will participants / data subjects not be debriefed?

Q31. At any stage in this research could researchers’ safety be compromised, or could the research induce emotional distress in the researchers?

Yes No

If “yes” - Give details and outline procedures to be put in place to deal with potential problems.

Please tick to confirm you agree with the following:

I will adhere to School guidance on risk assessment and health and safety and will seek advice on project and travel insurance prior to project commencement.

- I agree
- I do not agree
- Not applicable

Section 7: Participants and data subjects.

Q32. How many participants or data subjects are expected to be included in your research project?

It is expected that up to 24 participants across two groups will be expected to be recruited.

Q33. What criteria will be used in deciding on the inclusion and exclusion of participants/data subjects in your research project?

Group 1

Inclusion criteria includes the following:

1. Have capacity to give fully informed consent.
2. To have undergone an initial meeting with the dietician to assess the suitability of the programme for the individual.
3. First time beginning the programme.
4. Completed initial assessment with the dietician within the timeframe of one to three months.

Exclusion criteria includes the following:

1. If the individual is not able to comprehend and participate in an interview process.
2. If participant does not meet inclusion criteria.

Group 2

Inclusion criteria includes the following:

1. Have capacity to give fully informed consent.
2. Have engaged with the service consistently over the 2-year programme.
3. First time beginning the programme.
4. Must be at the time of recruitment within three months of finishing the programme.
5. Engagement with either dieticians and or psychology.

Exclusion criteria includes the following:

1. If the individual is not able to comprehend and participate in an interview process.

Q34. Are any of the participants or data subjects likely to be under 16 years of age?

Yes

No

If "yes" - Explain and describe the measures that will be used to protect and/or inform participants/data subjects.

Q35. Are any of the participants or data subjects likely to be children in the care of a Local Authority?

Yes No

If "yes" - Explain and describe the measures that will be used to protect and/or inform participants/data subjects.

Q36. Are any of the participants or data subjects likely to be known to have additional support needs?

Yes No

If "yes" - Explain and describe the measures that will be used to protect and/or inform participants/data subjects.

Q37. In the case of participants with additional support needs, will arrangements be made to ensure informed consent?

Yes No N/A

If "yes" – What arrangements will be made?

If “no” – Please explain why not

Q38. Are any of the participants or data subjects likely to be physically or mentally ill?

Yes

No

If “yes” - Explain and describe the measures that will be used to protect and/or inform participants/data subjects.

Q39. Are any of the participants or data subjects likely to be vulnerable or likely exposed to harm in other ways?

Yes

No

If “yes” - Explain and describe the nature of the vulnerability and the measures that will be used to protect and/or inform participants/data subjects.

Q40. Are any of the participants or data subjects likely to be unable to communicate in the language in which the research is conducted?

Yes

No

If "yes" - Explain and describe the measures that will be used to protect and/or inform participants/data subjects.

Q41. Are any of the participants or data subjects likely to be in a relationship (i.e., professional, student-teacher, other dependent relationship) with the researchers?

Yes

No

If "yes" - Explain and describe the measures that will be used to protect and/or inform participants/data subjects.

Q42. Are any of the participants or data subjects likely to have difficulty in reading and/or comprehending any printed material distributed as part of the study?

Yes

No

If "yes" - Explain and describe the measures that will be used to protect and/or inform participants/data subjects.

Q43. Describe how the sample will be recruited.

There are two groups of patients who will be eligible to take part in this research.

The first group, will be those who have been assessed by the dieticians and who are waiting to begin, or within three months of beginning, the Counterweight Plus programme. If the patient is interested, they will be asked if their details can be passed on to the chief investigator to discuss the research in more detail. An information sheet will be provided to the potential participant at this point. The chief investigator will contact the participants a minimum of 5 days following this to give participants time to consider if they would like to participate. The chief investigator will then call the participants and answer any questions they may have. If the participant is still interested at this point they will be sent an informed consent sheet via e-mail and a date and time for the interview will be arranged.

The second group of participants are those who are within three months of finishing the Counterweight Plus programme. The patients in this group will also be informed about the research by the dieticians on the programme and be provided with the participant information sheet if they show interest in participant. They will be asked if their details can be pass on to the chief investigator who will get in contact to arrange the interview.

Q44. Will participants receive any financial or other material benefits as a result of participation?

Yes

No

If "yes" - What benefits will be offered to participants and why?

Section 8: Participant or data subject information and consent

Q45. Will written or oral consent be obtained from all participants or data subjects?

Yes

No

If "yes" – attach participant information sheet and consent form and detail the process you will follow.

If "no" – explain why not and what process you will follow regarding consent, or if consent cannot or should not be sought for some reason, please provide a clear case and rationale for this (e.g. in international contexts where speaking to foreign researchers is prohibited).

Informed consent will be re-confirmed with participants verbally, prior to the commencement of the interview.

Several measures will be taken in order to ensure that the participants are fully informed and fully comprehend the potential risks of the research, the purpose of the research and the potential implications of the research (Nusbaum, Douglas, Damus, Paasche-Orlow & Estrella-Luna, 2017). Consent will be obtained through an online platform (Qualtrics). Participants will also be asked to fill in a demographic questionnaire on Qualtrics and given an e-mail address to contact the researcher. Participants will be informed that it will be possible to withdraw from the research up to the point of anonymous data characterization, as all qualitative data will be completely anonymous once the audio files are deleted post-transcript. As all potential participants will have initially been assessed by the dietician for suitability of the programme to their needs, it is not anticipated that issues regarding capacity to consent should arise.

Q46. Have you made arrangements to tell participants what information you will hold about them and for how long?

Yes

No

If "yes" - what arrangements have been made?

This information is included in the participant information sheet which will be provided to potential participants prior to them consenting to participate in the research.

If "no" – why not?

Q47. Have you made arrangements to tell participants whether you will disclose the information to other organisations?

Yes No N/A

If "yes" - What arrangements have been made?

If "no" – why not?

Q48. Have you made arrangements to tell participants whether you will combine that information with other data?

Yes No N/A

If "yes" - What arrangements have been made?

Q49. In the case of children participating in the research, will the consent or assent of parents be obtained?

Yes No N/A

If "yes" - Explain how this consent or assent will be obtained

If “no” – Please explain why you won’t be obtaining consent

Q50. Will the consent or assent of children participating in the research be obtained?

Yes No N/A

If “yes” - Explain how this consent or assent will be obtained

If “no” – Please explain why not

Q51. In the case of participants who are not proficient in the language in which the research is conducted, will arrangements be made to ensure informed consent?

Yes No N/A

If “yes” – What arrangements will be made?

If “no” – Please explain why not

Q52. Does the activity involve using cookies or tracking individual's activity on a website or the Internet in general?

Yes

No

If "yes" – Describe the arrangements you have put in place to obtain informed consent for the use of these tools

