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ORIGINAL ARTICLE

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Do people with type 2 diabetes find continuous and intermittent low-energy diets for weight loss and diabetes remission acceptable?

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Abstract

Background: The Manchester Intermittent versus Daily Diet App Study (MIDDAS) tested the feasibility and potential efficacy of two remotely delivered low-energy diet (LED) programmes (800 kcal/day) to support weight loss and remission of type 2 diabetes: continuous [CLED] (8 weeks of daily LED) and intermittent [ILED] (2 days of LED/week for 28 weeks). Understanding participant experiences can help us to understand the acceptability of LED programmes to people with type 2 diabetes, informing future programme development and implementation.

Methods: Twenty participants (10 CLED; 10 ILED) took part in interviews conducted at the end of the active weight loss phase (CLED week 12, ILED week 28). Interviews were transcribed and analysed thematically using the template analysis approach, with an a priori focus on acceptability. Four themes are presented: prospective acceptability, intervention coherence and perceived effectiveness, opportunity costs and self-efficacy.

Results: Both remotely supported CLED and ILED interventions appeared acceptable to participants. CLED participants found the rapid initial weight loss phase comparatively easy and highly motivating but expressed more concerns around weight maintenance. ILED participants found the more gradual weight loss initially frustrating but expressed greater confidence in their longer-term adherence. The importance of continued individualised support from healthcare professionals was emphasised, and evidence of weight loss and improvement in other medical markers through monitoring via the mobile phone app was useful.

Conclusion: Different approaches to remotely delivered LEDs appear acceptable; therefore asking patients which approach may be more acceptable to them may be a useful way to offer individualised and tailored support.

KEYWORDS

acceptability, continuous low-energy diet, diabetes remission, intermittent low-energy diet, qualitative, weight loss

Key points

We interviewed people with type 2 diabetes (T2D) who had taken part in a randomised controlled trial comparing a continuous low-energy diet (CLED) and an intermittent low-energy diet (ILED) about how acceptable they found the

interventions. We found that both diets appear to be acceptable to people with T2D. Discussing different (CLED/ILED) approaches and their potential benefits and challenges may better prepare patients for a LED, although further research to test the efficacy of ILED for diabetes remission is still required.

INTRODUCTION

Type 2 diabetes (T2D) affects 9% of the global population and presents a significant challenge to healthcare systems.[1] Continuous low-energy diets (CLEDs) using a low-energy formula-based total diet replacement (TDR) can be highly effective in achieving large weight loss and remission of T2D. One recent trial (DiRECT[2]) tested an intensive CLED programme (12–20 weeks of formula-based TDR [825–853 kcal daily] followed by 2–8 weeks of stepped food reintroduction) delivered in primary care, with structured support for weight loss maintenance for 2 years. At the end of this period, 36% of intervention participants (compared to 3% of control) were in remission, and greater weight loss increased the likelihood of achieving/maintaining remission.[3]

Qualitative work suggests CLEDs can be acceptable to participants.[4–6] The initial rapid weight loss associated with a CLED can be highly motivating,[5] and formula-based diets remove the challenge of decision making around food choices and promote nutritional ketosis which may reduce subjective hunger.[7] Yet despite these benefits, the use of formula-based CLEDs may not be appealing or achievable for all people with T2D. Transition to regular food and prevention of weight regain following the CLED can be difficult. Attrition in intensive CLED studies on people with overweight/obesity (+/−T2D) is approximately 25%.[3,8] An intermittent low-energy diet (ILED) is a potential alternative to a CLED, requiring the same number of low energy formula-based diet replacements only 2 days a week over a longer period of time. An ILED will lead to slower initial weight loss compared with a CLED but could be an acceptable alternative approach.

Regular ongoing behavioural support from healthcare professionals (HCPs) is instrumental in implementing LED interventions and facilitating weight loss maintenance,[4] with higher rates of attrition reported in studies with less frequent HCP contact.[9] A potential strategy for increasing adherence efficacy and reach of LED programmes may be to include high-frequency remote follow-up, which has been shown to be superior to low-frequency face-to-face contact in weight management interventions.[10]

The Manchester Intermittent versus Daily Diet App Study (MIDDAS[11]) tested the feasibility and potential efficacy of remotely supported ILEDs and CLEDs in people with T2D. Seventy-nine patients with overweight/obesity and diagnosed with T2D were randomised to either a CLED (8 weeks of an 820-kcal formula-based diet replacement followed by 4 weeks of food reintroduction) ($N = 40$ participants) or an ILED (2 days of the same diet replacement and 5 days of a portion-controlled Mediterranean diet for 28 weeks) ($N = 39$). All participants then undertook a weight maintenance/continued weight loss phase for the remaining 12 months (see Figure 1 for a summary diagram of the two dietary programmes). Participants in both groups received high-frequency remote multidisciplinary team support via a mobile app and/or telephone from a diabetes specialist dietitian, diabetes specialist nurse, exercise specialist and clinical psychologist (where required) (see Figure 1). The app was also used to facilitate self-monitoring of diet, weight and blood glucose.

Results of the MIDDAS trial are reported in full elsewhere.[12] At 12-month follow-up both groups had achieved similar weight loss, demonstrating the feasibility and potential efficacy of remotely delivered CLED and ILED programmes for weight loss and HbA1c reduction in people with T2D. The purpose of this nested qualitative study was to explore the acceptability of the dietary interventions for participants. Acceptability is recognised as a key concept in the development and delivery of healthcare interventions. Understanding how acceptable an intervention is to the target population may provide important insights into uptake and maintenance. A recently developed theoretical framework of acceptability (TFA)[13] identifies seven component constructs of acceptability (see Table 1). The TFA is increasingly being used for both quantitative and qualitative assessments of the acceptability of healthcare interventions (e.g., evaluation of a remote intervention encouraging medication adherence in people with T2D[14]).

The purpose of this qualitative descriptive study was to explore with a subset of MIDDAS participants how acceptable they found the LED they were allocated. Research aims were to (1) understand participant experiences of the MIDDAS interventions; (2) explore ways in which a remotely supported CLED and ILED might be more or less acceptable to people with T2D and the reasons for this; and (3) develop information to inform future programme development.

METHODS

The full trial (including the present embedded qualitative study) was granted NHS REC approval (ref: 17/NW/0389). For full details of the trial, see McDiarmid et al.[11,12] All participants had received regular remote support (via the Oviva app) from a multidisciplinary team, including a diabetes specialist dietitian, diabetes specialist nurse, exercise

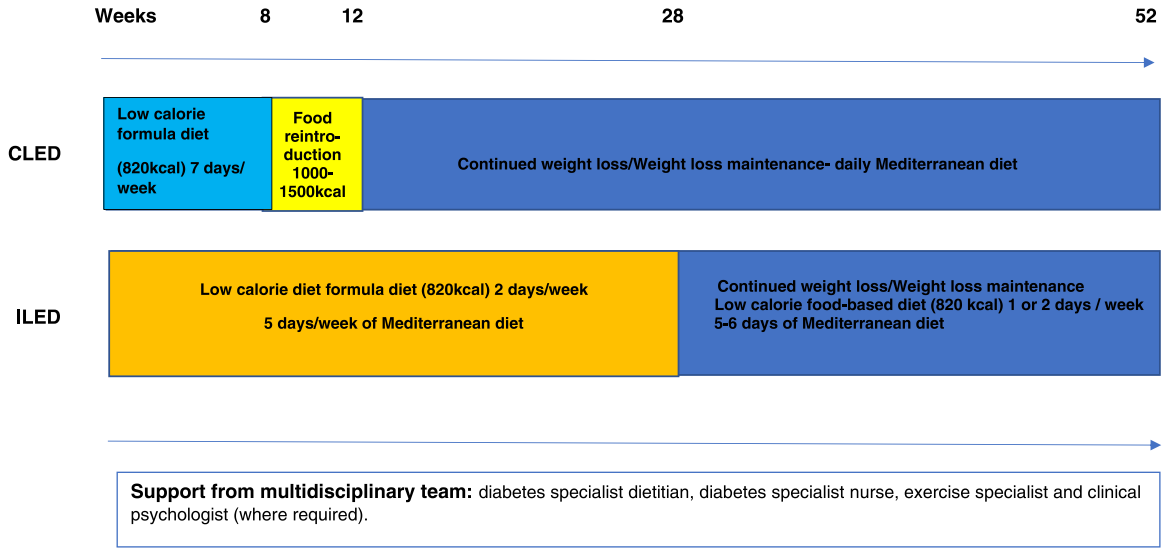

FIGURE 1 The two low-energy diet (LED) programmes followed by participants (continuous [CLED] and intermittent [ILED]).

TABLE 1 The component constructs of the theoretical framework of acceptability.[a,13]

Component construct	Definition	Proposed temporal assessment[a]
Affective attitude	How an individual feels about an intervention	Prospective (prior to participating in the intervention)
Burden	The perceived amount of effort that is required to participate in the intervention	Prospective (prior to participating in the intervention)
Ethicality	The extent to which the intervention has a good fit with the individual's value system	Prospective (prior to participating in the intervention)
Intervention coherence	The extent to which the participant understands the intervention and how it works	Concurrent (while participating in the intervention)
Opportunity costs	The extent to which benefits, profits or values must be given up to engage in the intervention	Retrospective (after participating in the intervention)
Perceived effectiveness	The extent to which the intervention is perceived as likely to achieve its purpose	Retrospective (after participating in the intervention)
Self-efficacy	The participant's confidence that they can perform the behaviour(s) required to participate in the intervention	Retrospective (after participating in the intervention)

[a]Sekhon et al. (2017) note that the extent to which constructs cluster or influence temporal assessments of acceptability is an empirical question.

specialist and clinical psychologist (where required) (see Figure 1).

Participants and procedure

Purposive sampling was used to select participants allocated to CLED or ILED with a range of weight loss success (see Table 2 and McDiarmid et al.[12] for full trial outcomes). In-person semi-structured interviews were conducted (by an independent research assistant trained in qualitative interviewing, not involved in delivering the intervention) with 10 CLED and 10 ILED participants at the participants' homes at the end of the active weight loss phase (CLED week 12; ILED week 28) (median 28 days, range 0–139 days). Interviews (lasting around 1 h) explored participant experiences and the acceptability of the remotely delivered LED programmes and the use of the Oviva app (see appendix 1 for the interview guide). Interviews were audio-recorded and transcribed verbatim for analysis.

Data analysis

Interviews were analysed using Template Analysis, a systematic technique in which qualitative data are hierarchically thematically coded through the iterative development of a coding template.[15] Template Analysis permits the definition of 'a priori' themes – themes

TABLE 2 Participant information table (full trial outcomes are reported in McDiarmid et al.[12]).

Participant ID and diet condition[a]	Age (year)	Sex	Ethnicity	Deprivation quintile[b]	Education level grouping	Baseline body mass index	Duration diabetes	Baseline HbA1c[c]	Weight change during active weight loss phase (kg)	Weight change from baseline at 52 weeks (kg)
CLED 1	66	F	White: British	5–6	No formal qualifications	43.3	<4 years	54	−8.7	−8.0
CLED 2	68	M	White: British	7–8	Secondary education	33	≥4 years	58	−15.2	−8.6
CLED 3	69	F	White: British	9–10	No formal qualifications	44.2	<4 years	48	−11.9	−10.8
CLED 4	59	M	White: British	9–10	No formal qualifications	31	<4 years	49	−8.1	−5.8
CLED 5	58	F	White: British	1–2	Secondary education	33.3	<4 years	72	−14.4	−4.4
CLED 6	57	F	White: British	7–8	Higher education	45.6	≥4 years	49	−12.8	−11.8
CLED 7	51	M	White: British	1–2	Higher education	41.4	<4 years	93	−8.9	Withdrew from study
CLED 8	67	F	White: British	5–6	No formal qualifications	41.5	<4 years	65	−6.3	−4.4
CLED 9	65	F	White: British	5–6	Higher education	39.2	≥4 years	55	−6.8	−3.8
CLED 10	63	M	White: British	7–8	Higher education	36	≥4 years	76	−4.5	1.7
ILED 1	59	M	White: British	1–2	No formal qualifications	33.6	<4 years	71	−8.5	−13.1
ILED 2	63	F	White: British	3–4	Higher education	30.1	<4 years	49	−12.2	−11.2
ILED 3	64	M	Black or Black - British: Caribbean	9–10	Higher education	29.7	<4 years	52	−10.3	−12.2
ILED 4	50	F	White: British	3–4	Secondary education	30.9	<4 years	58	−7.5	−1.9
ILED 5	57	M	White: British	5–6	Secondary education	38.2	≥4 years	57	−6.1	−4.7
ILED 6	55	M	White: British	1–2	Higher education	30.2	<4 years	51	−8.4	−5.4
ILED 7	57	F	Black or Black British: other Black	1–2	Unknown	49.8	≥4 years	66	−8.5	−11.4
ILED 8	41	F	Asian or Asian British: Indian	7–8	Higher education	35.4	<4 years	50	−5.0	−3.2
ILED 9	62	F	White: British	5–6	Unknown	34	<4 years	54	−13.8	−8.6
ILED 10	49	M	Black or Black British: other Black	1–2	Higher education	27.1	≥4 years	49	−1.3	Withdrew from study

Abbreviations: F, female; M, male.

[a]CLED: continuous low-energy diet programme; ILED: intermittent low-energy diet programme.

[b]English index of multiple deprivation score 2015: 1–2 most deprived; 9–10 least deprived.

[c]HbA1c (haemoglobin A1c) is a measure of blood sugar used in the monitoring and diagnosis of diabetes. ≥48 consistent with T2D.

identified in advance of analysis as helpful and relevant to the research focus, which are then refined and developed (in the present study, the dimensions of the TFA). Preliminary coding was initially undertaken on a subset of the data (eight interview transcripts: four CLED and four ILED) by working through each transcript highlighting relevant data and assigning these segments initial descriptive codes. Codes were organised into a preliminary thematic template, initially structured around the TFA constructs with sub-themes developed within each top-level thematic heading. This initial template was then applied to a further subset of data (eight further transcripts: four CLED and four ILED). A second version template was then constructed and modified to ensure it adequately captured the data – this included merging three themes capturing prospective acceptability (affective attitude, anticipated burden, ethicality) into one theme and collapsing two a priori themes (intervention coherence and perceived effectiveness) into a single theme (as participants were being interviewed shortly after the active weight loss phase, their reflections and views on how the intervention worked [coherence] and on whether the intervention worked [effectiveness] were consistently linked and intertwined, and so combining these into a single theme better reflected their views). This new version template was applied to the remaining transcripts and found to adequately represent the data. Finally, the final version template was applied to the full dataset. Analysis was led by the first author (an experienced qualitative researcher with previous experience of undertaking diabetes-related research) with regular ongoing discussions with the senior author (M.H. – a highly experienced research dietician with expertise in optimum diet strategies in the context of breast cancer and T2D) to discuss the ongoing analysis process and refine the emerging analysis. The final analysis was reviewed by all authors comprising professionals from different clinical and research backgrounds, including diabetology and endocrinology, dietetics, physiotherapy and health psychology.

RESULTS

Four themes are presented: prospective acceptability (how participants felt about the intervention before taking part), intervention coherence and perceived effectiveness (the extent to which participants understood the intervention and how effective they felt the intervention was), opportunity costs (the extent to which participants felt sacrifice was necessary to participate and how this was managed) and self-efficacy (the extent to which participants were confident they could undertake behaviours required by the intervention and felt able to maintain beyond the active weight loss and trial periods).

Prospective acceptability

This theme considers participants' attitudes towards the interventions, including views on ethicality and likely burden, prior to taking part (discussed retrospectively following the active weight loss period). Weight loss was a primary motivation for participation. Being overweight was understood by all participants as having negative consequences for health. The connection between weight and T2D was explicitly recognised (e.g., CLED5 *I knew I was overweight and that was causing the diabetes*), and the diabetes diagnosis often described in terms of an important '*wake-up call*' (ILED8). Participants had been warned (often in a healthcare setting where appointments felt rushed) in broad terms of serious health risks and advised to lose weight, but felt they were given little specific guidance or support. In contrast, the support provided by the MIDDAS programme was viewed positively:

> CLED2: *I thought, this is a wonderful opportunity – where could you get the opportunity like that, somebody's going to monitor you for 12 months, this was an opportunity to get proper support. I thought 'Well, you can't buy this can you?' sort of thing?*

As an evidence-based research study undertaken in the context of the UK National Health Service, the trial was viewed as credible, and the diabetes-specific and health focus helpful. Although participants' expectations of success in relation to both weight loss and diabetes management goals varied, taking part was seen as offering hope, even being described in terms of a final chance by some (ILED9: *I was quite happy to try anything because I was just so desperate to get my weight down*; CLED7: *It was either that or bariatric surgery. It was a no-brainer… it's a case of I needed to lose weight or die*). Taking part in the trial was seen as a welcome personal challenge although proposed weight loss goals were intimidating for some, especially in the context of previous failed dieting attempts.

Participants were aware their allocation to a particular diet (CLED/ILED) was random. Although some had initially wanted a different LED to the one allocated, retrospectively participants were generally happy that the LED they followed was suitable for them. CLED participants tended to report more concerns that they would feel hungry (CLED10: *You aim to eat 2000 calories so 800 is nothing, is it? There's no food there. So I was apprehensive*). The CLED was understood as more likely to facilitate initial rapid weight loss, which was seen as motivating and desirable, although there were also concerns that losing weight very quicky initially would simply result in rapid weight regain soon after.

Perceived benefits of the CLED prior to beginning the programme included its simplicity and clear structure

(CLED9: *It was so easy – just making a shake is so easy*), whereas participants allocated to the ILED suggested they perceived it as a potentially more sustainable approach (ILED9: *If you're losing weight that quickly, then putting it back on is going to be no problem at all, because it hasn't been in the past…I fancied learning how to eat properly, if you know what I mean*).

Intervention coherence and perceived effectiveness

This theme considers the extent to which participants reported they understood both how to follow the intervention and how the intervention works, as well as the extent to which they perceived it was effective. Participants saw the primary purpose of the intervention as weight loss, and most were delighted by their weight loss achievements. In addition to the regular monitoring of their weight, visual signs of weight loss (including clothing fit) were important evidence of effectiveness. The minority who felt they were some way off their weight loss goals attributed this to their own failure to adhere to the intervention (in turn attributed to factors outside their control e.g., being unwell with flu), rather than to the effectiveness of the intervention itself.

For CLED participants, rapid initial weight loss was highly motivating (CLED5: *I lost so much in the first week. So I thought, wow. Obviously the first week you do lose more weight but I felt good, I felt great, so obviously that motivated me to continue*). As this initial weight loss slowed, some CLED participants suggested that although they were confident the initial stage of the diet worked, they were less sure about the longer term and apprehensive about reintroducing food. Submitted readings via the app were felt to be acknowledged and appropriately responded to by staff through ongoing encouragement and direct contact to address any issues, including reassurance when weight loss plateaued. Some ILED participants were frustrated by the rate of weight loss and acknowledged some impatience, although a gradual decline in weight observed over a period of many weeks that could be mapped onto a graph (via the app) provided encouraging visual evidence of 'movement in the right direction'.

Participants were delighted and surprised by the effect of the intervention on their diabetes status and other medical markers. As opposed to weight loss (a broadly anticipated outcome), changes in medical markers (diabetes status, blood pressure, cholesterol) seemed less expected and described in terms as '*a massive bonus*' (ILED2). Participants described improved mobility and energy, and for many the intervention had achieved important benefits beyond weight loss (CLED6: *I feel just better. I just feel more normal. I can go in shops and know that I'll be able to get clothes …the whole thing has been life changing for me*).

The structure of the dietary intervention was generally well received (e.g., CLED1: *I need a structure, the diet it tells you to eat this and eat that, and I needed a bit of a structure to tell me to do that*), and most found the meal replacement shakes palatable. CLED participants were enthusiastic about how straightforward the regime was to follow (no requirement to cook or meal plan, easily portable, delivery worked well). Although some ILED participants felt that boredom would have been difficult for them to manage on the CLED, CLED participants had not found this problematic (CLED9: *I could have lived like that for ever really; it was fine*), and other ILED participants reported following the same weekly set menu for ease.

A limited number of participants characterised the interventions as simply 'more of the same' suggesting the programme provided no new learning and that the core requirements of weight management were simple and straightforward and already well understood, if not necessarily well adhered to (ILED2: *You've got to eat differently and exercise more, there's no magic answer*). Most participants though described the intervention as facilitating genuinely new and important learning (CLED8: *It was a totally different way of thinking*). Previous diets had tended to focus solely on calorie intake, and the specialist focus on dietary management in the context of diabetes specifically in both diet conditions was well received. Clear, comprehensive and easily comprehensible explanations in multiple formats (verbal and written) about the role of different macronutrients (carbohydrates, proteins, fats), portion sizes and the physiological impact of foods were powerful in helping participants understand the rationale for the diet and facilitating adherence.

> ILED4: *It's where that weight is. And it's more across your midriff, your waist, your belly, and that area, 'cause that's where it's storing fat, which is then obviously impacting on your liver, impacting your pancreas, and it's stopping what it's supposed to do. But until you look into it properly and you understand it with the diet and everything you don't – well I didn't – I didn't get it. I do now*.

Participants favourably contrasted the trial with their previous experiences of dieting and HCP support. The availability of staff support and monitoring via the app were a key difference between this and previous experiences (ILED8: *On and off, I've maybe tried to eat a bit healthier but there wasn't the sort of intensive support and accountability that you have to provide, that's what has been really positive*).

The few participants who chose not to engage with the app tended to attribute this to personal preferences (e.g., CLED7: *For me, being one of the old ones, I prefer the telephone*) rather than anything specifically related to

the app itself or the specific diet they were following. The extent to which the app was understood by participants as facilitating individualised and accessible interaction with and support from staff impacted on the extent to which it was viewed as a useful tool.

> ILED7: *Loved it, totally loved it because it was just like I don't have to call anybody and leave a message or hope that they're going to be about. I know that if I send a message someone will pick it up, someone will reply. You could connect with someone very, very easily and my experience is that they always come back to you very quickly… to have a diabetic nurse, a dietitian, a psychologist, to me it was like getting superstar treatment to do this.*

Managing expectations around response times on the app appeared important – although most participants reported they could contact staff easily and received a response in a timely way, a small number were unhappy they did not receive immediate responses.

Monitoring activities through the app were also generally well understood and acceptable to participants. Being able to monitor and track progress was seen as useful, although there were some usability issues reported by some, including specific difficulties around recording activity, editing of entries and device compatibility problems. Knowing they were taking part in a research trial was also important as participants described an obligation to adhere to and submit accurate records (food intake, weight, blood sugars, etc.) regularly and as requested. Although some described the regular submission of readings as tiresome, for most this had quickly become routine and monitoring was reflected on in generally positive terms as reassuring (ILED9: *All those people are watching me… it sort of gives you this feeling of, well, support, I suppose, as well as the not wanting to let people down*).

Opportunity costs

'Opportunity costs' captures the extent to which participants felt sacrifice was necessary to participate in the programme and how this was managed. In the TFA, 'opportunity costs' captures the extent to which participants felt benefits or values must be given up to engage in the intervention, including the extent to which these were anticipated and managed. The focus here, as we developed this theme through analysis, is more specifically relational. Participants reflected on the impact of following the diet programme they were assigned on their relationship with food and on their social relationships with others.

Participants taking part in the CLED generally reported anticipating more difficulties but finding the diet easy to follow in practice (CLED2: *Overall I didn't find it difficult at all*). This was attributed to expecting to (but not) feeling hungry and initial rapid weight loss being highly motivating. CLED participants generally reported experiencing very little in the way of cravings or hunger during the active weight loss phase. Those who did experience mild hunger and/or cravings found these more problematic in the evenings but attributed this to habit or boredom and felt these were relatively easy to manage. ILED participants were more likely to describe the diet as difficult to adjust to but tended to reflect on this as a transition period in the context of a long-term and sustainable lifestyle change (ILED10: *The first two weeks was the most difficult, they were very difficult … essentially, it's a transition, it is a transition your body has been in*). ILED participants frequently reported feeling hungry and experiencing cravings on their 'shake' (LED) days, and evenings were highlighted as particularly challenging with some reporting sleep problems due to hunger. Participants understood this as a 'retraining' of their body after a lifetime of eating in a different way.

A small number of participants felt that the change in diet and lifestyle required by both programmes was simply too arduous or removing something that brought them pleasure. Participants talked about foods as a form of self-care in terms of being a treat to oneself and as a comfort. In these cases maintaining the diet represented too great a loss in terms of quality of life (e.g., CLED8: *I don't drink, I don't smoke, I don't bother with men because you can't count your husband, so I'm entitled to something that's nice and a bit sinful*). Some ILED participants reported that food preparation on healthy eating (non LED) days was burdensome, and some participants across both conditions reported they either did not like or quickly became tired of eating similar (vegetable-based) foods. Where participants were managing difficult domestic situations (e.g., relationship breakdowns) or had significant caring responsibilities (e.g., full-time carer for spouse with dementia) they could not always prioritise adhering to the intervention; finding time to undertake any form of exercise was especially difficult. Several participants reported not adhering to the diet when they felt unwell (e.g., CLED10: *When you're ill you want something you can chew*) and the time of year and weather played a role for some – it was easier to maintain the diet during the summer months but '*when it's cold and it's dark and it's wet, all you want is stodge*' [ILED5] (the perception being that 'stodge' was not possible or permissible).

Eating was seen by many as social and had previously featured as a regular leisure time activity. It was at social events that participants most strongly reported feeling they were 'missing out' and giving something up to engage in the interventions or felt judged by others for not participating. Holidays and celebration events (e.g.,

weddings, birthdays) were given as examples of times participants would not necessarily keep to the diet as intended (CLED7: *I had my two kids' birthdays fell just before the diet actually finished. And you can't sit there and say, 'I'm sorry*, [I] *can't have cake'*). Although participants tended to discuss this in terms of 'cheating', they also typically described such lapses as to be expected, justifiable and even necessary (ILED2: *I think you've got to have some respite somewhere, haven't you? Otherwise you'd just be thinking 'This is terrible, what's my life come to?'*).

Participants had been able to incorporate the diet into their home lives and adapt family meals (this was also viewed as having a wider beneficial impact on family members' health). However, some participants suggested the presence of others in the home environment made adherence more difficult. Being on the diet disrupted some established family routines and although family members were generally described as supportive, there were examples of others (often seemingly inadvertently) undermining adherence. Some participants found it especially difficult to reject offers of food presented as an act of care and affection (ILED5: *My mum…she says, you're looking a bit peaky, I've made you a sandwich, you know, white thick bread, proper butter on and a lump of ham that she's carved off that you could use as a doorstop and she's 85, so I can't say, 'No you're alright Mum'*). Socio-cultural and family norms around foods and weight were also identified by some participants as barriers to engaging in the intervention. This could be because foods included in the diet were not part of participants' cultural backgrounds (e.g., CLED3: *I've never cooked with oil in my life… when I was young, growing up with the family, we used to use lard*; ILED7: *That cooker has only been used by me once since I moved here and that was to prepare some Caribbean food… I don't think that I can eat just Mediterranean food, I don't feel that I really wanted it to be my norm*).

Most participants found the responses of others to their weight loss generally encouraging. However, some felt less comfortable with the change in their body shape (CLED4: *I just didn't feel 100 per cent with it, I just felt all my clothes were dropping off me, I felt skinny… I feel if I would have carried on eating on the diet, I would have lost quite a bit more weight, probably too much in my opinion*) and reported that others too had commented on their weight loss in ways which could be interpreted as pejorative (ILED10: *They say, 'What the hell is wrong with you? You are as thin as a stick'*; ILED3: *At the gym they've all noticed the difference in me. One of them said I'm wasting away*). Personal unease around weight loss and disparaging comments from others were notably experienced more by male participants. One participant additionally commented on how cultural views around weight differed significantly:

> ILED10: *In my culture it is generally considered that the bigger you are the more affluent you are…Being big, it's very important for them, when someone wears a suit and you have a big belly, that's when you're given that respect. They would respect somebody like that, as opposed to somebody who is skinny with no belly like myself, because that is the person who has the money, who is the wealthy, who is the aristocrat, or whatever you want to call it.*

Self-efficacy

This theme explores the extent to which participants perceived they would be able to maintain behaviour changes and continued weight loss or weight loss maintenance beyond the active weight loss period, developing their own strategies alongside decreasing expert support.

Those who felt the intervention had been successful at the end of their initial weight loss phase were proud of what they had achieved, and this instilled greater self-confidence and a sense of personal control. Even those who had not achieved their weight loss goals perceived new useful learning, health benefits and valued improvements. For some CLED participants, the rapid weight loss results achieved were attributed to facilitating an irreversible and permanent behavioural shift (CLED6: *It's like a lightbulb has switched)*. Generally, participants across both LEDs discussed the extent to which they felt behaviour changes had become (or were becoming) automatic and routine when reflecting on their confidence to maintain changes (ILED6: *This is like a lifetime change of lifestyle… I know what to do, I've been given the tools*). Participants across both groups reported becoming accustomed to and feeling satiated despite eating less. They also reported enjoying using newly acquired skills (e.g., cooking) and a shift in dietary preferences (notably eating significantly more vegetables, fish and wholegrains; and finding sweets, crisps and red meat less palatable). Where participants talked more in terms of following the requirements of the trial, they appeared less confident in their ability to maintain behaviour change (CLED2: *Their system is smashing, I do appreciate that, and the chance and all the rest of it, but at the end of the day, when the support goes in 12 months I have to manage*).

An important element of self-efficacy was the extent to which participants felt confident they could prepare and eat a healthy diet without relying on the meal replacement drinks (CLED6: *It's a bit difficult, I have to say, just getting used to thinking about food after being on the shakes because it's – it sounds a bit lazy, it is lazy I know but you don't have to think)*. Participants following

the CLED frequently reported some difficulties adjusting to the weight maintenance phase of the diet without the meal replacement drinks. Several had regained weight, some had needed to recommence diabetes medications they had been able to stop and a number reported experiencing cravings they had not experienced during the active weight loss phase. There was no suggestion that these cravings were caused by or in any way worse as a result of the diet. How participants had been able to manage cravings and any other difficult periods over the intervention (described in the preceding theme) impacted on the extent to which it was felt behaviour change could be maintained over the longer term. The attributions made for any lapses during the active weight loss period seemed to have important influences on expectations around self-efficacy beyond the trial period. Lapses could lead to participants concluding that external events beyond their control made it impossible for them to follow the diet or that the intervention itself was impracticable. Alternatively, when participants felt themselves to have successfully faced and overcome challenges and developed strategies to support adherence (either independently or with professional staff support and guidance), this facilitated greater self-confidence in their ability to manage in the future.

For all participants continued monitoring and recording (of food intake, blood sugars, weight) beyond the active weight loss period were useful, providing continued structure, an ongoing sense of accountability and encouragement, and evidence of progress. The importance of the ongoing support of the HCP team over this period was repeatedly emphasised with a number of participants expressing concerns about managing without this. Although recognising that support would be gradually tapered over the maintenance period, participants suggested that perhaps an even more gradual reduction was required.

> ILED8: *I think some people need more time to make a true change. The next three months are more important because of the sustainability of a lifestyle choice, which is where, I don't know what the data shows but if a lot of people were like me, this is where you sort of fall down.*

DISCUSSION

Findings presented suggest that the remotely supported CLED and ILED interventions used in the MIDDAS trial appeared acceptable to people with T2D. Overall, participants were positive about their experiences of participating in their allocated LED even if this differed from their original preference. Very rapid weight loss was motivating to CLED participants, who also reported fewer difficulties adapting to the dietary regime. ILED participants felt that the longer active weight loss period allowed them to develop personal strategies to manage hunger and cravings which were useful in facilitating a lasting behaviour shift. Participants favourably contrasted the information and support they received with previous experiences of engaging with healthcare services. Evidence of weight loss through monitoring and recording via the app provided participants with useful encouragement. The importance of a sense of accountability facilitated by being part of a clinical trial and continued individualised support from HCPs was emphasised across both LEDs. Remote support and monitoring were acceptable to and generally well received by participants.

A systematic review of qualitative studies published in 2018 investigating participant experiences of LEDs[16] identified three publications, which reported on continuous LED approaches of various durations (one with gradual food reintroduction[17]) and only one of which focused on the experience of patients with T2D specifically.[7] Our findings add to the still-limited qualitative research in this area, provide further support for the acceptability of LEDs specifically in the context of T2D and additionally suggest that ILED approaches are acceptable to participants. Participants appeared to spend less time adapting to the CLED than to the ILED. This may reflect the simplicity of the CLED which removes the challenge of decision making around food choices, the shorter duration and perhaps the associated nutritional ketosis, which may reduce subjective hunger.[7] Intentions to change behaviour do not always translate into the actual behaviours (the 'intention-behaviour' gap).[18] The Health Action Process Approach model (HAPA) posits that health behaviour change involves a motivational phase and a volitional phase, with planning (action planning and coping planning) key to converting intention to action in the volitional phase.[19] Action planning and barrier identification/problem solving are behaviour change techniques previously used in interventions for people with T1D which are associated with clinically significant improvements in HbA1c.[20,21] Our findings illuminate some of the specific barriers and problems encountered by participants in relation to specific LEDs as well in relation to LEDs more generally. Helping patients identify potential barriers may enable those taking up an LED to better plan strategies to implement and sustain behaviour change.

Given the relational focus (the importance of close others) in our 'opportunity costs' theme, developing materials for family members explaining the rationale for LEDs in the context of T2D might also be a useful area of future work. Although a family focus has been recommended,[22] there are few trials and interventions adopting this recommendation.[23] Education, including a clear explanation and rationale for dietary management in the context of T2D, is important to engage patients. In

line with previous work, our findings highlight that programme flexibility and a level of individual tailoring are needed to sustain behaviour modification.[6]

Potential limitations include that all study participants were highly motivated to take part in the MIDDAS trial, accepted the link between overweight/obesity and diabetes (and other health conditions) and understood self-management through diet as possible and appropriate. This may limit the transferability of our findings beyond our study population. Where people with T2D are not persuaded of this rationale, they may be less willing to contemplate engaging with a LED. A recent overview of systematic reviews[24] identified potential for personal benefit and trust as key facilitators of research participation with treatment preference, distrust of research (often culturally specific), practical difficulties associated with participating and an expressed dislike of randomisation among the barriers identified. Participants in the MIDDAS study were allocated to either the CLED or ILED programme as part of the trial. Previous studies have shown that allocation to diets by a HCP appear to have greater adherence than diets which are self-selected, perhaps due to extrinsic motivation to please the HCP.[25]

As interviews were conducted at the end of the active weight loss phase (week 12 CLED; week 28 ILED), a further limitation of this work is that our analysis cannot capture participant experiences over the full maintenance phase. Future research could focus on better capturing acceptability of remotely delivered LEDs longitudinally – for example, diary research[26] could usefully capture experiences with the process along the way.

The cohort in the MIDDAS study and this embedded qualitative work has a low representation of ethnic minorities other than White. This is a widely reported limitation among studies looking at diabetes remission and LEDs despite the fact that certain ethnic groups (e.g., south Asian) are known to be at higher risk of T2D and have historically been less successful in weight loss programmes compared to the White population.[27] Recent work suggests that LEDs can achieve diabetes remission in people with T2D from the Middle East and North Africa region,[28] but it remains the case that more work is needed looking at how acceptable remotely delivered LEDs may be to different patient groups. Co-developing and evaluating tailored interventions which are more culturally acceptable may help to ensure LED interventions are accessible and acceptable to specific high-risk populations.[29]

At the time of the interviews (week 12 CLED; week 28 ILED) 4 CLED participants (out of 40) and 7 ILED participants (out of 39) had withdrawn from the study. An important and acknowledged further study limitation is that we did not interview participants who dropped out during the intervention stage or who opted not to take part in the study, although two of the participants interviewed (one CLED; one ILED) did subsequently withdraw from the trial after interview and before the end of the full 52-week study period (see Table 2). The obvious difficulties inherent in undertaking work with those who withdraw from research studies have been acknowledged previously in this and in other research settings.[30,31] Nonetheless, we recognise that eliciting the views of those who do not undertake or complete LCDs (as well as those who do) is needed for a fuller understanding of any adaptations required in content and presentation to maximise the accessibility and acceptability of these dietary interventions.

CLEDs have been established as highly effective in achieving large weight loss and remission of T2D, but it has been suggested that there exist widely held negative beliefs about CLEDs (e.g., LEDs can be difficult to adhere to or unpleasant to undertake). The profile of LEDs is rising (e.g., in England a 12-week CLED for people with T2D is currently available through the National Health Service in selected localities).[32,33] This study suggests that both CLEDs and ILEDs appear to be acceptable to patients with T2D. However, further research is required to test whether ILED is effective for diabetes remission. Discussing and offering different (CLED/ILED) approaches and their potential benefits may be an important element in better preparing patients for a LED, facilitating informed choice, planning and potentially improving uptake and sustaining intervention outcomes.

AUTHOR CONTRIBUTIONS

Joanna Brooks is the corresponding author and led the qualitative analysis and drafting of the manuscript. Helen Ruane undertook the research interviews and provided feedback on drafts of the manuscript. Sarah McDiarmid recruited patients to the study, delivered the interventions, collected quantitative data for the main MIDDAS study and provided feedback on drafts of the manuscript. Avni Vyas recruited patients to the study, delivered the interventions, collected quantitative data for the main MIDDAS study and reviewed this manuscript. Basil Issa co-led on design and management of the overall study and this embedded qualitative study and reviewed this manuscript. Michelle Harvie co-led on design and management of the overall study and this embedded qualitative study, contributed to the qualitative analysis and provided feedback on drafts of the manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors declare that they have no competing interests. Néstle Health Science, as the funder of the trial, is also the manufacturer of the nutritional products used in the trial. Oviva provided the smartphone application used on the trial.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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