

DR LUCIA REHACKOVA (Orcid ID : 0000-0003-4099-7899)

PROFESSOR ROY TAYLOR (Orcid ID : 0000-0001-6273-0170)

DR PROF MIKE LEAN (Orcid ID : 0000-0003-2216-0083)

MR GEORGE THOM (Orcid ID : 0000-0002-8871-9524)

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Delivering the Diabetes Remission Clinical Trial (DiRECT) in primary care: A mixed-methods study of experiences of health care professionals.

Lucia Rehackova¹, PhD., Roy Taylor², Prof., Mike Lean³, Prof., Alison Barnes⁴, Ms., Louise McCombie³, Ms., George Thom³, PhD, Naomi Brosnahan³, PhD, Wilma S. Leslie³, PhD., Falko F. Sniehotta^{1†}, Prof.

Affiliations

1. Policy Research Unit Behavioural Science, Population Health Sciences Institute, Newcastle University UK
2. Magnetic Resonance Centre, Translational and Clinical Research Institute, Newcastle University, UK
3. Human Nutrition, School of Medicine Dentistry and Nursing, University of Glasgow, Scotland.
4. Human Nutrition Research Centre, Population Health Sciences Institute, Newcastle University UK
5. Policy Innovation Research Unit, London School of Hygiene and Tropical Medicine, London, UK

Corresponding author:

† Faculty of Behavioural, Management and Social sciences (BMS), Twente University.

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Dr. Lucia Rehackova
Magnetic Resonance Centre
Campus for Ageing and Vitality
Newcastle upon Tyne
NE4 5PL, UK

Policy Innovation Research Unit
London School of Hygiene and Tropical Medicine
London, UK
lucia.rehackova@newcastle.ac.uk

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Novelty statement

- The Diabetes Remission Clinical Trial (DiRECT) achieved sustained remission of type 2 diabetes (T2D) in primary care over 2 years. We report on healthcare professionals' (HCPs) experience with DiRECT delivery.
- Trust of HCPs towards the research team, perceived credibility of the study, and HCPs' personal beliefs were important in adoption of DiRECT, while ongoing training and support infrastructure facilitated its implementation.
- Withdrawing anti-diabetes and anti-hypertensive medications was challenging.
- Involvement in DiRECT inspired changes in the treatment of other people with T2D in routine practice, with more focus on behaviour modification.
- Recommendations for future scale-up are made based on these findings.

Abstract

Objective: The Diabetes Remission Clinical Trial (DiRECT) used a formula total diet replacement programme followed by structured weight loss maintenance to induce and sustain weight loss and remission of type 2 diabetes in 36% of participants after two years. Nurses and dietitians delivering DiRECT in 22 primary care practices in Tyneside and Scotland provided behavioural support to participants. Participant experiences with DiRECT highlighted the key role of support by healthcare professionals (HCPs). We evaluated HCPs' experiences with DiRECT. **Research Design and Methods:** HCPs delivering DiRECT were interviewed at 12 months, while GPs were sent an implementation questionnaire. The interviews were analysed thematically. The questionnaires were analysed using frequencies and a narrative synthesis. **Results:** HCPs representing 11 out of 22 intervention practices were interviewed and 10 out of 22 GPs completed questionnaires. HCPs' initial concerns over perceived potential negative intervention effects, particularly withdrawing anti-diabetes and anti-hypertensive medications, were barriers to engagement. Trust of HCPs towards the research team and perceived credibility of the study facilitated engagement and adoption.

Ongoing support by research dietitians was key to the management of participants.

Involvement in DiRECT inspired more focus on behaviour modification in the treatment of other people living with type 2 diabetes in routine practice. **Conclusions:** DiRECT was considered highly appropriate for the management of type 2 diabetes in primary care when supported by trained dietitians. Addressing limitations, including varying training needs of HCPs may improve intervention scale-up and tailoring to clinical contexts.

Keywords:

Diabetes remission, evaluation, implementation, healthcare professionals, general practitioners, mixed methods.

Introduction

Remission of type 2 diabetes can be achieved and sustained through substantial weight loss using a structured 3-phase programme including formula total diet replacement stage (TDR), stepped food reintroduction (FR) and weight loss maintenance (WLM), all underpinned by behavioural support, delivered in primary care ¹⁻³. The Diabetes Remission Clinical Trial (DiRECT) allocated 49 primary care practices to standard diabetes care, or to an intervention of 12-20 weeks of TDR (825–853 kcal per day, Counterweight PRO800 provided by Cambridge Weight Plan), followed by 6-8 weeks of FR, and structured support for WLM for 2 years ⁴. T2D remission was achieved in 46% and 36% of intervention participants at 12 and 24 months, respectively ^{1,2}. In England, a pilot programme is under way to offer similar remission programmes to 5,000 people with type 2 diabetes within the National Health Service (NHS) ⁵, with similar steps being taken by NHS Scotland ⁶.

Some challenges around translation of type 2 diabetes remission research into clinical practice could be overcome by evaluation of experience of healthcare professionals (HCPs) to inform the most effective approaches to implementation ⁷. A qualitative evaluation of participant experiences with DiRECT concluded that while the intervention was challenging,

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significant weight loss and increased physical and psychological well-being provided ongoing motivation needed to overcome difficulties including tiredness, hunger, and fluctuations of weight and behaviour in most participants⁸. To better understand the challenges and facilitators of implementation of DiRECT in primary care at individual and practice levels, and to improve the chances of a successful rollout, we evaluated the views of HCPs involved in the delivery of DiRECT.

Methods

Intervention description

DiRECT was a cluster-randomised control study, with general practices (GP) in the North East of England and across Scotland as units of randomisation. DiRECT recruited 306 participants aged 20-65 years with a BMI of 27–45 kg/m² diagnosed with type 2 diabetes within previous 6 years. The intervention was designed to achieve and maintain weight loss of ≥15kg. A weight gain of more than 2kg during the WLM phase would trigger an optional relapse treatment (RT)⁴.

HCPs delivering DiRECT were either practice nurses or dietitians who received an initial 8-hour structured training on the TDR and FR phases of the Counterweight-Plus programme and trial procedures, delivered one to one⁴. This was later followed by a 4-hour programme covering longer-term WLM. Open telephone, email, and text support by DiRECT research associates (RAs, registered dietitians) was available to HCPs throughout training and delivery of DiRECT. HCPs were provided practitioner educational materials for each stage of the intervention. Mentoring was provided by the RAs until the HCPs felt confident in independent intervention delivery. The full protocol of DiRECT and baseline characteristics of the participants have been published^{4,9}. The intervention has been summarised in a TiDier checklist⁸. Control participants received best practice diabetes management

according to guidelines from NICE ¹⁰ and SIGN ¹¹. Ethical approval was obtained from the West of Scotland Research Ethics Committee (reference number: 13/WS/0314).

Study design

This was a pragmatic, mixed-methods study embedded in the DiRECT cluster-randomised trial combining qualitative interviews with a questionnaire to maximise data collection efficiency and minimise participant burden. Practice nurses or dietitians were interviewed approximately 12 months after they started delivering DiRECT. All interviews were semi-structured, audio recorded, and transcribed. A short implementation questionnaire was sent to GPs after completion of 12 months of the intervention. Participation was voluntary. No incentive was provided to participants.

Participants and sampling

a) GP questionnaire

GPs from intervention practices were involved in the decision for the practice to participate and gave clinical approval to withdraw anti-hypertensive and anti-diabetic medications from participants as per protocol ⁴, but not in intervention delivery. They were sent an online implementation questionnaire (Appendix 1) directly by the principal investigators (RT, ML) by email. The questionnaire consisted of 9 closed and 3 open-ended questions on GPs' views of DiRECT; their experiences with its implementation; and any changes observed in participants or in their own practice as a result of participation in DiRECT. The questionnaire designed and distributed through Qualtrics software ¹², where anonymous responses were also collected.

b) Interviews with HCPs delivering the intervention

We aimed to recruit 10-14 HCPs across Tyneside and Scotland. The interviews were conducted at 12 months to enable reflection on HCPs' experiences delivering all three phases (TDR, FR, WLM) of DiRECT. The purpose of the interviews was to learn about

HCPs' engagement with the intervention and to identify challenges and facilitators of its delivery. DiRECT recruited 86 intervention participants from 14 practices in Scotland and 71 participants from 8 practices in England. Practices participating in this embedded study were selected at random, using Sealed Envelope ¹³, matched by the number of participants HCPs were managing. If there were multiple HCPs delivering DiRECT at one practice, only one of them was randomly selected. If a HCP was not willing to be interviewed (low numbers of managed participants, perceived lack of experience), a replacement practice with the highest number of participants was contacted instead to ensure richness of data.

Interview procedure

After random selection of practices and HCPs to be interviewed, the interviewer (LR) sent a consent form and an information sheet to HCPs by email before contacting them by telephone. LR had no prior contact with the interviewed HCPs. Interviews were semi-structured and conducted either face-to-face at the participating practices or over telephone. Practices were reimbursed to compensate for 90 minutes of HCPs' time scheduled for the interviews as part of the project funding by Diabetes UK.

Interview documents

A pilot interview was conducted with one HCP to refine the topic guide. This indicated that HCPs would best be interviewed after they had more experience delivering the full intervention. Interview topic guides included questions about HCPs' experiences with their training and mentoring; delivery of the intervention; and perceptions of DiRECT participants' experience with the intervention (Appendix 2). Field notes were made to facilitate the interviews and data analysis.

Analysis

GP questionnaire

Descriptive statistics and frequencies were used to analyse the questionnaire data, and a narrative synthesis was used to analyse answers to open-ended questions. The data were managed in SPSS v27 and Microsoft Excel v.16 softwares.

Interviews with healthcare professionals

All interview recordings were professionally transcribed and anonymised, retaining a code consisting of a random order number and study site for the purposes of a potential subgroup analysis. We used thematic analysis to analyse the transcripts¹⁴. We then continued the process of familiarisation with data by first re-reading and hand-coding hard copies of the transcripts. Full coding was facilitated by NVivo12 software¹², where the data was managed. Initially identified themes were refined and reviewed. Coding within each theme was further reviewed separately, and drawings were used to develop understanding of the themes and associations between them. The coding process and identified themes were discussed in the team (LR, FFS, RT, ML). The coding, themes, hierarchy and relationships between them, as well as interpretations in light of the existing participant narratives^{8 b} were refined during write up. Experiences of HCPs delivering the intervention were validated against the GP questionnaire, and areas that were complementary, dissonant, or overlapping are reported.

Results

The implementation questionnaire was sent to 22/23¹ (95.7%) GPs. Out of these, 19/22 (86.4%) GPs started the survey, and ten (45.5%) GPs completed it. Nine GPs (41%) did not provide any data after opening the questionnaire. Due to the anonymous nature of the questionnaire, we were unable to compare the views of GPs from the 2 study areas (Tyneside/Scotland). Table 1 summarises the questionnaire data. We also conducted a narrative synthesis of answers to open-ended questions.

¹ One out of 23 recruited practices did not recruit any participants by the time of interviews taking place.

One HCP interview was used to pilot the interview guide. Five practices in Tyneside and six in Scotland were then selected for HCP interviews. Two practices in Scotland were replaced because the HCPs did not feel confident to give an interview due to managing too few participants. Overall, ten HCPs were interviewed, representing eleven out of twenty-two (50%) participating intervention practices with recruited participants (5 out of 8 practices in Tyneside, excluding the pilot practice; 6 out of 14 practices in Scotland), and accounting for seventy-eight participants (43 in Tyneside, 35 in Scotland) at the time of interviews (Table 2). All HCPs were women. One interview was conducted over telephone, nine were conducted face to face. Interviews took between 45 and 86 minutes overall, with a median of 63 minutes. The median duration of interviews was 51 minutes (45-86 minutes) in Scotland and 68 minutes (58-73 minutes) in Tyneside.

The questionnaire and interview data were combined in the narrative of HCPs' experiences with implementation of DiRECT. We identified three themes related to adoption, delivery, and other intervention impacts: 1) The role of trust of HCPs towards the research team and credibility of the study in engagement and adoption of the intervention; 2) Support infrastructure facilitating intervention delivery, and 3) Observed changes resulting from participation in DiRECT.

Barriers and facilitators in engagement and adoption of DiRECT

The extent to which healthcare professionals engaged with DiRECT appeared to vary across practices. Trust of HCPs towards researchers involved in DiRECT and credibility of the study helped resolve the tension between HCPs' curiosity about the intervention, and concerns about the intervention's effectiveness and participants' health.

Novelty of the intervention facilitating interest from HCPs

Being an early adopter of DiRECT, if proven a successful intervention, was perceived as providing a competitive advantage, a sense of achievement in terms of care provision, and service and skill development.

“It was a great opportunity professionally for the members of the team to develop and, I suppose reputationally for us to be involved in a trial that was hopefully going to be very effective” (HCP 2, Scotland).

Some saw DiRECT as an intervention that could fill the gap in availability of treatments for people who did not qualify for bariatric surgery, and for whom weight management using a behaviour change approach on its own did not work, helping their service to widen their treatment options.

“The use of orlistat and use of very low-calorie diets were a couple of areas within the recommended potential options some places were not offering. But the fact we would participate in this pilot meant that we did have the ability to do that“ (HCP 5, Scotland).

Medical concerns and personal beliefs as barriers to adoption of DiRECT

Despite their general interest in the study, many HCPs were initially sceptical about the intervention’s potential effectiveness. Their reservations usually stemmed from beliefs about formula low energy diets, or diets producing significant weight losses within a relatively short time.

“It’s quite controversial in terms of the intensity and kind of goes against current guidance in a certain respect in terms of the traditional weight loss” (HCP 1, Scotland).

HCPs noted one of participants’ main reasons for taking part in the study was the possibility to reduce or stop anti-diabetic, anti-hypertension and other medications causing them negative side-effects, explaining the strength of their motivation for T2D remission.

“The number one thing everybody says is that they wanted to treat their diabetes. They didn’t want to be on medications. So that was a big pull that they could be taken off their medication” (HCP 2, Scotland).

However, taking participants off anti-diabetic and anti-hypertensive medications was one of HCPs' major concerns. Some were apprehensive and scared to do it due to worries over potentially serious impacts on participants' health.

"You are talking about taking these patients off their medication and then replacing their diet with soups and shakes to the tune of 800 calories a day and you're thinking "my god, is this going to work, are we going to get a lot of people who are unwell". I've been a practice nurse for 35 years and the thought of removing somebody off their diabetic medication was scary stuff" (HCP 3, Tyneside).

"[Stopping blood pressure medication] frightened me more than stopping diabetic meds, because the diabetic meds you could always put back on, but if their blood pressure went up, they could have a stroke, and I was like "oh my god, we're stopping these diabetic meds, these hypertension meds and the implications of doing that" (HCP 5, Tyneside).

Similar concerns were, to some extent, reflected in the GP questionnaire. Most GPs found stopping all oral anti-diabetic medications slightly (n= 5/10) or moderately (n=2/10) challenging, while 3/10 GPs did not find this challenging at all. Stopping all oral hypertensive medications was also perceived as slightly (6/10) or moderately (2/10) challenging, while 2/10 did not find this challenging at all.

While considered an opportunity to test a different approach to weight and type 2 diabetes management by some HCPs, others found it too challenging an idea, conflicting with more established approaches to weight loss, which seemed to affect engagement of healthcare staff.

Evidence provision and trust-building as facilitators of intervention adoption

The balance between the HCPs' motivation to help people living with type 2 diabetes, and negative beliefs about rapid weight loss using TDR and concerns about medication withdrawal seemed to have affected the initial engagement and adoption of DiRECT.

Perceived peer disapproval experienced by some HCPs may have contributed to cautious engagement.

“You weren’t getting the support from your colleagues because they are all thinking you are going mad. “You are taking metformin off them [participants]. Do you think that is wise? You have a responsibility here” (HCP 3, Tyneside).

Established long-term working relationships between some HCPs and members of the DiRECT team fostered professional trust, and the study’s backing by Newcastle and Glasgow Universities, together with the provision of evidence of efficacy of formula total diet replacement lent the research credibility that helped HCPs overcome some of the initial concerns.

“When I heard his [principal investigator’s] presentation and the idea of what he’d discovered with his first trial, the Newcastle Study, and he talked about that and the changes he’d noticed within the pancreas and the liver in that, that I must admit was the seeing his picture, images of the change in, the rapid change, in the fatty infiltration of the pancreas, that absolutely persuaded me” (HCP 4, Scotland).

Engagement with the team before the study helped HCPs clarify any questions and get reassurance. The process of engagement of HCPs and adoption of the intervention in the context of more conservative treatments for obesity and lack of explicit clinical recommendations for it is exemplified in the quote below.

“We were reluctant, with a lot of questions about using a dietary replacement approach because it is not a first line for dietitians... From speaking to the team who put together Counterweight Plus, we have really good long-term, I mean over a career long-term, working relationships with [research dietitian], and a sense of professional trust in what they do, and we know that what they do is evidence based and it wouldn’t be the same sort of thing. We knew it was something different. So we learned more about DiRECT and the fact Professor Taylor and Professor Lean were involved in it, and because it was ratified by the university as well, it seemed like this is something different to get involved in” (HCP 2, Scotland).

All GPs were “extremely satisfied” with the experience of their practice participating in DiRECT. Most GPs also found implementation of the intervention extremely (n=6/10) or somewhat (n=3/10) easy, 1 found it neither easy nor difficult. Most GPs (n = 9/10) found the intervention extremely appropriate as a diabetes management strategy.

Support infrastructure facilitating intervention delivery

Training and mentoring of HCPs by research dietitians

GPs reported “Adequate [research] dietitian support was what made it low impact on practice workload” (GP7). The support included training HCPs in intervention delivery, ongoing mentoring, and shadowing, which enabled HCPs to observe intervention delivery in practice. It also helped HCPs gain confidence in intervention delivery skills, and address challenges with participant adherence and with other individual dietetic and behavioural needs. This was an important element of the intervention, mostly to HCPs who had not been previously trained Counterweight Plus, and those who were not dietitians. The learning outcomes for HCPs previously trained in Counterweight-Plus were mostly familiarisation with the protocol and learning about the differences between Counterweight Plus and DiRECT rather than learning about the intervention content, while others reported learning a lot about behaviour change, weight management, communication, and participant management.

“Other dietitians, if they were not diabetes trained, or they had not done the Counterweight Plus, would definitely gain a massive amount of experience” (HCP 5, Scotland, previously trained in Counterweight Plus).

“The first session of training we had was quite intensive, it was quite a lot to take in all at once” (HCP 4, Tyneside, not previously trained in Counterweight Plus).

Three out of ten GPs found fitting the intervention into routine practice (e.g., regarding time, resources, preparation, supply etc.) very (n=1) or moderately (n=2) challenging, and a few (3/10) indicated moderate effort was required to keep participants engaged.

Compared to Tyneside, where none of the HCPs reported having been trained in Counterweight Plus before engaging in DiRECT, four out of five HCPs in Scotland had been delivering Counterweight Plus as part of their weight management service. This likely made it easier for trained dietitians to adopt DiRECT in their practices with more confidence.

Availability of ongoing support of HCPs by research dietitians facilitating participant management

Participant experiences with DiRECT highlighting fluctuations of psychological effort and perceptions of WLM as more challenging than the TDR³ were echoed by HCPs' narratives. TDR provided a simple routine and a break from solid food. The perspectives of HCPs aligned with our previous findings about participant difficulties letting go of the sense of security and control TDR provided⁸.

"The patients were anxious about reintroducing food because the shakes were very secure. The biggest decision you would have to make in a day was what flavour you were going to have, whereas all of a sudden, when we introduced food, it was like well what am I going to have, how am I going to cook it, what calorific value is it, what portion do I need it to be" (HCP 3, Tyneside).

"Many didn't want to finish the shakes...and then when they started the food reintroduction there was that inevitable weight gain, and I think that knocked us all" (HCP 4, Scotland).

It seemed easier for HCPs to provide support and guidance during the TDR, when participants' motivation was high, outcomes were nearly immediate, and the difference between adherence and non-adherence was clear, which was rewarding for both sides. However, the FR and WLM stages were more challenging. To maintain weight loss, participants needed to learn about food composition, portion sizes, and make decisions about food and physical activity, a process that usually took about four months. This period often led to fluctuations in weight, psychological resourcefulness, and effort, which HCPs needed to manage to help participants maintain their weight within a 2-kilo range, otherwise triggering an optional Relapse Treatment (RT).

“[Weight maintenance] is the bit folk struggle with most and it’s difficult to keep on managing and to keep on encouraging and to keep them going. I think the weight loss is probably the easiest bit because everybody is so motivated” (HCP 3, Scotland).

Managing participants who had difficulties or negative views of themselves during WLM often included conversations about life events, social life, or emotions, which was sometimes perceived by HCPs as wearing. When participants struggled, some HCPs wondered whether it was their lack of skill or knowledge that contributed to participants’ lack of WLM. Ongoing support of research dietitians through shadowing and case-by-case advice provided additional resources to help with participants who HCPs found challenging to manage.

“[The support from research dietitians] has been very good. Very consistent and clear in how we delivered it and what was needed. I think [research dietitian] has been very reassuring and when she’s been present with patients, they’ve always sort of reacted well to her” (HCP4, Tyneside).

“[Research dietitian] sat in with me and I shadowed her a good few times before she even expected me to deliver anything. So that was good, that shadowing experience of [research dietitian]. I still benefit from that now which I’ll ask her to come in and see patients with me and being able to watch her and learn from her, not just at the beginning but now, is really helpful” (HCP 3, Scotland)

Similarly to participants’ experiences of continuous effort during WLM as they transitioned to regular food and social life, HCPs recognised the different socio-psychological influences they needed to help their participants manage.

“I thought initially that everybody would be really easy. I thought this would be the magic cure. They would lose that weight and they would just continue to maintain it, but it is not like that, because there are lots of other issues going on in people” (HCP 6, Tyneside).

The role of HCPs was to balance out the fluctuations in participants' weight and behaviour through monitoring and tailored support. Parts of the training programme for HCPs included motivational interviewing and person-centered behaviour change techniques enabling them to not only tailor the intervention to participants' circumstances, but to also encourage them to find solutions to their difficulties, potentially increasing participants' WLM self-efficacy.

“Some of the ways of discussing things with the patient where we've been trained to sort of ask questions an open question, that's been quite a good thing to learn as well and to practice that with them because that was something I didn't probably do enough. Letting them find their own solutions to problems or how they're going to overcome any problems with the diet, which was more to do with the management of the patient than really the diet side of things.” (HCP 4, Tyneside).

The support infrastructure, including the initial training, shadowing, and ongoing guidance seemed to facilitate adoption and implementation of DiRECT in practices, which might otherwise not have had the resources or professional capacity to offer the intervention. Once HCPs feel confident in intervention delivery, reliance on this support might decrease. Ongoing support was valuable as a source of experience and confidence in the management of participants during the WLM stage, which was more challenging than the TDR, for both participants and HCPs.

Observed changes resulting from DiRECT implementation

Seven out of ten GPs reported noticing changes in DiRECT participants, including increased motivation, confidence, mood, awareness of lifestyle factors contributing to development of type 2 diabetes, and increased control of it. DiRECT.

“Engagement varies over time. A degree of good patient behaviour seen amongst those who have stuck it out-they want to do well for the study team, possibly more than for themselves. But they see the differences and like them-energy, less meds, sense of control to some degree over their diabetes/life” (GP1).

Almost all GPs (9/10) reported working with DiRECT inspired changes in how they managed other people living with type 2 diabetes routinely (e.g., weight management approaches, drug prescriptions, allocation of resources, giving advice, change of opinions, attitudes, behaviour). The changes were described in terms of *“more focus on lifestyle/diet modification and the benefits it can bring”* (GP2). Some started providing *“increased lifestyle advice early on”* (GP3), advocated a *“stronger push for early weight loss in newly diagnosed type 2 diabetes”* (GP7), and promoted *“more focus and encouragement with weight loss as an initial or an additional treatment”* (GP10). One GP reported that *“other patients were keen to join in even if [they] did not meet study criteria and some would pay for their own supplements”* (GP5). It appears the intervention created a ripple effect to other people living with type 2 diabetes.

GPs thought the study was *“very enjoyable and rewarding”* (GP10) and reported that *“feedback from those involved had been positive”* (GP1). Some appreciated the rapid outcomes and thought it was *“great to have a research trial with immediate measurable benefit for the participants”* (GP7). Some praised the *“excellent supportive organised team”* (GP5), highlighting the importance of the involvement of a study dietitian.

HCPs reflected on how the skills and knowledge learned in DiRECT helped them manage other people with type 2 diabetes, or those at risk. DiRECT was also reported in the media around the time of the first year’s results, which seemed to have led to an increased interest in the intervention and in weight loss amongst people living with type 2 diabetes outside the study.

“My attitude to diabetes is completely different. I do actively encourage people to lose weight. I have told them about portion control on their plates. I am not saying you should go off and get some shakes, but I have initiated some of the things we use for food reintroduction into the way I treat normal diabetic patients now” (HCP 3, Tyneside).

“I have really enjoyed doing it and I think it has been good to put in practice in all of our new diabetics or patients of high risk of diabetes because it is nice to think patients can change

rather than adding medications. There has been lots on TV as well. I think that has been good for patients to see on TV and come back and say can I do this, and we have been reducing medications as well with those patients, so that has been fantastic to see” (HCP 2, Tyneside).

Having been involved in DiRECT had a positive impact on practices through the acquired skills HCPs were using in the management of other people with type 2 diabetes, as well as through the publicity the study received..

Discussion

We identified key challenges and facilitators of implementation for HCPs, which would likely affect success of the intervention delivered at scale.

HCPs’ concerns about withdrawal of anti-diabetic and anti-hypertensive medication at the beginning of the trial, and their preconceived ideas about complications of rapid weight loss were major barriers to initial engagement and adoption of DiRECT. Prevalence of people’s adherence with oral anti-diabetic medication is reported to be low and to vary widely, between 38-93%¹⁵. Reasons for non-adherence include concerns about side effects, dislike of medications, dislike of non-natural treatments, perceived inefficiency of long-term treatments, or lack of perceived symptoms of diabetes¹⁶. The possibility of reducing or stopping diabetes-related medication therefore provides strong motivation for people with type 2 diabetes to attempt remission¹⁷. However, we found the wish of people with type 2 diabetes to be medication-free was initially met with HCPs’ reluctance to withdraw medication due to concerns about potential harm, contributing to the existing discrepancy between views on medication use¹⁸. HCPs’ initial concerns were dissolved by provision of relevant research evidence for safety and efficacy of the intervention, clarity of information and structure of the programme, and availability of support infrastructure. The study protocol included a plan for medication withdrawal and reintroduction, but there is a need to discuss

medication use thoroughly with HCPs who may have reservations about safety of the intervention.

Personal approachability of DiRECT RAs and the principal investigators enhanced trust of HCPs towards the research team, lending the study additional credibility. We do not know the reasons for HCPs deciding not to get involved in DiRECT delivery which may have included lack of support by colleagues about use of TDR delivered under medical supervision, despite the increasing evidence of effectiveness and acceptability of this approach ^{1-3,8,19-22}. A report of lessons learned from implementation of the Diabetes Prevention Programme (DPP) in England found raising awareness of the programme was vital to the uptake of the intervention, suggesting a national campaign by the NHS at the right level and time might facilitate “brand recognition” ²³ and engagement of potential users and HCPs.

We found that HCPs trained in Counterweight Plus and those who were dietitians had an advantage of knowledge and experience with delivery of dietary interventions compared to practice nurses, for whom the training and mentoring programme appeared more valuable. A recent systematic review of HCPs’ perceived barriers and enablers of dietary management of adults with T2D in primary care found that while physicians and nurses felt confident giving dietary advice, there were gaps in their knowledge and skills. At the same time, the review identified service users’ reluctance to see dietitians in general, while highlighting that in the UK, nurses perceive dietary advice to be their responsibility, while the expertise of dietitians potentially remains under-utilised (26). Considering the type of HCP to deliver DiRECT in future implementation may be important in determining the resources needed for training and ongoing mentoring.

HCPs strongly valued the support infrastructure facilitating delivery of the intervention, DiRECT participants reported regularity and tailoring of clinical and behavioural support was important ⁸. A larger scale implementation might require a proportionate scale-up of the HCP support network. A mechanism for sharing of information and learning between experienced and novice HCPs, and between areas of provision may be beneficial ²³. An active

cooperation between researchers, implementers, and policymakers might help avoid potential deviations from protocol and reduced effectiveness of diabetes remission programmes if scaled up ²⁵, while allowing flexibility to adapt it to specific contexts that may vary by sites or regions ²⁶.

Limitations

Despite efforts to design the GP survey to be as concise as possible, only ten out of twenty-two (45.5%) GPs completed it. This means that some experiences may not have been represented in the results, and the views of GPs on implementation of DiRECT may need further exploration. Collecting more detailed information about the practices the GPs were serving could enable comparison of sites and improvement of the intervention.

GP practices reported the potential time commitment and staff needed if allocated to the intervention arm as the main barrier to participation (9). Understanding any other reasons for lack of engagement or uptake would help address concerns or needs of practices and HCPs that might facilitate implementation of DiRECT in primary care in the future.

Interviewing HCPs who felt more confident and experienced in the delivery of the intervention provided richness of data, however this may have led to under-estimation of the training needs reported by HCPs. About half of the HCPs delivering the intervention were dietitians, most of them previously trained in Counterweight Plus. It is likely that, should the intervention be scaled-up, with a higher proportion of nurses, more resources (e.g. time in mentoring, shadowing or on-call availability, number of trainers) may be needed to accommodate these learning and support needs, while potentially fewer resources may be needed with a higher proportion of dietitians delivering a DiRECT-style intervention.

Collecting data on time spent mentoring the different HCPs might provide further insights into their training and support needs.

The first-year results of the DiRECT study attracted media attention and were widely reported. The publicity may have affected the motivation, commitment, and experiences of not only the existing participants, but also of HCPs delivering the intervention. On the other

hand, the ongoing awareness of the possibility of T2D remission and interest from people with T2D as well as HCPs indicates an expectation of a positive uptake of the intervention during a wider implementation in the future.

Conclusions

HCPs reported DiRECT to be highly appropriate as a type 2 diabetes management strategy. Use of learned skills and knowledge was generalised to the management of other people with type 2 diabetes. This evaluation highlights the importance of professional relationships and trust, provision of clear and robust evidence, and ongoing support/mentoring of HCPs from experienced practitioners in adoption and implementation in primary care.

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Conflict of interest:

AB reports speaker honoraria from Novo Nordisk and Eli Lilly and unpaid programme content creation 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.

WL reports funding for conference attendance from Cambridge Weight Plan outside the submitted work.

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. General Practitioners' responses to DiRECT implementation questionnaire

Questionnaire item	N	Median	Range
How satisfied or dissatisfied were you with the experience of your practice participating in the DiRECT trial? (1 = Extremely dissatisfied - 5 Extremely satisfied).	10	5	0
How easy or difficult was implementation of the Counterweight-Plus intervention of dietary weight loss at your practice? (1 = Extremely easy - 5 = Extremely difficult).	10	1	2
Thinking about the intervention delivery, how did you find the following: - Stopping all oral anti-diabetic medications at the start of the weight loss period? (1 = Not challenging at all - 5 = Extremely challenging).	10	2	2

Thinking about the intervention delivery, how did you find the following: - Stopping all oral hypertensive medications at the start of the weight loss period? (1 = Not challenging at all - 5 = Extremely challenging)

10

2

2

Thinking about the intervention delivery, how did you find the following: - Fitting the intervention in your routine practice (e.g. time, resources, preparation, supply etc.) (1 = Not challenging at all - 5 = Extremely challenging).

10

2

3

How appropriate do you think the DiRECT intervention is as a diabetes management strategy? (1 = Extremely inappropriate - 5 = Extremely appropriate).

10

5

1

How much effort do you feel you have had to put into keeping participants in the programme? (1 = Far too little - 5 = Far too much).

10

3

1

Table 2. Summary of practices participating in healthcare professional interviews.

Participating practice ID	Site	Number of DiRECT participants managed by the interviewed HCP
1	Tyneside	4

2	Tyneside	13
3	Tyneside	13
4	Tyneside	2
5	Tyneside	11
6	Scotland	4
7	Scotland	9* (4 + 5)
8	Scotland	
9	Scotland	5
10	Scotland	11
11	Scotland	6
	Total number of managed participants	78

*One HCP serving two practices.

Appendix 1: An intervention implementation questionnaire for General Practitioners.

Q1 How satisfied or dissatisfied were you with the experience of your practice participating in the DiRECT trial?

- Extremely satisfied Somewhat satisfied Neither satisfied nor dissatisfied Somewhat dissatisfied
- Extremely dissatisfied

Q2 How easy or difficult was implementation of the Counterweight-Plus intervention of dietary weight loss at your practice?

- Extremely easy Somewhat easy Neither easy nor difficult Somewhat difficult Extremely difficult

Q3 Thinking about the intervention delivery, how did you find the following?

	Extremely challenging	Very challenging	Moderately challenging	Slightly challenging	Not challenging at all
Stopping all oral anti-diabetic medications at the start of the weight loss period?	o	o	o	o	o
Stopping all oral hypertensive medications at the start of the weight loss period?	o	o	o	o	o
Fitting the intervention in your routine practice (e.g. time, resources, preparation, supply etc.)	o	o	o	o	o

Q4 How appropriate do you think the DiRECT intervention is as a diabetes management strategy?

- Extremely appropriate Somewhat appropriate Neither appropriate nor inappropriate
- Somewhat inappropriate Extremely inappropriate

Q5 How much effort do you feel you have had to put into keeping participants in the programme?

- Far too much Moderately too much Neither too much nor too little Moderately too little
- Far too little

Q6 Have you noticed any changes, outside of the study outcomes, in the patients (e.g. attitudes or behaviour)?

- Yes No

Skip To: Q8 If Q6 = NO

Q7 Please describe the changes you have noticed.

Q8 Has working with DiRECT led to any changes in how you manage other patients with type 2 diabetes routinely? (e.g. weight management approaches and emphasis, drug prescriptions, allocation of resources and staff, giving advice, change of opinions, attitudes, behaviour).

- Yes No

Skip To: Q10 If Q8 = NO

Q9 Please describe the changes in your own or your colleagues` practice as a result of the intervention implementation and being involved in the study.

Q10 Please use this space to write any further comments or suggestions you would like to make.

This is the end of the survey. Thank you for your answers.

Appendix 2: Topic guide for healthcare professionals delivering the DiRECT intervention

Thank you again for agreeing to take part in this interview, I am pleased that you are able to help. The first part of this interview focuses on your views of the study and your experience with the training provided, and the second part focuses on your experience with delivering the intervention.

Introductory question

- 1) How did you get involved in the DiRECT study?
- 2) Why did you get involved in the DiRECT study?

Training –related questions

- 3) Tell me about your experience with the training provided for the TDR stage of the DiRECT intervention (Prompts: intensity, length, pace, staff interaction, support)
- 4) What was your experience with the training provided for the FR stage of the intervention? (Prompts: intensity, length, pace, staff interaction, support)
- 5) What was your experience with the training provided for the WLM stage of the intervention? (Prompts: intensity, length, pace, staff interaction, support)
- 6) How appropriate was the training to prepare you to use the provided resources? (Prompts: Flipchart, Appointment planner, Practitioner workbook, Intervention protocol, Are they user-friendly? Has using them become a routine?)
- 7) Would you suggest any changes to the training you received in order to deliver the intervention? (What would that be and why?)
- 8) Would you suggest any changes to the intervention materials? If yes, what would they be?
- 9) Would you suggest any changes to any of the three stages of the intervention? If yes, what would they be?

Mentoring –related questions

5. How did you find the mentoring and the ongoing support provided by the study dietitian? (Prompts: confidence in delivery, usefulness, helpfulness)

Delivery-related questions

- 6) What has your experience been with delivering of the low-calorie diet? (Prompts: barriers/facilitators, managing challenging situations; confidence in delivery?)
- 7) What has your experience been with stopping the medication at the start of the diet? (Prompts: concerns, practical problems, patient responses/satisfaction)
- 8) What has your experience been with reintroducing food after the low-calorie diet? (Prompts: barriers/facilitators, managing challenging situations; confidence in delivery?)
- 9) On reflection, how does the actual delivery of the TDR and FR stages differ from your prior expectations?
- 10) What are your experiences with delivering the WLM intervention so far? (Prompts: barriers/facilitators, managing challenging situations; confidence in delivery, motivation?)
- 11) On reflection, how does the actual delivery of the WLM stage differ from your prior expectations of it?
- 12) How does delivery of the WLM stage differ from the TDR and FR stages of the intervention?
- 13) How does delivering the intervention fit with your routine practice? (competing tasks, time constraints, need for preparation, practical resources)
- 14) What do you think of the TDR as a diabetes management intervention? How does the low calorie approach compare to other weight loss options available to your patients?
- 15) What do you think of the WLM as a diabetes management intervention? How does the structured WLM approach compare to other WLM options available to your patients?
- 16) What procedures or ways of working have helped the GP practice implement this intervention? Would there be anything else the practice staff could do?

Participant-related questions

- 17) From your experience, what type of patients agree to take part in the study? What did the patients enquire about before making the decision to take part?

- 18) Have you noticed what type of patients benefit most from the intervention? What type of person benefits the least?
- 19) Do you have an impression of who will or will not be successful on this programme early on?
- 20) Have you noticed any facilitators or barriers to following the TDR or the WLM (e.g. language, literacy, education, sex, culture, influence of spouse/partner)?
- 21) Have you had any patients who struggled with following the TDR or the WLM? How do you manage them? How confident do you feel in providing support in challenging situations?
- 22) How much effort do you feel you have put into keeping participants in the programme? What did you do and what was the result? Do you keep a log of these actions?
- 23) Do you receive any feedback on the intervention delivery (DiRECT staff, patients, colleagues)?
- 24) Have you noticed any changes (outside of the study outcomes) in the patients' attitudes or behaviour and what were these?
- 25) Have you made use of the flexibility of the programme during any of the stages of the intervention? (Prompts: time off, non-starchy veg, home-made food etc..). How, and how did it work?

QUESTIONS related with potential changes to practice

- 26) Has anything in the study or during the intervention delivery led to changes in your own practice, or the practice of your colleagues generally? Prompts: giving advice, weight management approach; change of opinions, attitudes, behaviour)

END of interview. Thank you for your time today.