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## **Participant experiences in the Diabetes REmission Clinical Trial (DiRECT)**

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**Novelty statement:**

- Participant experiences with the DiRECT intervention for weight loss and diabetes remission using a low-energy formula diet are reported.
- A process of behavioural adaptation to change was identified.
- The first few weeks of the diet were challenging, but overall, the weight loss phase was reported to be easier than expected. Rapid outcomes provided ongoing motivation.
- Transition to food was challenging due to fear of weight regain. Some participants chose to extend the diet.
- Weight loss maintenance was characterised by fluctuations of behaviour and weight.
- Ongoing behavioural support by healthcare professionals was instrumental to success of the DiRECT intervention.

**Abstract**

**Introduction:** The Diabetes REmission Clinical Trial (DiRECT) has shown that sustained remission of type 2 diabetes in primary care is achievable through weight loss using total diet replacement (TDR) with continued behavioural support. Understanding participants' experiences can help optimise the intervention, allow implementation into healthcare, and understand the process of behaviour change. **Methods:** Thirty-four DiRECT participants were recruited into this embedded qualitative evaluation study. In-person and telephone interviews were conducted before the TDR; at week 6-8 of the TDR; 2 weeks into Food Reintroduction (FR); and at 1 year, to learn about participant experiences with the programme. Transcribed narratives were analysed thematically, and we used interpretation to develop overarching themes. **Results:** Initiation of the TDR and transition to FR were challenging and required increased behavioural support. In general, adhering to TDR proved easier than the participants anticipated. Some participants chose the optional extension of TDR. Rapid weight loss and changes in diabetes markers provided ongoing motivation. Further weight loss, behavioural support and occasional use of TDR facilitated weight loss maintenance (WLM). A process of behaviour adaptation to change following regime disruption was identified in 3 stages: 1) Expectations of the new, 2) Overcoming difficulties with adherence, and 3) Acceptance of continuous effort and establishment of routines. **Conclusions:** The DiRECT intervention was acceptable and regularity, continuity, and tailoring of behavioural support was instrumental in its implementation in primary care. The adaptation process accounts for some of the individual variability of experiences with the intervention and highlights the need for programme flexibility.

### **Keywords**

Type 2 diabetes remission, total diet replacement, weight loss, weight loss maintenance, qualitative evaluation

### **Introduction**

A breakthrough in the understanding of aetiology of type 2 diabetes has led to studies demonstrating remission and restoration of non-diabetic pancreatic function and blood

glucose control<sup>1,2</sup>. This depended upon the effectiveness of achieving sustained weight loss using a low-energy formula diet and long-term supportive follow-up<sup>3-7</sup>, which previous research found generally acceptable<sup>2,4,8-10</sup>. This marks significant progress for the 9% of the world's population with type 2 diabetes<sup>11</sup>. The DiRECT intervention included 12-20 weeks total diet replacement (TDR)(825–853 kcal per day) followed by 2-8 weeks of stepped food reintroduction (FR), and structured support for weight loss maintenance (WLM) for 2 years<sup>12</sup>. At 12 months, intervention participants were significantly more likely to achieve diabetes remission (46%) than control participants (4%), and greater weight loss increased the likelihood of achieving remission<sup>1</sup>. After 24 months, 36% of intervention and 3% of control participants were in remission, and greater weight loss increased the likelihood of achieving/maintaining remission<sup>13</sup>.

DiRECT was the first randomised-controlled trial of remission of type 2 diabetes in primary care, and participant response to potential remission of type 2 diabetes had not previously been systematically described. Previous research identified several barriers to adherence with meal replacements for weight loss and diabetes remission, including lack of variety of flavours of meal replacement products, restriction of social activities, or hunger, whereas facilitators include regular support from healthcare professionals (HCPs), social support, and satisfaction with outcomes<sup>8,10,14,15</sup>. Longer-term follow up of participants would enable a better understanding of the process of behaviour change during such intervention. As DiRECT was delivered by the Primary Care staff who provide routine treatment, understanding participant experience would provide insight into potential widespread application of this new approach to management of type 2 diabetes. An NHS pilot scheme for remission of type 2 diabetes, building on the findings of DiRECT, is already underway. The aims of this report are to 1) Understand participant experiences of the DiRECT intervention delivered in primary care; 2) Derive information which healthcare professionals can adopt and share widely, to implement behavioural weight-loss induced remissions of type 2 diabetes; and 3) Understand and define the process of change throughout the intervention, with a view of future programme improvement.



## Methods

### *Intervention description*

Participants in DiRECT were allocated by practice, in a cluster-randomised design, to routine care, or to a behavioural intervention (Counterweight-Plus). The intervention was designed to achieve and maintain weight loss of  $\geq 15$  kg using a TDR (825–853kcal/day) for 12 weeks (extendable up to 20 weeks at the request of the participant), followed by structured FR (2–8 weeks) and WLM for up to 2 years. Full details of DiRECT can be found in the published protocol<sup>12</sup> and **Appendix 1**. Healthcare professionals (HCPs) received 8 hours of TDR training delivered by research dietitians, with additional 4 hours covering the FR and WLM phases. Further support from research dietitians was available to HCPs on the phone/by emails throughout the study. Participant behavioral and clinical support provided by HCPs was available throughout the study. Participants who regained  $>2$  kg were offered relapse management including a short period back on TDR to replace up to 2 meals a day for 4 weeks and orlistat with each meal. Those who gained  $>4$  kg, or to  $<15$  kg below starting weight were offered 4 weeks of TDR, with a fortnightly review followed by 2–4 weeks of FR, individualised dietary advice during WLM, and orlistat for the remainder of the WLM<sup>16</sup>.

Control participants received usual diabetes and obesity management care as per current best clinical practice guidelines from NICE<sup>17</sup> and SIGN<sup>18</sup>. Ethical approval was obtained from the West of Scotland Research Ethics Committee (reference number: 13/WS/0314).

### *Research design*

The research design of this embedded study was based on a qualitative methodology. It is theoretically positioned in a relativist ontology<sup>19</sup>, which suggests that emotions, social norms, and experience form how reality is constructed subjectively. Our epistemological position is constructionist<sup>20</sup>, seeking to generate contextual understanding of peoples' experiences with the DiRECT intervention through their engagement with it and interpretations of their experiences.

We used the interview method as a data collection tool to explore individual experiences with the intervention and generate the contextual understanding of the process of behaviour change in participants during the intervention.

### *Participants and sampling*

We aimed to recruit 10-14 participants per trial area (England/Scotland) from the intervention arm. Participants were recruited in parallel with the main study, with matching by gender and socio-economic status (SES). SES was estimated by the participants' postcodes, using the Scottish and English indices of multiple deprivation (IMD)<sup>21,22</sup>. The 10-point IMD scale was split into 3 categories for matching: high (SES 10-8), medium (SES 7-5), and low (SES 4-1). Participants who withdrew from the qualitative study were replaced with participants of the same gender, in the same study location, and SES group wherever possible while recruitment progressed.

Participants were interviewed four times: before starting TDR (T1), during week 6-8 of TDR (T2); 2 weeks into FR (T3); and 1 year from T1 (T4). Participation in interviews was voluntary and no incentive was provided. All interviews were semi-structured, and audio recorded.

### *Interview procedure*

Participants who agreed to take part were contacted by an interviewer to arrange the first interview before starting on the TDR. At this interview, participants verbally consented to the follow-up interview(s), which were then arranged by email or phone. The follow-up interviews took place directly after the regular study appointments at participants' GP practices whenever possible, otherwise they took place at the Magnetic Resonance Centre at Newcastle University; Glasgow Royal Infirmary; or by phone. Participants who discontinued the intervention or withdrew from this qualitative evaluation study at any point were asked for permission to be interviewed as soon as possible afterwards.

### *Interview documents*

Interview topic guides were based on our previous research exploring experiences with a total diet replacement plan among people with Type 2 diabetes (the Counterbalance study)<sup>10</sup>. The topic guides focused on participants' expectations of the intervention and actual experience with it, their initial and continuous motivation; barriers and facilitators of adherence; and behaviour regulation at each stage of the intervention. The interview schedules were further amended to satisfy the current research questions (**Appendix 2**) and explored satisfaction with outcomes, and suggestions for improvement. As one of the suggestions was wanting to share experience with others, we also asked about what the participants would tell someone thinking about taking part in DiRECT in the last interview.

### *Analysis*

All interview recordings were transcribed and anonymised. Transcripts were managed in NVivo12 software, and analysed thematically<sup>23</sup>. The analysis was primarily conducted at each time point to develop understanding of participant experiences at the distinct phases of the intervention, but the findings were contrasted between the phases to understand the process of change during the intervention at the group level. This approach was employed to avoid loss of data due to possible withdrawals or inability of individuals to attend an interview. Two analysts (LR, NB) first coded the same 6 TDR interviews independently and discussed similarities and differences in their coding and identified themes, with a high level of agreement. Additional checking of coding was done at T2 (LR, AMR), T3, and T4 (LR, GT) interviews. The team discussed key concepts and their clinical importance in regular analytical workshops. The concepts and relationships between them, and any underlying mechanisms were refined in the process of theme development. Final coding was primarily undertaken by one researcher (LR) and the team (FFS, RT) met regularly in data clinics to discuss themes, theory, interview context, and possible practical implications. Themes, sub-themes, and higher order interpretations were further refined during write-up.

### **Results**

Thirty-four intervention participants from 12 out of 48 (25%) practices delivering DiRECT agreed to and were available for interviews at T1, 27 at T2, 25 at T3, and 19 at T4.

Participant information is in **Table 1**. Intervention participants who were interviewed were comparable to those not interviewed. There were no differences in age, diabetes duration, weight, and BMI at baseline (T1), and there were no differences in weight and BMI at 12 months (T4) (**Table 2**). Interviews took a median of 26 minutes at T1 (11-50 minutes), 26 minutes at T2 (13-46 minutes), 47 minutes at T3 (17-70 minutes), and 38 minutes at T4 (23-72 minutes).

Out of those participants who were unavailable for interviews (n=3) or recorded withdrawal from the study before the second interview (n=3), 2 had gained weight. Of those who were unavailable for interviews (n=3) or recorded a new withdrawal between the second and third interview (n=2), 2 had gained weight. Of those who did not attend the last interview either due to lack of availability (n=5) or new withdrawal (n=2), 2 had achieved weight losses of <2%, but achieved diabetes remission, 3 had achieved between 10-12% weight losses, but not diabetes remission, and 2 had achieved weight losses between 12-15% and also diabetes remission. Overall, the highest non-attendance and withdrawal rates seemed amongst those who gained weight early in the intervention. The rest of the participants who did not attend between the third and the fourth interview, with a few exceptions, tended to not have achieved diabetes remission. The results therefore need to be interpreted in light of these findings.

It became clear during the analysis that the participants' experiences of and responses to the intervention varied a lot, and consequently the report focuses on the narrative of fluctuation of experience and adaptation to it, and which reflects the positive and challenging experiences throughout the intervention. Main themes are in bold and sub-themes are in italics. Information in brackets includes an anonymised participant number and interview time point, respectively.

While the TDR, FR, and WLM phases of the intervention were experientially different, these experiences seemed to follow a similar process of adaptation to change consisting of

themes of expectations of the new, learning and overcoming difficulties with adherence and transitions, continuous effort and establishment of routines, and the roles of behavioural and social support. The ability of individuals to adapt to the fluctuating experiences within the different intervention phases and the transitions between them contributes to the explanation of the range of weight loss successes. Equally, the process of continuous adaptation justifies flexibility of the programme and the tailored behavioural support.

### **Expectations of the total diet replacement**

Most participants shared a hope that the DiRECT intervention would help them make a definite and lasting change in their health, weight, and wellbeing, including increased mobility, longevity, and energy levels. Participation was often facilitated by existing motivation to change, but also by the participants' trust in the study, underpinned by its association with the involved universities, and by the research evidence it was built on. Curiosity about the experience of not eating regular food and the prospect of diabetes remission, not taking medication, and weight loss, encouraged commitment to the study.

*“It was the potential outcome of the weight loss and diabetes potentially going into remission” (P24, T1).*

*“I thought, maybe this will just give me the kick start, take me off the metformin tablets, because they kill my stomach...I was feeling sick and everything with them” (P17, T1).*

### **Learning new behaviours and overcoming difficulties with adherence to total diet replacement**

Participants' expectations were tested in the first few weeks, which were generally found most difficult within the TDR phase. The experiences varied individually, but common challenges were hunger and fatigue. For most participants, these diminished over time, but still tended to fluctuate within the TDR phase.

*“Initially the first few days were terrible. I felt miserable. And then as promised, after about day four I stopped feeling hungry, my headache went away and I felt good” (P3, T2).*

*“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 (P6, T3).*

Ability to adapt to the regime change by using the available behavioural support and strategies were important for overall adherence to the programme. Around midway through the TDR, boredom with the lack of variety of flavours of the meal replacements set in for most participants. Maintaining motivation became exhausting. For some, weight loss had slowed down, and social events and holidays required additional planning and support from HCPs to keep on track with weight loss goals. The lack of solid food and the monotony of the shakes noticeable in the second half of the TDR meant that many participants often felt they had to modify the diet to continue. Modifications included adding flavours to the shakes, adding low calorie vegetables to the soups to introduce crunching, or replacing the soups with a bouillon or a different meal replacement within the same calorie limit.

*“I used to cheat and have a Cup of Soup instead, which was something like 93 calories. I couldn’t cope with the soups. But the shakes were fine” (P19, T2).*

*“[I’ve had] nothing except for the carrots, and they said I could have them in the soup...I heat it up and I blend it and I put it in a bowl, so it’s as if I’m having soup. I know it’s a shake but it’s like having a plate of soup. So I look forward to that” (P17, T2).*

Other most commonly reported strategies to support adherence with the TDR were drinking a lot of liquids (e.g. water, tea, black coffee, adding more water to shakes to increase volume), planning dietary deviations, and distraction.

*“I do patchwork and quilting, so if I was feeling that I couldn’t get over the hunger I just went and sewed for a while and that got me over it” (P1, T2).*

It was not unusual for participants to report deviations from the TDR plan, often around unavoidable events such as weddings or pre-planned holidays. These were situations that needed careful planning with the HCPs, including support in getting back on the TDR plan afterwards (as per protocol). For some, a break during the most intensive intervention stage seemed to interrupt the built-up motivational momentum, with participants gaining weight, and finding it hard to return to the TDR plan.

*“I actually found it very difficult to go back on to just having the shakes and soups. I had obviously come out of that state where you are not hungry, so what I found is that having taken some food, I was then hungry. If I had not gone on holiday, I think I would have managed to actually get down to the 13 stone, which is what we were looking for” (P8, T3).*

While modifications to the individual journeys on the programme seemed to facilitate adherence to it in the longer-term, taking more substantial breaks too early given the individual level of adaptation could threaten the progress and achievement of the weight loss goals.

### **Rapid improvements in physical and psychological well-being providing ongoing motivation for continuous effort**

While the first 2-3 weeks of the TDR were challenging due to the steep learning curve and adaptation to the change through overcoming difficulties with hunger and tiredness, the rest of TDR was challenging mostly due to its monotony, a level of weariness of the participants, and the anticipation of the FR phase. However, most participants identified and developed strategies that worked, accepted the fluctuating challenges, and settled into the programme.

*“Now I’ve got used to it, it is what it is, it’s what I do. I sort of don’t think about it, it’s almost like a routine” (P25, T2).*

For most participants, the rapid reduction in weight and in blood glucose levels achieved during the TDR was rewarding and provided continuous motivation despite the experienced challenges. In addition to metabolic outcomes, improved physical and mental wellbeing and energy levels seemed to further increase satisfaction.

*“I don’t feel as tired. I just feel as if I’m doing a lot more. I just get up and I always feel as if I have had a good sleep and I have got more energy to do things” (P16, T3).*

The weight change was also more obvious at this point, which attracted compliments from others, providing further encouragement.

### **Transition to regular food as disruption of adaptation**

Transition from TDR to WLM through FR seemed a critical time of the intervention. It was often characterised by the participants’ difficulty letting go of the certainty and safety that using meal replacements provided, and by the anxiety about having to rely on their own resources. Many participants decided to continue losing weight by taking an optional TDR extension (up to 8 weeks) before transitioning to FR.

*“When you start you can’t imagine you’re even going to get to 12 weeks...[Then] you think “oh well I’ve got a bit of a rhythm going so I’ll keep going”” (P18, T3).*

The extension facilitated achievement of weight goals and building of a “leeway” for potential weight fluctuations during WLM. Nineteen out of 25, and 9 out of 19 participants reported trying to lose more weight at T3 and T4, respectively. The weight “leeway” provided a sense of safety and a level of control, while enabling occasional treats and social events without risking weight gain or the return of diabetes.

*“I’m still pretty worried about introducing food again. I just don’t know if I’m going to end up with the same eating habits as I had before. There will be some ups and downs and I think I’d just be happy those ups and downs were below my*



*acceptable weight rather than up and down above my acceptable weight” (P24, T3).*

## **Learning maintenance behaviours and overcoming difficulties with weight loss maintenance**

### *Experiences of fluctuation*

The FR and WLM phases required energy, behavioural control, and continuous effort and support.

*“...there was that pendulum and then gradually I’ve kind of got to know it’s just a little bit this way a little bit that way” (P1, T4).*

Maintaining weight often felt like a pendulum, swinging from weight regain to weight loss before settling down in about four to six months. Most participants found their weight fluctuate, which was managed by mindful observation, monitoring (e.g. portion control, reading product labels, weighing self and food, using a diary), and compensatory (e.g. exercise, reducing calories) behaviours.

*“I found that if you write things down, you are actually conscious about what you are eating, especially now when you are going back on to food. And I have got a Fitbit, which is brilliant, and I use that on a daily basis” (P32, T4).*

By engaging in this process of learning, participants had to repeatedly find motivation and resources to recover from setbacks, requiring continuous effort and resilience, which was perceived as more difficult than the TDR.

*“I found the maintenance really, really hard. I kept saying to the nurse every week I could go back on shakes” (P31, T4).*

Being diabetes and medication free were strong avoidance drivers for additional weight loss during WLM. The participants’ confidence and determination seemed to grow with their

achievement of weight loss, diabetes remission, and improved physical and mental wellbeing over time.

*“I just don’t want to go back down the line of having diabetes. I feel a lot better for it. I’ve had one close shave with it and climbed out, so I just don’t want to go back down that line again” (P28, T4).*

#### *Using meal replacements to facilitate weight loss maintenance*

A regulated reduction in the use of the meal replacement sachets built into the programme seemed to facilitate the transition period. Continuous use of meal replacements seemed to provide many participants with an anchor and a certainty of having *some* control over their food, while learning self-regulatory and meal preparation skills. For others, using sachets for brief intervals also offered a level of respite from the continuous effort they felt was required for WLM, especially when various life stressors were affecting participants’ resourcefulness.

*“I will be back to two shakes and a meal. I just needed that two-week kind of period to not to have to worry and think about food on top of everything else. And it is helping. It’s almost a relief just not to be adding to the things that I need to think about” (P11, T4).*

Some participants reported using the meal replacement regularly to help them on days of calorific compensation or reduction.

#### **Increased awareness of eating behaviours and continuous weight loss maintenance effort**

Compared to the WL stage, there was no obvious end point to WLM. Participants often talked about becoming more comfortable with the routine they had created after about four or five months, while highlighting the continuous effort to maintain their weight.

*“I weigh myself the same time every morning and it goes between a certain parameter, that’s an alarm then I’ve got to do something about it that day, because I’ve got time to compensate. That’s the way I balance it out. Before, I couldn’t control it. It was out of my hands” (P5, T4).*

Accepting that the continuous effort might have to become a way of life seemed to facilitate WLM. However, this level of acceptance was not achievable for everyone by the end of the intervention, and some had doubts about long-term sustainability of the effort-to-benefit ratio, as illustrated by the examples below.

*“I had to make the choice as to what standard of life I wanted. I didn’t want to be on a diet for the rest of my life, which was what I was feeling it was becoming like” (P8, T4).*

*“I think the routine is talking to myself. I don’t think it’s automatic. I just think I’ll have the conversation with myself for the rest of my life” (P18, T4).*

While the first quote conveys weariness with the process and a level of doubt about acceptability of the perceived level of restriction as a way of living, the second conveys a realisation that the WLM process requires continuous effort to keep the achieved benefits.

### **The roles of behavioural and social support during the DiRECT intervention**

#### *Continuity and flexibility of behavioural support by healthcare professionals*

Continuous behavioural support from HCPs was vital. Regular appointments offered participants an opportunity to talk openly, including discussing behavioural strategies or planning for holidays. Being seen by the same HCP enabled trust and rapport, which meant HCPs understood the participants’ situation better and thus could advise them better. It was also important that this support was flexible and tailored to individual needs. The participants’ sense of accountability to the HCPs and the research team provided additional motivation and commitment.

*“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” (P3, T4).*

#### *The role of other social interactions during the intervention*

While healthcare professionals helped with tailoring of the intervention to individual circumstances, nutritional advice, and strategies to improve adherence, social support from family, friends, or colleagues was important on a daily basis. While lack of this support was not often highlighted as a barrier, positive support was perceived as a facilitator of WL and WLM. Supportive actions of others included asking whether certain foods were appropriate for the participant, cooking healthier food, plating smaller portions, not offering food or moving it away, or even making their eating routines healthier and losing weight themselves.

*“All my colleagues, nobody provoked me by saying here eat this or eat that. Nobody has done anything like that” (P28, T3).*

*“My son, he is not exactly on a diet but he’s losing weight as well.” (P25, T3).*

#### **Discussion**

This qualitative evaluation reports on participant experiences of a diabetes remission intervention delivered in primary care. The observation of individual differences in experiences of weight management programmes is not new, but it is an essential finding to reiterate as it emphasises the importance of intervention tailoring including individualised support. Individual variability tends to be reflected in health outcomes, and it is one of the challenges of WL and WLM requiring innovation<sup>24</sup>. In DiRECT, it was enabled and

accommodated by the regular support by HCPs and the flexibility of the programme. The importance of regular appointments with trained supporters during WL and WLM has been emphasised in previous qualitative studies reporting that it enabled sharing of experiences, helped with behaviour regulation strategies, and provided accountability<sup>9,25</sup>.

The level of alignment between the behaviours of participants and their close ones may have also facilitated the process of adaptation and behaviour change, and the spill-over of the intervention effects on others. This idea of “behavioural contagion”<sup>26</sup> represents the unintended effects of the intervention, potentially resulting in weight loss and increased well-being of others who co-participated by eating healthier food, being more physically active, or embarking on weight loss journeys themselves.

Despite the challenges, many participants decided to extend the TDR, to 16 weeks on average<sup>1</sup>. This enabled many participants to increase their chances of achieving diabetes remission if not achieved by the 12<sup>th</sup> week, create a “leeway” to prevent diabetes from returning, and achieve self-determined weight and health goals, likely increasing satisfaction with outcomes, which is thought to increase the likelihood of diabetes remission and improved WLM<sup>27,28</sup>.

During the TDR phase of the intervention rapid weight loss, diabetes remission, improvements in physical and psychological wellbeing and compliments on weight loss from other people provided ongoing motivation<sup>8-10</sup>. Compared to TDR, WLM was experienced as more challenging, and required continuous effort over an open-ended period, a finding echoed by previous research<sup>15,29</sup>. After weight loss, people tend to be more aware of their eating behaviour, vigilant towards weight fluctuations, and adopt compensatory self-regulation strategies<sup>8,15,25-27,30</sup>. WLM is an ongoing struggle requiring compromises and a flexible approach to eating<sup>30</sup>. Acceptance of this may remove the negative affect of evaluating lapses as failures, preserving psychological resources that may become depleted with continuous effort<sup>31</sup>.

Future programme improvements

Participants' suggestions for improvement included provision of more guidance on physical activity during the weight loss maintenance stage, for example by getting help with the planning of an exercise regime, or even partnering up with local gyms and providing an easier route to developing physical activity habits. Some participants would have liked to interact with other people on the programme, which could take the form of an online forum. As a result, we added a question to the interviews at the end of the weight maintenance stage asking participants what their message to someone thinking about taking part in the programme would be. We hope that the appended list of "Messages to others" will, to some extent, facilitate sharing of the experience, and help future participants develop accurate expectations of the process in addition to the experience described in the paper.

### **Limitations**

All participants in DiRECT and this qualitative study were of white ethnic background. Experiences of the intervention, or facilitators and barriers to adherence with it may be experienced differently by people from other ethnic backgrounds, which needs to be accounted for in future implementation of DiRECT-style interventions. We were unable to interview all participants at all four time points due to participants' unavailability and some communication delays. About half of the participants who were interviewed at baseline were also interviewed at 12 months. It is possible that the themes we have identified may not fully account for the experience during the maintenance phase of the intervention.

Even though matching by gender, age, and SES between the trial sites was attempted to balance the qualitative sample between the study sites, the SES of participants in Scotland was on average higher than that of participants in Tyneside, which may have affected their experience in the trial.

DiRECT was widely reported in the media after the first-year results were published and this may have affected the motivation, commitment, and perceptions of the existing participants. Although the study was set in primary care and it was delivered by primary care staff, it is

likely that the fact of participating in a research study may have affected experiences and outcomes.

Future research could focus on further understanding of potential differences in experiences between people of different genders, SES, or ethnic backgrounds, which were beyond the aims of this study.

## **Conclusions**

The DiRECT intervention was attractive to people with type 2 diabetes by offering substantial weight loss and freedom from diabetes and its medications. The low-energy formula total diet replacement was challenging to adhere to initially, but overall proved easier than the participants had anticipated, with many participants choosing to extend the TDR to achieve weight loss and diabetes remission goals. Transition to regular food was challenging and weight maintenance required continuous effort supported by healthcare professionals

The observed individual adaptation to sustain behaviour modifications emphasises the need for programme flexibility and a level of tailoring to participants. These observations are important for large scale implementation of the remission programme delivery.

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## **Conflict of interest disclosures:**

AB reports honoraria from Novo Nordisk and Eli Lilly and programme content creator for Discover Momenta Diabetes Remission Programme outside the submitted work.

NB was previously employed by Counterweight Ltd and reports personal fees for freelance work and shareholdings from Counterweight Ltd during the conduct of the study and funding

of PhD fees and conference attendance from Cambridge Weight Plan outside the submitted work.

GT reports funding for PhD fees, conference attendance and departmental research support from Cambridge Weight Plan outside the submitted work.

LM reports employment by Counterweight during the conduct of study, and reports consultancy fees from Cambridge Weight Plan and Counterweight Ltd outside the submitted work.

MEJL reports support for meeting attendance and departmental research support from Cambridge Weight Plan outside the submitted work, lecturing fees from Nestle and Oviva, and has provided unpaid consultancy to Counterweight Ltd.

RT reports grants from Diabetes UK to conduct DiRECT, lecture fees from Novartis, Janssen and Lilly, author of book 'Life without Diabetes' during the conduct of the study, and consultancy fees from Wilmington Healthcare outside the submitted work.

All other authors declare no competing interests.

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**Table 1.** Participants' characteristics and attended interviews.

Site	ID	Sex	Age (years)	SES	T2DM duration (years)	BMI at baseline (kg/m <sup>2</sup> )	BMI at 12 months	Weight change at 12 months (%)	Remission at 12 months	T1	T2	T3	T4
Scotland	1	woman	55	Low	1.1	43.4	36.9	-15.1	Yes	X	X	X	X
	2	man	48	Low	4.7	39.5	36.7	-7.2	No	X	X	NT	X
	3	man	44	High	0.8	29.1	27.0	-7.2	No	X	X	N/A	X
	4	man	44	Medium	4.3	29.8	28.8	-3.1	No	X	X	N/A	N/A
	5	man	61	High	5.6	34.0	26.1	-23.3	Yes	X	X	X	X
	6	woman	48	High	1.7	30.8	27.8	-9.6	No	X	X	X	N/A
	7	woman	32	High	4.7	30.0	30.1	0.6	No	X	X	N/A	W
	8	man	49	Medium	1.1	28.6	27.1	-5.2	No	X	X	X	X
	9	woman	38	Low	2.1	42.5	N/A	N/A	No	X	W		
	10	man	53	High	2.0	28.8	28.1	-2.5	No	X	X	X	X
	11	woman	52	High	5.1	37.0	33.6	-9.3	Yes	X	X	X	X
	12	man	53	Low	1.1	32.5	30.3	-6.5	Yes	X	X	X	X
	13	woman	59	High	4.5	34.8	34.2	-1.6	Yes	X	X	X	N/A
	14	woman	65	Medium	4.5	34.4	30.3	-11.9	No	X	N/A	X	W
	15	woman	43	High	2.3	39.2	N/A	N/A	No	X	W		
	16	man	57	N/A	1.3	44.0	37.1	-15.6	Yes	X	X	X	X
	17	woman	55	Medium	4.4	34.7	29.4	-15.2	Yes	X	X	X	N/A

England	18	woman	59	High	6.0	28.3	25.3	-10.8	Yes	X	X	X	X
	19	woman	62	Medium	5.1	32.2	24.5	-23.9	Yes	X	X	X	X
	20	man	58	High	4.3	41.2	29.4	-28.7	Yes	X	X	X	X
	21	man	38	Medium	1.8	37.4	N/A	N/A	No	X	W		
	22	woman	44	Medium	0.7	33.4	33.7	1.1	No	X	X	W	
	23	man	63	Medium	2.7	29.9	24.0	-19.7	Yes	X	N/A	X	X
	24	man	44	Medium	3.9	35.6	32.1	-9.8	No	X	X	X	N/A
	25	man	45	Medium	1.9	38.2	33.5	-12.2	Yes	X	X	X	N/A
	26	woman	54	High	2.6	43.6	41.5	-4.8	Yes	X	C	X	X
	27	man	46	Low	4.5	33.2	33.4	0.8	No	X	N/A	N/A	W
	28	man	46	Medium	2.5	33.8	28.8	-14.8	Yes	X	X	X	X
	29	woman	56	Medium	1.9	35.5	34.6	-2.3	No	X	X	X	X
	30	woman	59	Low	4.4	28.5	28.9	1.3	No	X	W		
	31	woman	39	Low	2.0	40.5	30.4	-24.8	Yes	X	X	X	X
32	woman	53	Low	1.2	38.4	37.8	-1.7	Yes	X	X	X	W	
33	woman	57	Low	4.3	32.7	26.4	-19.3	Yes	X	X	X	X	
34	man	55	Low	5.2	28.9	26.6	-7.8	Yes	X	X	X	X	
<b>Totals</b>										<b>34</b>	<b>27</b>	<b>25</b>	<b>19</b>

**Note.** SES = socio-economic status (high (SES 10-8), medium (SES 7-5), and low (SES 4-1). T2DM = Type 2 diabetes, Remission = remission of type 2 diabetes, "X" = attended interview, N/A = not available, W = withdrew from study, C = corrupt interview; NT = interview not transcribed due to poor audio quality, T1= interview before the TDR, T2= interview at 6-8 weeks of TDR, T3= interview at Food reintroduction, T4= interview at 12 months.

**Table 2.** Comparison of baseline and follow-up measures between interviewed and not interviewed intervention participants.

		Interviewed		Not interviewed		
		Med	Range	Med	Range	p value
Baseline <sup>a</sup>	Age	52.7	32.3	53.3	32.5	0.14
	Duration* (years)	2.6	5.3	3.2	5.9	0.75
	Weight (kg)	96.9	77.4	101.0	77.0	0.28
	BMI (kg/m <sup>2</sup> )	34.2	15.7	34.3	17.4	0.64
12 months <sup>b</sup>	Weight (kg)	85.7	55.3	88.2	89.7	0.15
	BMI (kg/m <sup>2</sup> )	28.8	18.2	30.7	20.4	0.09

a. T1= interview at baseline, N= 149, participants interviewed n= 34; participants not interviewed n= 115

b. T4= interview at 12 months, N= 137, participants interviewed n= 19; participants not interviewed n= 118

\*Duration = duration of type 2 diabetes since diagnosis

## **Appendices**

Appendix 1: Tidier checklist

Appendix 2: Interview topic guides

Appendix 3: “Messages to others”