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Synopsis

Evaluation of the NHS England Low-Calorie Diet implementation pilot: a coproduced mixed-method study

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Abstract

Background: National Health Service England piloted a low-calorie diet programme, delivered through total diet replacement and behaviour change support via 1 : 1, group or digital delivery, to improve type 2 diabetes in adults with excess weight.

Aim: To coproduce a qualitative and economic evaluation of the National Health Service low-calorie diet pilot, integrated with National Health Service data to provide an enhanced understanding of the long-term cost-effectiveness, implementation, equity and transferability across broad and diverse populations.

Research questions: What are the theoretical principles, behaviour change components, content and mode of delivery of the programme, and is it delivered with fidelity to National Health Service specifications? What are the service provider, user and National Health Service staff experiences of the programme? Do sociodemographics influence programme access, uptake, compliance and success? What aspects of the service work and what do not work, for whom, in what context and why? Can the programme be improved to enhance patient experience and address inequities? What are the programme delivery costs, and policy implications for wide-spread adoption?

Methods: A mixed-methods study underpinned by a realist-informed approach was delivered across five work packages, involving: semistructured interviews with service users (n = 67), National Health Service staff (n = 55), service providers (n = 9); 13 service provider focus groups; and service user surveys (n = 719). Findings were triangulated with clinical data from the National Health Service England's first cohort analysis (n = 7540).

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Ells LJ, Brown T, Matu J, Clare K, Rowlands S, Maynard M, *et al.* Evaluation of the NHS England Low-Calorie Diet implementation pilot: a coproduced mixed-method study. *Health Soc Care Deliv Res* 2025;**13**(29). https://doi.org/10.3310/MPRT2139

Results: Fifty-five per cent of service users who started total diet replacement completed the programme and lost an average of 10.3 kg; 32% of those with data available to measure remission achieved it. Examination of programme mobilisation identified barriers around referral equality and the impact of COVID-19, while effective cross-stakeholder working and communication were key facilitators. Service delivery and fidelity assessments identified a drift in implementation fidelity, alongside variation in the behaviour change content across providers. Perceived barriers to programme uptake and engagement aligned across service providers and users, resulting in key learning on: the importance of person-centred care, service user support needs, improvements to total diet replacement and the social and cultural impact of the programme. Early National Health Service quantitative analyses suggest some socioeconomic variation in programme uptake, completion and outcomes. Insights from the evaluation and National Health Service data were combined to develop the programme theory and underpinning context, mechanisms and outcomes. These were used to develop a list of recommendations to improve the cultural competency of programme delivery, total diet replacement delivery, peer support and address psychological support needs. Cost-effectiveness analyses using short-term follow-up data indicated there is potential for the programme to be cost-effective, but not cost saving.
Conclusions: The National Health Service low-calorie diet can provide a clinically effective and potentially cost-effective programme to support weight loss and glycaemic control in adults with type 2 diabetes. However, this evaluation identified areas for improvement in referral equity, uptake and completion, and fidelity of delivery, which have informed the development of the programme, which has now been rolled out nationally. Ongoing programme monitoring and long-term follow-up are now required.
Future work and limitations: The real-world setting limited some data collection and analysis. Future work will focus on the analysis of long-term clinical and cost-effectiveness, and addressing inequalities.
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Introduction

Rationale for research and background

Type 2 diabetes (T2D) is now one of the leading causes of death globally, and it affects millions of people in the UK.[1,2] Currently, over a quarter of adults in England live with obesity:[3] the most significant risk factor for developing T2D.[4] However, obesity and T2D do not affect all populations equally, with higher prevalence in older age groups, those living in area-level deprivation, and people of black and South Asian ethnicity.[5] It is estimated that the NHS and wider societal costs associated with obesity and diabetes will continue to accelerate unless urgent action is taken.[4] The NHS long-term plan[6] therefore pledged to provide targeted support, and access to weight management services in primary care for people with a diagnosis of T2D and a body mass index (BMI) of ≥ 27 (adjusted appropriately for ethnicity), with the aim of significantly improving health, reducing health inequalities and cutting associated NHS costs.

The most recent trial[7–11] systematic[12,13] and narrative review[14] evidence has shown that a low-calorie diet (LCD) achieved by total diet replacements (TDRs) can lead to clinically significant weight loss and support remission of T2D. Based on evidence from two large UK trials [Doctor Referral of Overweight People to Low Energy total diet replacement Treatment (DROPLET) and Diabetes Remission Clinical Trial (DiRECT)],[7,10] a commitment was made by the NHS to pilot a LCD programme delivered through TDR with behaviour change support, for people living with overweight/obesity and T2D. This pilot programme was launched in 2020, initially across 10 sociodemographically diverse Integrated Care Board (ICB) areas (wave 1), with a further 11 ICB areas added in 2022 (wave 2). The pilot was delivered by a range of commercial service providers, commissioned through NHS procurement processes to provide a service aligned to a standard service specification. A summary of the programme is provided in *Figure 1*, but in brief: adults (18–65 years) residing in the pilot ICB localities, with a recent (< 6 years) diagnosis of T2D and a BMI of ≥ 27 (adjusted appropriately for ethnicity) who did not meet the NHS exclusion criteria (which includes use of insulin, active cancer, eating disorder, heart failure, renal impairment, bariatric surgery, or an inability to follow or attend the programme) were eligible to be referred through primary care. Once referred, service users received an initial assessment (IA), then commenced the programme of 12 weeks TDR, followed by 4–6 weeks of food reintroduction (FR), then weight maintenance (WM) support until the end of the programme (52 weeks). Behaviour change support was delivered via one of three delivery models: 1 : 1, group or digital delivery [where each area was allocated one delivery model and one commissioned service provider (SP)]. As the programme was launched during the COVID-19 pandemic, 1 : 1 and group support was initially delivered remotely, with in-person delivery tested from 2022 in wave 2.

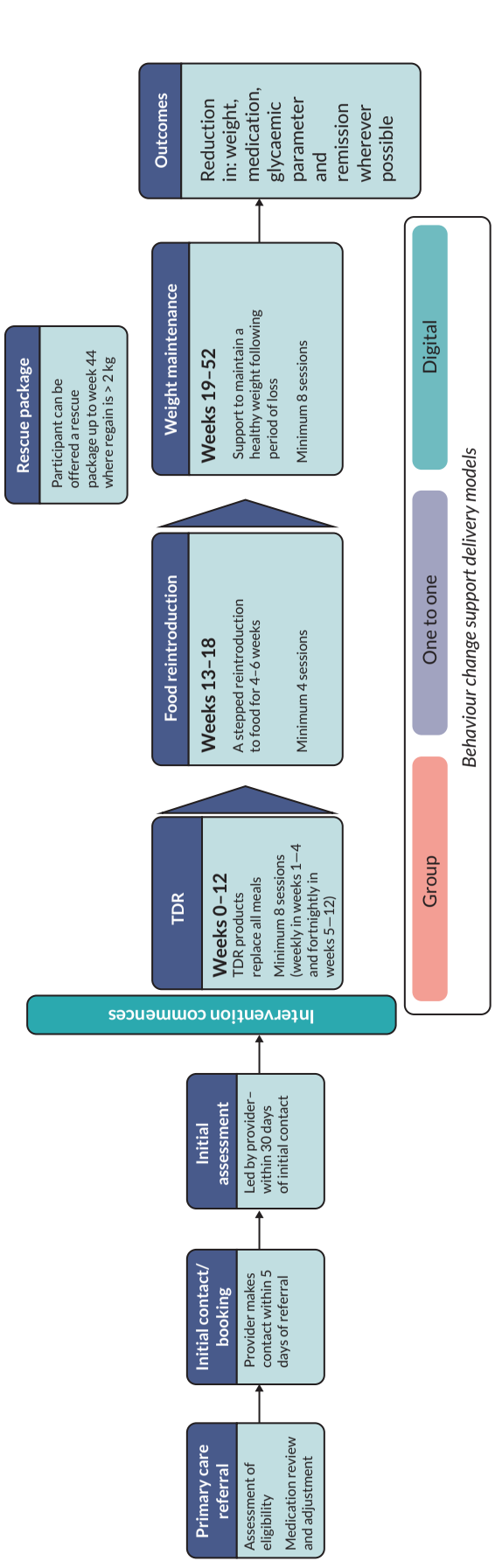

FIGURE 1 An overview of the NHS LCD programme.

A comprehensive evaluation of the translation and implementation of the LCD intervention into real-world practice was critical, particularly given the lack of diversity in ethnicity (primarily white), SPs (only Counterweight/ Cambridge Weight Plan) and behaviour support models (only one-to-one support) within the underpinning trials. The Re:Mission study reported here provides the outcome of this independent evaluation funded by the National Institute for Health and Care Research (NIHR) Health Service and Delivery Research stream.

Aim

To deliver a coproduced, comprehensive qualitative and economic evaluation of the NHS LCD pilot, that will be integrated with the NHS England (NHSE) quantitative analyses, to provide an enhanced understanding of the long-term cost-effectiveness of the programme and its implementation, equity, transferability and normalisation across broad and diverse populations.

Objectives

Each objective is assigned to a designated work package (WP):

1. assess different providers' experiences of the programme, including any barriers and facilitators to implementation across the different populations (WP2)
2. assess the experiences and attitudes of NHS staff involved in mobilising the programme across each pilot area and referring and supporting patients on the programme, and their opinions on the management of the programme implementation (WP2)
3. assess patients' experiences of the programme: including patients with a range of sociodemographics (e.g. socioeconomic status, ethnicity, sex, start BMI), and with differing engagement experiences (e.g. adhered to, or dropped out of the programme) within each of the different delivery models, to gain insight into what worked, and what did not, for whom and why, and how the programme could be improved in the future (WP3)
4. estimate the long-term cost-effectiveness of each NHS LCD delivery model [in terms of incremental cost per quality-adjusted life-year (QALY)] when compared to a counterfactual scenario, including how this varies by delivery model, to enable comparisons with other demands on healthcare resources and thus support commissioning decisions (WP4)
5. assess national roll-out of the NHS LCD through a transferability and policy impact assessment (WP5)
6. integrate findings from WP2 to WP5 with the quantitative analyses conducted by NHSE, using a realist-informed approach, to provide a comprehensive understanding of the programme implementation and impact, to inform future service development and commissioning (WP1).

Research questions and methods

A mixed-methods approach was undertaken involving documentary reviews, session observations, semistructured interviews, focus groups and surveys. These data were drawn together with findings from the NHSE clinical data analyses, using a realist-informed approach to understand what works, what does not work, for whom, why and in what context. A comprehensive description of the methods deployed within each WP is provided in the study protocol v6,[15] but a brief overview of the WP methods and associated research questions (RQs) is as follows, with a schematic presentation of the research pathway shown in *Figure 2*. Methods and learning from the associated study within a study programme (SWAP) are provided in *Appendix 1*.

Work package 1 project management, coproduction, patient involvement and dissemination

(1) facilitated liaison with all key stakeholders, NHSE and the LCD advisory and patient groups: ensuring that patient involvement and coproduction underpin every stage of each WP; (2) provided overarching project management: ensuring timely completion, cohesive working and quality assurance; (3) co-ordinated the interim and final evaluation reports: drawing together the evidence from WP2 to WP5 with NHSE quantitative analyses; (4) delivered a comprehensive programme of dissemination and communication.

Work package 2 service delivery and fidelity

Used a combination of documentary review session observations (two sessions observed from start to finish for each delivery model and provider); thematically analysed semistructured interviews with NHS staff (19 referral staff and 10 locality leads – 1 from each of the wave 1 pilot sites interviewed at years 1 and 2); focus groups with providers (n = 13); and additional semistructured interviews with 7 coaches from, or responsible for delivery to, diverse ethnic groups, to answer the following RQs:

> *RQ1 What are the theoretical principles, behaviour change components, content and mode of delivery of the programme, and how do these vary across sites and providers?*
> *RQ2 To what extent does the staff training delivered by each provider address behaviour change theory*

FIGURE 2 A schematic representation of the research pathway. PPI, patient and public involvement. DUK, Diabetes UK, ICB: Integrated Care Board; PPI, patient and public involvement; SU, service user; SP, service provider.

and content, and how does this vary across sites and providers?
RQ3 To what extent is the delivery of the NHS Low Calorie Diet delivered with fidelity to the specification as set out by NHSE?
RQ4 What are provider and NHS support staff experiences of the service, and what do they perceive to be the key barriers and facilitators to effective delivery, integration and normalisation into routine care?

Work package 3 service user experience and inequalities

Were underpinned by a pluralistic approach, undertaken using cross-sectional and longitudinal service user surveys (n = 719), semistructured thematically analysed cross-sectional (n = 37) and longitudinal (n = 30) interviews supported by adapted photovoice methodology. These findings will be aligned to, and integrated with quantitative process and outcome data from NHSE, to answer:

RQ5 To what extent is the content of the NHS Low-Calorie Diet understood and applied by service users?
RQ6 Do sociodemographic characteristics (such as sex, socioeconomic status and ethnicity) influence access, uptake, compliance and success on the NHS Low-Calorie Diet, and does this vary across the different (1 : 1, group or digital) behaviour change delivery models?
RQ7 What aspects of the service work and do not work, for whom, in what context and why?
RQ8 If effective, how can the service be improved in the future, to enhance service user experience and ensure any inequities are addressed?

Work package 4 Economic evaluation

Used patient-level simulation modelling to estimate the long-term cost-effectiveness of the NHS LCD (in terms of incremental cost per QALY) when compared to a counterfactual scenario. This enabled comparisons with other demands on healthcare resources and thus supported commissioning decisions, and included a micro-costing exercise for each of the three delivery models, to address:

RQ9 What are the costs of delivering the NHS Low-Calorie Diet programme from an NHSE perspective and how do they (i) differ across the different delivery models and (ii) compare to estimates provided in the DiRECT trial?
RQ10 What are the costs of the NHS Low-Calorie Diet programme to participants, and how do they differ by delivery model and service user-level characteristics?

These cost estimates were then used along with the patient-level demographic and clinical information collected over 12 months by NHSE as inputs in the patient-level simulation model to answer:

RQ11 What is the long-term cost-effectiveness of the NHS Low-Calorie Diet (in terms of incremental cost per QALY) when compared to a counterfactual scenario, and how does this vary by delivery model and patient characteristics?

We also compared the cost and short-term outcome data collected in this study with those from DiRECT, to enable comparison with the cost-effectiveness estimates, to answer:

RQ12 How does the cost and (short-term) outcome data collected in this study affect the estimates of cost-effectiveness in previous trials?

Work package 5 transferability assessment

Employed a theoretical model for the assessment of transferability and normalisation of health interventions to understand the role of the delivery context in influencing the implementation and service user outcomes, and the implications for widespread adoption of the programme. We undertook semistructured interviews with locality leads (n = 7), referrers (n = 9) and providers (n = 9) in sites involved in stage two of the pilot (whereby the programme was delivered in further 11 areas ahead of the national roll-out). Interviews were structured and thematically analysed according to constructs within the Population, Intervention, Environment, Transfer[16] conceptual model of transferability with emerging findings from WP2 to WP4 reflected upon during interviews. Similarities and differences between sites with respect to delivery models were also explored to address:

RQ13 What are the core elements of the intervention that are required to achieve impact?
RQ14 What elements can be adapted to suit local context?
RQ15 What are the policy implications for widespread adoption of the programme?

Results summary

A realist-informed framework was used to draw together learning across the study (see *Appendix 2*) to provide

a comprehensive understanding of the programme implementation and impact, as well as inform future service development and commissioning. The clinical outcome data from the first available cohort of service users analysed by NHSE using the LCD minimum data set (MDS)[17] are summarised in *Box 1*. These quantitative NHS findings were contextualised within key study findings from across the threaded publication series [Research Articles (RA) – see *Box 2*], which are presented under each WP and associated RQs below.

Higher remission rates were related to higher weight losses, lower starting glycated haemoglobin (HbA1c) and those with a more recent T2D diagnosis (< 1 year).

BOX 1 A summary of findings from the NHSE analysis of clinical outcomes from the first cohort of the LCD service users: September 2020 to December 2022

A summary of the clinical and sociodemographic outcome data from the first available cohort of LCD service users – provided by NHSE:[17]

- 7540 people were referred to the NHS LCD from September 2020 to December 2022.
- At referral:
  - 43% were men.
  - Average age was 50 years.
  - 19% were of Asian, 8% of black, 3% of mixed, 1% of other and 64% of white ethnicities.
  - 26% were from the least deprived areas and 14% from the most affluent.
  - 47% had been diagnosed with diabetes for < 1 year.
  - Average: weight was 109.2 kg, BMI 38 and glycated haemoglobin (HbA1c) was 58.5 mmol/mol.
  - 50% were taking one, 16% were taking more than one and 34% were not taking any glucose-lowering medication.
  - Younger adults, those diagnosed with diabetes 4–6 years before referral, of mixed ethnicity and from more affluent backgrounds, were more likely to start TDR.
  - Men, older adults, those with a BMI between 25 kg/m^2 and 29 kg/m^2 or of Asian, black or other ethnicity were less likely to start TDR.
- Of the 1740 people who started TDR and had sufficient time to complete the programme by December 2022:
  - 84% finished TDR.
  - 79% finished FR.
  - 55% completed the programme.
- Average time on the programme was 8 months.
- People who were more affluent, had a lower starting BMI (25–30) and aged 50–65 years were more likely to complete the programme.
- There were differences in completion rates between providers but not delivery models.
- People of Asian, black and mixed ethnicities lost a smaller proportion of their starting weight compared to those of white ethnicity.
- There were differences in weight change between provider and delivery models.
- Service users who had the required two HbA1c measurements to calculate remission rates revealed a remission rate of 32%.

Data extracted with permission from Valabhji *et al*.[17]

BOX 2 Threaded publications synthesised in this synopsis

RA1_WP1: Clare K, Ojo A, Teke J, Willis M, Akhtar G, Clegg B, *et al*. 'Valued and listened to': the collective experience of patient and public involvement in a national evaluation. *Perspect Public Health* 2022;**142**:199–201. https://doi.org/10.1177/17579139221103184

RA2_WP2: Evans TS, Hawkes RE, Keyworth C, Newson L, Radley D, Hill AJ, *et al*. How is the NHS Low-Calorie Diet Programme expected to produce behavioural change to support diabetes remission: an examination of underpinning theory. *Br J Diabetes* 2022;**22**:20–29. https://doi.org/10.15277/bjd.2022.341

RA3_WP2: Evans TS, Dhir P, Radley D, Duarte C, Keyworth C, Homer C, *et al*. Does the design of the NHS Low-Calorie Diet Programme have fidelity to the programme specification? A documentary review of service parameters and behaviour change content in a type 2 diabetes intervention. *Diabet Med* 2023;**40**:e15022. https://doi.org/10.1111/dme.15022

RA4_WP2: Jones S, Brown T, Watson P, Homer C, Freeman C, Bakhai C, Ells L. Commercial provider staff experiences of the NHS Low Calorie Diet Programme pilot: a qualitative exploration of key barriers and facilitators. *BMC Health Serv Res* 2024;**24**:53. https://doi.org/10.1186/s12913-023-10501-y

RA5_WP2: Evans T, Dhir P, Matu J, Radley D, Hill AJ, Newson L, *et al*. Behaviour change techniques in low-calorie and very low-calorie diet interventions for weight loss: a systematic review with meta-analysis. *Obes Rev* 2025:e13896. https://doi.org/10.1111/obr.13896

RA6_WP2: Drew KJ, Homer C, Radley D, Freeman C, Kinsella K, Maynard M, *et al*. Equity and Local Health Systems – a qualitative evaluation of the experiences of Local Health Service Leads during the first two years of the NHS Low Calorie Diet Programme pilot. *Br J Diabetes* 2023;**23**:77–85. https://doi.org/10.15277/bjd.2023.416

RA7_WP2: Marwood J, Kinsella K, Homer C, Drew KJ, Brown T, Evans TS, *et al*. Is the NHS low calorie diet programme delivered as planned? An observational study examining adherence of intervention delivery to service specification. *Clin Obes* 2024;**14**:e12652. https://doi.org/10.1111/cob.12652

RA8_WP2: Evans TS, Drew KJ, McKenna J, Dhir P, Marwood J, Freeman C, *et al*. Can the delivery of behavioural support be improved in the NHS England Low-Calorie Diet Programme? An observational study of behaviour change techniques. *Diabet Med* 2024;**41**:e15245. https://doi.org/10.1111/dme.15245

RA9_WP2: Radley D, Evans TS, Marwood J, Keyworth C, Homer C, Ells LJ. The NHS Low-Calorie Diet Digital Programme: fidelity of behaviour change technique delivery. *Diabet Med* 2024;41:e15350. https://doi.org/10.1111/dme.15350

RA10_WP3: Homer C, Kinsella K, Brown T, Marwood J, Drew K, Radley D, *et al*. 'A Fresh Start': qualitative experiences of the Total Diet Replacement phase of the NHS Low Calorie Diet Programme Pilot. *Br J Diabetes* 2024;**24**:60–66. https://doi.org/10.15277/bjd.2024.435

RA11_WP3: Dhir P, Maynard M, Drew KJ, Homer C, Bakhai C, Ells L. South Asian individuals' experiences on the NHS low calorie diet programme: a qualitative study in community settings in England. *BMJ Open* 2023;**13**:e079939. https://doi.org/10.1136/bmjopen-2023-079939

RA12_WP3: Marwood J, Radley D, Evans T, Matu J, Clare K, Bakhai C, Ells LJ. A cross-sectional analysis of emotional and binge eating in UK adults enrolled on the NHS low-calorie diet pilot for type 2 diabetes. *Clin Obesity* 2025;e70025. https://doi.org/10.1111/cob.70025

RA13_WP3: Radley D, Drew KJ, Homer C, Brown T, Kinsella K, Clare K, *et al*. Participant experiences during the NHS Low Calorie Diet Programme Pilot: findings from an online survey. *Br J Diabetes* 2024;**24**:88–94. https://doi.org/10.15277/bjd.2024.431

RA14_WP4: Martin A, Zabula T, Tebaldi D, Yang M, Brown T, Ells LJ. Economic evaluation of NHS England's Type 2 Diabetes Path to Remission pilot scheme: evidence from real-world data and patient simulation modelling. Submitted *Pharmacoecon Open* 2024 (under review).

RA15_WP5: Burton W, Padgett L, Nixon N, Ells L, Drew KJ, Brown T, *et al*. Transferability of the NHS Low Calorie Diet Programme: a qualitative exploration of factors influencing the programme's transfer ahead of wide-scale adoption. *Diabet Med* 2024;**41**:e15354. https://doi.org/10.1111/dme.15354

RA16_WP3: Drew KJ, Homer C, Radley D, Bakhai C, Ells L. A qualitative study of the experiences of individuals who did not complete the NHS Low Calorie Diet Programme Pilot. *Br J Diabetes* 2024;**24**:81–7. https://doi.org/10.15277/bjd.2024.434

RA17_WP2: Drew KJ, Homer C, Radley D, Jones S, Freeman C, Bakhai C, Ells L. Normalisation and equity of referral to the NHS Low Calorie Diet Programme Pilot: a qualitative evaluation of the experiences of health care staff. *BMC Public Health* 2024;**24**:152. https://doi.org/10.1186/s12889-023-17526-2

RA18_WP1: Dhir P, Evans TS, Drew KJ, Maynard M, Nobles J, Homer C, Ells L. Views, perceptions, and experiences of type 2 diabetes or weight management programmes among minoritised ethnic groups living in high-income countries: a systematic review of qualitative evidence. *Obes Rev* 2024;**25**:e13708. https://doi.org/10.1111/obr.13708

RA19_WP3: Homer C, Kinsella K, Brown T, Marwood J, Drew K, Radley D, *et al*. 'Life changing or a failure'? Qualitative experiences of service users from the Weight Maintenance Phase of the NHS Low Calorie Diet Programme Pilot for Type 2 Diabetes. *Br J Diabetes* 2024;**24**:74–80. https://doi.org/10.15277/bjd.2024.432

RA20_WP1: Homer C, Kinsella K, Ells L, Marwood J, Brown T, Radley D, *et al*. The Re:Mission study. Evaluating the NHS Low Calorie Diet pilot – an overview of service user data collection methods. *Br J Diabetes* 2024;**24**:56–9. https://doi.org/10.15277/bjd.2024.433

RA21_WP2: Dhir P, Maynard M, Drew KJ, Homer C, Bakhai C, Ells L. A qualitative evaluation in community settings in England exploring the experiences of coaches delivering the NHS Low Calorie Diet programme pilot to ethnically diverse participants. *BMJ Open* 2024;**14**:e085200. https://doi.org/10.1136/bmjopen-2024-085200

RA22_WP3: Homer C, Kinsella K, Brown T, Marwood J, Drew K, Radley D, *et al*. Trying to make healthy choices': The challenges of the food reintroduction phase of the NHS Low Calorie Diet Programme Pilot for Type 2 Diabetes. *Br J Diabetes* 2024;**24**:67–73. https://doi.org/10.15277/bjd.2024.436

RA23_ WP3: Flint SW, Goldberg E, Kaykanloo M, Sherman S, Radley D, Kingsbury SR, Ells L. Is personality associated with the lived experience of the NHS England low calorie diet programme: A pilot study. *Clin Obes* 2025 Feb 25:e70003. https://doi.org/10.1111/cob.70003

Service delivery and fidelity (RQ1–4)

Our service delivery and fidelity assessment were undertaken on the four providers responsible for the first wave of service delivery. To understand the underpinning behaviour change theory used by each provider, we used theory coding analysis of providers programme plans and training materials. Unfortunately, it was not possible to observe and code live staff training as this had been largely completed prior to the study commencement. Our analyses revealed that the application and type of behaviour change theory varied significantly across all providers (RA2). The analyses we were able to undertake found that SP1 included the Transtheoretical Model (Stages of Change) within their training content, while SP2 described multiple theories underpinning their programme design [including Capability, Opportunity and Motivation - Behaviour (COM-B) model, Health Beliefs Model, Transtheoretical Model and the Cognitive Behavioural Model Service]. SP3 also included the Cognitive Behavioural model, in addition to the Antecedents–Behaviour–Consequence model, while SP4 included COM-B and Social-Cognitive Theory in their programme logic model. When BCTs in providers' programme designs were analysed for the extent to which they linked to theory, constructs or predictors revealed that SP1 linked no BCTs, SP2 linked 63% of BCTs, SP3 linked 70% of BCTs and SP 4 linked all 100% BCTs.

Our assessment of the extent to which the NHS LCD is delivered with fidelity to the specification as set out by NHSE was reported across four publications:

RA3 described and compared the different provider programme designs against the NHSE service specification using the Template for Intervention Description and Replication Framework and Behaviour Change Technique (BCT) taxonomy, to assess drift in fidelity of service parameters and BCTs. This study found that all four providers demonstrated fidelity to most but not all of the stipulated service parameters. Providers included between 74% and 87% of the 23 BCTs identified in the NHS specification: 12 of these BCTs were included by all 4 providers; 2 BCTs were consistently absent. An additional 7–24 BCTs (not in the NHS specification) were also included across providers.

Fidelity of BCT delivery was reported in two papers, both of which used the BCT checklist developed for RA3. RA9 examined the BCT delivery across the digital materials (online/app content and supporting app chat – SP2 and phone call transcripts – SP4) delivered by the two digital providers. Fidelity of BCT delivery was found to be high with 78% and 83% of the BCTs identified in the NHS service specification delivered by the digital providers, and the fidelity of BCT delivery to those specified in providers' programme plans was 60–65% for SP2 and 82% for SP4. RA8 reported on observed remote delivery of 1 : 1 and group-based programmes across the different providers. A total of 122 sessions were observed across eight samples and two providers completed (despite extensive efforts, the remaining SP delivering 1 : 1 sessions did not engage in the evaluation process). Our findings demonstrated that the complete delivery of the programme was undertaken in five of the eight samples. Fidelity ranged from 33%

to 70% across samples and was higher for group-based delivery models (64%) compared with 1 : 1 models (46%). Although this finding should be interpreted within the context of each provider's delivery style, since the provider with predominantly group-based programmes delivered content through structured activities that appeared to support the delivery of BCTs. A qualitative analysis found facilitators to effective BCT delivery to include alignment with the programme's target behaviours and outcomes, structured session content, enough available time, effective time management, and not deviating from the session plan.

Learning from RA8 was further supported by the qualitative observations from across the 122 sessions, and how they compared to key delivery criteria within the NHS service specification findings (RA7). These findings demonstrated that adherence to the service specification varied across delivery models and providers, but overall was stronger for more measurable outcomes such as weight and blood glucose, while less tangible elements of the specification, such as empowering service users, reducing health inequalities and person-centred delivery, were less consistently observed. The more interactive and diverse delivery observed in the providers delivering more BCTs seemed to enhance participant engagement. Other observed variations between providers included: (1) level of cultural adaptation of the programme; (2) discrepancies in advocacy of non-starchy vegetables (intended as an option to supplement TDR for service users experiencing difficulty with compliance) and physical activity promotion (which should not be actively advocated during the TDR phase of the programme). Overall, 1 : 1 sessions were more successful in their person-centred delivery, and the skills of, and continuity in, the coaches delivering the sessions had a strong impact on adherence to the service specification. Critical to effective person-centred delivery were friendly and accessible communication, an ability to provide positive feedback, and dedicated efforts to establish connections and build relationships, with some groups using platforms such as WhatsApp to promote peer support. The observations also highlighted some gaps in the support needs of service users in relation to emotional eating and psychological support during the programme, although not a requirement within the specification, it identified an area for future service specification and delivery development.

The experiences and perceived barriers and facilitators to effective delivery, integration and normalisation into routine care were reported for providers (RA4 and RA21), NHS referral staff (RA17) and NHS locality lead staff (RA6). RA4 found that the programme did fulfil requirements for normalisation from the providers' perspective. Identified facilitators to effective delivery included good internal teamwork, trusting coach and service user relationships, and a wider choice of TDR products. Barriers were identified in engaging general practices (GPs) and receiving sufficient and appropriate referrals, in addition to supporting service users through challenges to remain compliant. Reasons for non-compliance that were discussed by providers were associated with personal characteristics, environment, skills and preferences (such as psychological support needs, multiple life events, busy lifestyles, work commitments that revolve around food, people with larger families, or who do not work but have a lot of 'thinking time'). The providers reported the main barriers to effective delivery disproportionately impacting diverse ethnic groups, with multiple and intersecting barriers including ethnicity, culture, language and translation requirements, digital competency, dietary requirements, taste preferences, needs of the family and time to attend sessions.

Given the significant barriers identified around the support needs of ethnically diverse communities, a further study was undertaken to interview coaches either from, or with responsibility for delivery to, diverse ethnic communities (RA21). This study identified variations in communication and training between provider sites. Areas for learning and improvement included adapting systems and processes and closing the gap where the needs of service users are not fully met. The themes identified highlighted the varying cultural competency of coaches and the potential impact of knowledge gaps on programme delivery, and the need for comprehensive cultural competency training, to address language barriers, utilise culturally tailored resources, understand diverse cultures and implement effective cultural tailoring strategies with an understanding of cultural nuances.

Interviews with healthcare professionals involved in referring service users to the first wave of the programme (RA17) highlighted the impact of COVID-19 and competing demands on primary care; differences in the expertise and knowledge of referrers; variation in patient identification and the referral process; and barriers to referrals. These barriers included the impact of referrals on workload, confidence in deprescribing, and the intensity and level of commitment required. When equity of referrals was discussed, nearly half of the referral staff felt the referral process was inclusive, although some did report on the potential inequalities of remote delivery and digital exclusion. Language was identified as a potential barrier to referrals but also a facilitator in areas where the programme referral and delivery could occur in another

language. Our findings demonstrated that at the time of interview the referral process had not yet been normalised into routine care, with variation and potential inequities in the referral processes across settings identified.

Themes from the referral staff also aligned with those arising from the locality lead interviews (RA6) which highlighted the impact of COVID-19 and primary care capacity and engagement; different methods of communication; and variation in approaches to training, incentivisation and referrals. Barriers to referrals were discussed and included ineligible referrals and time taken to refer, staff turnover in the local health system (LHS) and referrer confidence and expertise. A key facilitator to effective mobilisation of the programme was effective collaboration across all stakeholders.

Service user experience and inequalities (RQ5–8)

The extent to which the content of the NHS LCD programme is understood and applied by service users, and how sociodemographic characteristics and delivery model impact access, uptake, compliance and success on the programme, builds on learning from RQ1 to RQ4 and the quantitative analysis of the LCD MDS undertaken by NHSE (see *Box 1*).[17] We conducted our own service user participation survey (RA12, RA13, RA23) and service user interviews (RA10, RA11, RA16, RA19, RA20, RA22), to provide understanding and context to the NHS process and clinical data provided by the MDS. We also invited our longitudinal interviewees to complete the MyFood24 dietary assessment; however, only 16 out of 30 participants opted to complete this at 12 weeks, which dropped to 11 and 8 in weeks 18 and 52, respectively. This, therefore, limited the utility of the dietary data collected (which is summarised in *Appendix 3*), but for those who completed the assessment, the only significant findings were an increase in fat over the 52 weeks, while fibre intake remained consistently low, and fruit and vegetable intake remained below recommended intake throughout. At 52 weeks, the average energy intake remained below standard recommended values.

A summary of key learning from across the service user interviews and surveys, alongside NHS quantitative findings, is provided by programme stage:

Referral

Early insights from the first 7540 people referred to the NHS LCD programme (September 2020 to December 2022) reported that 43% of those referred were men, 55% were in the oldest age bracket (50–65 years), and were of Asian (19%), black (8%), mixed (3%), other (1%) and white (64%) ethnicities. A higher proportion of referrals were from service users living in the most deprived areas (26%) compared to the least deprived areas (14%), and around half (47%) had a T2D diagnosis of < 1 year at referral.[17] Average weight at referral was 109.2 kg, average BMI was 38.0 kg/m^2 and average HbA1c was 58.5 mmol/mol.[17] For the 66% of people taking glucose-lowering medication at referral, the most common medications were: metformin followed by sodium-glucose co-transporter protein 2 inhibitors, dipeptidyl peptidase 4 inhibitors, glucagon-like peptide-1 analogues and sulfonylureas.[17] Our service user survey (RA13) and initial interview data (RA10) showed that service users were motivated to be referred in order to improve their T2D, weight and health. Although most were satisfied with the referral process, the survey (RA13) and interview data (RA10) highlighted some inconsistencies in referral knowledge, with suggestions that more programme information at referral would have been helpful.

Initial assessment and starting total diet replacement

Of those referred with sufficient time to start the programme, 5115 attended an IA and 4340 started TDR,[17] with those who were more affluent, younger, of mixed ethnicity, or with a T2D diagnosis 4–6 years prior to referral, more likely to start TDR, while males, older adults, those with a lower starting BMI (25–29) or of Asian, black or other ethnicity were least likely to start TDR. The majority of our survey respondents reported that the information provided at IA was clear (RA13), although some survey respondents and interviewees (RA10) identified some inconsistencies between providers in the IA information provided, and the time point at which service users received their starter packs/course materials. Concerns were also raised by some of our interviewees around the cultural competence of the programme (RA11), which may explain the reduced uptake across some ethnically diverse communities. The perceived service user costs may also have deterred participants living in areas of socioeconomic deprivation. The higher uptake in those who have lived with T2D for longer may also reflect the high motivation to improve health when starting the programme (RA13). This concurs with additional artificial intelligence analysis of the survey and linked MDS data which concluded that personality rather than demographic characteristics determine motivation to continue the programme (RA23).

Food reintroduction and weight maintenance

Of the 1740 participants who started TDR and had sufficient time to finish the programme, 84% were active at the end of TDR, 79% were still active at the end of FR and 55% completed WM (i.e. the whole 12-month programme). Those who were least likely to complete

were living in the most deprived quintile, had a BMI of 40+, or were younger (18–39 years).[17] While there were some differences between providers, there were no significant differences by delivery method, sex, years since diagnosis or ethnicity identified.[17] However, in terms of clinical outcomes service users of Asian, mixed and black ethnicities lost a lower percentage of their baseline weight compared to those of white ethnicity, with no other significant differences by other sociodemographic characteristics. Where data were available to measure remission, 32% achieved it, which was more likely in those who had a more recent T2D diagnosis.[17]

It is clear that while the LCD programme is successful in achieving the desired improvements in weight, glycaemic control and remission in many people living with T2D, the full 12-month programme was only completed in just over half of all those who started. There are also some population groups: younger adults, those living with severe obesity, or living in areas of socioeconomic deprivation who may need additional support to complete the programme. The clinical outcome data also highlight a need for further adjustments to help improve the impact of the programme for service users of Asian, mixed and black ethnicities. Aggregated findings from our service user survey (RA12, RA13, RA23) and interviews (RA10, RA11, RA16, RA19, RA20, RA22), provide critical insights to help understand the observed attrition and sociodemographic inequities, and inform future service development. These key learning points are summarised below:

- *Range and delivery of TDR products* was an issue for service users where products were delivered in bulk which created storage issues and a lack of flexibility in changing products, most TDR products were also very tailored to a Western palate.
- *Allowance of supplementary foods* such as non-starchy vegetables, or a day 'off' (i.e. a short return to normal foods) during TDR, supported adherence to the programme for some, although the use of this approach varied across providers.
- *Social impact of TDR* was reported by some service users, who found going out, socialising, and family meals and celebrations involving food challenging during TDR. This was particularly important if there was a cultural, employment or family role linked specifically to food or food preparation, or where socialising was an important part of everyday life.
- *Variation in cultural competence of programme content and delivery* was apparent. Examples of good practice were provided that included session delivery in other languages, matching the background of coaches to service users, and the use of tailored resources such as supporting guidance for TDR during religious festivals, which were reported to improve engagement and success across ethnically diverse participants. Additional culturally tailored recipes, adaptations of traditional cooking methods and culturally adapted meal plans were identified as a gap.
- *Person-centred delivery and good service user–coach relationships* helped tailor the programme to individual needs and were seen by service users as key to success on the programme, yet the degree of person-centredness varied, and was more difficult to achieve in group and digital delivery. This is important given assumed health literacy did not always align with that of the service user. Service users from ethnically diverse backgrounds sometimes reported challenges in understanding, due to sociocultural barriers that can exist with a coach from a different background to their own.
- *Increased support and availability of coaches* was a need expressed by some service users, particularly during FR and WM when session numbers decreased and service users experienced difficulties in contacting their coach or provider out of set session times.
- *Additional psychological support needs* were reported by some service users experiencing mental health and or life event challenges, which were frequently reported as reasons for non-completion, missing sessions or difficulties engaging with the programme. Service users felt more flexibility in programme attendance may overcome the impact of life events.
- *Family and peer support* was frequently reported as critical to the success of the programme, with some service users finding support from WhatsApp groups. Service users from different cultural and ethnic backgrounds found peer support and exchange of cultural adaptations helpful.
- *Emotional and disordered eating support needs* were reported by several interviewees and were reflected in the large proportion of survey respondents, demonstrating high scores for emotional and disordered eating [just less than a quarter of the sample screened positive on the Binge Eating Disorder Screener (BEDS-7) for likely binge eating disorder (BED), and the mean emotional eating subscale score from the Three Factor Eating Questionnaire-R21 was 2.58 (out of a range of 1–4)].
- *Concern about FR* was frequently raised by interviewees, and survey respondents many of whom reported a continued reliance on TDR products (outside of the service provision – nearly 20% of survey respondents at 52 weeks reported purchasing their own TDR products), with calls for more structured resources to support FR and

the consideration for a longer FR phase with more frequent sessions than bi-weekly.
- *Wider benefits of the programme*, where reported, with outcomes beyond weight and glycaemia, important to service users, these included improved appearance, daily physical functioning, improved social relationships and the extended benefit on the health of friends and family.

Economic evaluation (RQ9–12)

When service user costs were assessed through the evaluation survey, we found that for those who reported spending money on resources they attributed to enrolling on the programme, the average spend was £125.99 over the whole programme (RA14). There were no statistically significant differences in terms of additional expenditure that service users incurred during the programme by gender, ethnic group, or socioeconomic status. The main component of this additional expenditure was purchases of additional TDR products (during the TDR phase, e.g. to replace flavours they didn't like and couldn't exchange, or to continue the use of TDR 'off programme' during WM). Other items of expenditure listed by patients included extra glucose monitoring strips, diet and cookbooks.

Data were gathered on costs of delivering the programme from NHSE records of SP payments and cross-checked against other sources: NHS weight management guidelines, our own survey of SPs using an adapted STAR-LITE questionnaire[18] and the DROPLET and DiRECT trials. Despite small differences in how the costs were estimated, the majority fell within the range of costs reported in the DiRECT trial paper as represented by the 95% confidence interval (CI) between £1147 and £1294 per service user. None of this evidence indicated substantial or consistent differences in costs by delivery model; however, since most services had been disrupted by the COVID-19 pandemic and were being delivered remotely, there remains a need for future studies to assess these cost differences to ensure that value for money is achieved.

Real-world clinical data were collected by commercial SPs and GPs and then linked to National Diabetes Audit data and cost data. A commercially available, pre-built patient-level simulation model [United Kingdom Prospective Diabetes Study (UKPDS) Outcomes Model] utilised data collected pre-referral and at 12 months to predict health economic outcomes for the service users at 24 months and annually until death. Additionally, a counterfactual scenario portraying potential outcomes for the same service users without the intervention was generated utilising only pre-referral data. It was necessary to test various different assumptions regarding weight regain and HbA1c trajectories among service users at 24 months onwards, relative to the counterfactual scenario. These scenarios indicated that the programme could be cost-effective against a £20,000/QALY threshold if weight and HbA1c trajectories remain below those in the counterfactual scenario for at least 6–7 years (£19,759.80/QALY assuming 7 years) and against a £30,000/QALY threshold if those trajectories remain apart for 4–5 years (£27,625.99/QALY assuming 5 years). More rapid weight and HbA1c trajectories would mean the intervention is less likely to be cost-effective. This finding does not vary by ethnicity, area-level deprivation nor in sensitivity analyses, which included: (1) running the model across a range of different time horizons, including 10 years, 15 years and 20 years; and (2) altering the intervention costs to reflect possible differences in cost by delivery model.

This overall finding contrasts with the results of the DiRECT study which found the comparable Counterweight-Plus intervention to be cost saving, in the sense that it improved health outcomes and decreased (rather than increased) costs to the NHS.[19] In our study, this would be the case if a societal perspective were adopted, due primarily to the money service users are likely to save on their usual grocery shopping. However, it seems unreasonable to include these in healthcare commissioning decisions.

Compared to existing clinical trials of similar interventions, our sample was larger (n = 838 vs. e.g. 149 in the DIRECT study intervention arm) and more sociodemographically diverse. While our sample had a comparable mean HbA1c to DiRECT, the mean baseline weight was higher (+ 10 kg). After 12 months, the reduction in HbA1c in our study was smaller (2.3 vs. 9.8 mmol/mol in DiRECT), but mean weight loss was similar (9.9 kg vs. 10.6 kg in DiRECT). Differences in HbA1c and weight reductions were noted across ethnic groups and, to a lesser extent, by area-level deprivation. In the DiRECT trial, 46% of participants in the intervention arm achieved T2D remission after 1 year compared to 4% in the usual care arm, with an intervention cost of £2939 per incremental case of remission.[19] In comparison, 27% of participants achieved remission in the real-world data used in our study, which was also reported in a cohort analysis by NHSE.[17] Over a longer period, DiRECT showed that 36% of LCD participants achieved remission at 2 years,[7] and after 5 years, 10% (n = 12) achieved remission[20] (compared to 5% in the control group), with an intervention cost exceeding £20,000 per incremental case of remission.

Transferability assessment (RQ13–15)

Our transferability assessment (RA15) determined that the core elements required to achieve impact included confidence in the programme, multidisciplinary working and good communication, across all stakeholders and a choice of delivery model to promote acceptability and accessibility. Local adaptations to referral strategies were also deemed necessary such as utilising local population characteristics data on deprivation and ethnicity to inform efforts to drive equitable uptake, and referrals that reflect the local target population. Adaptations to programme delivery such as ensuring a person-centred approach and incorporating cultural tailoring were again highlighted to ensure the needs of individual patients were met. Policy implications for widespread adoption should include referral strategies to reach under-represented groups, a choice of delivery model to optimise uptake, and the provision of timely data from SPs on access and programme benefits.

Implications for decision-makers: policy and practice recommendations

Learning from across WPs has refined our programme theory through a realist-informed approach (supporting evidence statements and context are provided in *Appendix 2*). We are therefore able to provide a list of recommendations for policy and practice that are aligned to the optimisation of programme outcomes and delivery mechanisms for each stage of the programme. Recommendations are provided to cover areas that either require strengthening, more universal provision across all providers, or new material/action to address specific evaluation findings.

Pre-referral

Desired outcomes

All eligible patients are identified, and the SPs develop evidence-based person-centred LCD programmes that meet the NHS service specification and incorporate current best practices and evidence.

Mechanisms required to achieve outcomes

- All eligible patients are made aware of the programme, with framing as a positive opportunity.
- The LHS has the capacity and resources to proactively support equitable mobilisation.
- Referrers have the adaptive capacity, capability, opportunity and motivation to refer equitably and effectively.
- Providers engage with LHSs to mobilise the programme.
- Providers co-develop their programme content with target populations to enhance person-centredness and resource tailoring to meet population needs.
- Providers develop their programme based on the NHS service specification and best practice evidence and theory.

Recommendations

- Providers should provide feedback on service users' progress to primary care, to maintain awareness and impact of the programme across primary care.
- Providers should further develop the cultural competency of their service and communication of this to target populations.
- Develop and distribute more service user-facing information about the programme and what it involves. This should be delivered through a variety of communication channels, languages, and targeted at a range of health and language literacy levels to maximise reach and engagement with all eligible populations.
- NHSE should regularly review eligibility criteria, to ensure maximal reach and impact and ensure this is effectively communicated to all referral staff, to ensure it remains in line with the latest available evidence, and everyone who may benefit if provided with the opportunity.
- Local health systems need to ensure that all referral staff understand the programme and are confident in the referral process and deprescribing practices, in order to deliver appropriate person-centred referrals to the programme.
- Local health systems need to consider increasing opportunistic touchpoints raising awareness of the programme and widening out referrals to a range of healthcare professionals such as practice pharmacists, in order to help increase access and uptake across broad and diverse communities.
- Local health systems need to work together with primary care to develop (and keep updated) an equity impact assessment, to ensure that processes are in place to ensure referrals are equitable and reflect the demographics of the local eligible target population.
- Providers include a health psychologist in the programme development and training delivery to enhance the uptake and fidelity of behaviour change techniques across the programme.
- Explicit behavioural theory should be used in programme design, and evidence of its implementation should be a requirement of future

NHS commissioning processes and ongoing service development.

Referral

Desired outcomes

All eligible patients are offered a referral to the programme, and the demographics of patients referred reflect the sociodemographic of the target local population.

Mechanisms required to achieve outcomes

- Service users have the capability, opportunity and motivation to take part in the programme.
- The referral process is person-centred.
- Referrers have the adaptive capability, opportunity and motivation to refer effectively and equitably.
- Providers work proactively with referrers to support effective, equitable referrals.
- Local health systems develop referral opportunities that are appropriate for their local population.
- Effective communication and collaboration occur across all stakeholders involved in the referral process and LHS.

Recommendations

- All referrers provide consistent person-centred information about the programme so that every service user has the same detail about the programme at the point of referral, with additional detail provided for those who may require it (e.g. patients with low language or health literacy).
- Any mental health concerns are noted at the point of referral and managed as appropriate while on the programme.
- Referral staff recognise the importance, and include the assessment, of, patient-reported outcome measures in engaging patients in the programme.
- Referral opportunities should be equal across all referring practices.
- All eligible patients should be offered a referral, which could be facilitated by widening points of referral across different community settings (e.g. such as GP pop-ups in community venues).
- Referral data should be continually monitored by the LHS to ensure equality in access and uptake, and targeted referrals considered where equity improvements are required.
- Providers and referrers should work together closely to streamline the referral process.

Initial assessment

Desired outcomes

All referred patients attend their initial individual assessment and start the programme, those starting the programme reflect the sociodemographics of the local population.

Mechanisms required to achieve outcomes

- Service users understand the programme, what it involves and any medication changes required, irrespective of language or health literacy.
- The programme is acceptable to all potential service users.
- Providers have the necessary system and processes in place to facilitate successful on boarding/initiation of the programme to all eligible participants.
- Providers have the adaptive capability, opportunity and motivation to support service users and provide a person-centred approach to onboarding.

Recommendations

- Providers undertake further work to improve the uptake of service users aged 50–65 years, and of different ethnicities who are less likely to start TDR.
- Where possible, providers match coaches to service users who share similar cultures or ethnicity, to help improve uptake.
- Providers should ensure that all service users acquire a comprehensive understanding of the programme – some may need more support than others to understand the programme, which needs to be accommodated.
- Providers should ensure that every service user understands any required medication changes that were provided by their referrer.
- If possible, offer service users the chance to access different models of delivery, so that the delivery model can be optimised to their preference.
- Providers should 'on board' service users within a time frame agreed with the service user.
- All service users should be provided with access to programme information before the start of the programme.
- Providers or primary care should screen for emotional and disordered eating and have the capacity to appropriately manage the outcome of these screening measures (i.e. there needs to be support in place or appropriate referral mechanisms for ongoing care).
- Providers need to understand the sociodemographics of their service user population, and demonstrate the

additional support in place for those groups that are less likely to complete or succeed on the programme.

Total diet replacement

Desired outcomes

All service users adhere to and successfully complete TDR, lose weight and improve glycaemic control. There are no sociodemographic differences in outcomes and all comorbidities and side effects are effectively monitored and managed.

Mechanisms required to achieve outcomes

- Service users understand how to successfully complete the TDR stage, irrespective of health or language literacy.
- Family support is actively encouraged and access to peer support is facilitated.
- Mental health challenges and unexpected life events are appropriately supported.
- Service users are able to undertake medication changes and monitor blood pressure (where required), blood glucose and weight.
- Service users develop positive management strategies to undertake the programme.
- TDR session delivery is person-centred.
- Providers have the necessary systems and processes in place to facilitate successful session delivery, support and provision of TDR products/monitoring equipment.
- TDR products work for all service users (i.e. variety, taste acceptable, manage hunger, no or managed side effects).
- TDR dietary adaptation (i.e. the use of non-starchy vegetables and techniques to adapt products to palette preferences) is person-centred and accommodates any dietary intolerances or cultural requirements.

Recommendations

- Providers offer a range of TDR products to appeal to a wide range of palettes, and enable service users to taste products before ordering, to avoid situations where lack of suitable TDR prohibits programme adherence.
- Providers provide consistent guidance on the inclusion of non-starchy vegetables.
- Providers ensure TDR products are delivered regularly in small quantities to avoid storage issues and provide the flexibility for service users to change products.
- Providers need to ensure all information and behaviour change content are relevant to TDR, and as specified by NHSE.
- Providers should be aware of different cultural and religious events that may impact service users' compliance during TDR and provide tailored support and management strategies towards continued adherence during significant events.
- All programme delivery needs to be more person-centred, i.e. adaptive and flexible to individual service user needs and literacy levels.
- Providers need to be proactive in translating resources for service users who do not have English as their first language and move the onus away from service users to find family support for translation.
- Providers should acknowledge the importance of family and peer support and provide more tailored behaviour change support to help service users overcome some of the social and cultural barriers that can occur at mealtimes and family/peer gatherings.
- Providers should offer peer support groups and consider using mobile applications such as WhatsApp.
- Providers should ensure that all programme materials are provided to service users prior to the first TDR delivery session.
- Providers should provide support and/or signposting for service users with mental health concerns and/or emotional and disordered eating.
- Providers need to be contactable out-of-hours and coaches enabled to provide more responsive support on a person-to-person basis.
- Discharge procedures within the service specification require review to ensure service users are not penalised for life events, and provider staff are trained in compassionate discharge procedures.
- Consideration should be given to providing additional glucose monitoring strips, which should be provided where service users wish to undertake additional monitoring to enhance compliance.
- Processes to streamline the collation of service user measurements should be undertaken, particularly for digital and remote delivery, where there is a reliance on self-reported data collection.

Food reintroduction

Desired outcomes

All service users are able to adhere to and complete the FR stage (including coming off TDR completely). All service users retain or continue weight loss and improved glycaemic control. There are no sociodemographic differences in outcomes, and all comorbidities and side effects are effectively monitored and managed.

Mechanisms required to achieve desired outcomes

- Service users understand how to successfully complete the FR stage, irrespective of language or health literacy.
- Anyone with emotional or disordered eating receives the support needed to enable them to adhere to and complete FR.
- Service users have appropriate peer/family support.
- Service users are able to buy, store and cook culturally appropriate, affordable and healthy foods.
- Service users are able to undertake medication changes and continue to monitor blood pressure (where required), blood glucose and weight.
- Service users have opportunities to be physically active, without cultural, financial or environmental barriers.
- Service users develop positive management strategies to undertake the FR stage and expectations around weight change.
- FR session delivery is person-centred.
- Mental health challenges and unexpected life events are appropriately supported.
- Providers have the necessary system and processes in place to facilitate successful session delivery, support (to facilitate implementation within everyday life) and provision of TDR products/monitoring equipment.

Recommendations

- Providers should work with local communities and utilise existing literature to tailor resources, such as the use of ethnic-specific Eatwell guides, and culturally tailored recipes and meal plans.
- Delivery staff should all receive cultural competency training which considers social, cultural, environmental and socioeconomic factors to optimise effective FR delivery.
- Delivery staff should receive training and resources to support service users with emotional or disordered eating and psychological support needs.
- FR delivery should be person-centred incorporating flexibility and understanding of individual circumstances.
- Some service users may benefit from more frequent and intensive support sessions and additional structured meal-planning resources during FR.
- Providers should acknowledge the impact of social stressors and life events and build flexibility into session attendance to accommodate this.
- Providers need to be contactable out-of-hours, and coaches enabled to provide more support on a 1 : 1 basis, given the heightened concern experienced by many during FR.
- Discharge procedures within the service specification require review and staff require training about how to handle discharge in a sensitive compassionate way.
- All providers should provide electronic and paper copies of diet and cookbooks or resources that can support service users, to avoid inequities generated by a reliance on service users' ability to purchase recommended supporting resources.

Weight maintenance

Desired outcomes

All service users complete WM and maintain weight loss and improvements in glycaemic control and remission (where achieved). There are no non-biologically driven sociodemographic differences in outcomes, and service users are equipped to sustain behaviour change over the long term. There are no ongoing adverse events (physical or psychological), and service users are discharged into suitable monitoring and ongoing lifelong person-centred care. Programme is cost saving to the individual, and local and national health systems.

Mechanisms required to achieve desired outcomes

- Service users are empowered to become effective self-managers to maintain long-term behaviour changes.
- Service users have appropriate peer/family support.
- Service users eligible for a rescue package are made aware of it, and receive it if required.
- Service users are able to buy, store and cook healthy, culturally appropriate foods.
- Service users are able to build physical activity into everyday life, without cultural, financial or environmental barriers.
- Service users understand the process for continued monitoring and ongoing support.
- Anyone with emotional or disordered eating or psychological support needs receives the tailored support to enable them to successfully adhere to and complete WM.
- WM session delivery is person-centred.
- Providers have the necessary system and processes in place to facilitate successful session delivery, support and ongoing monitoring.

Recommendations

- Providers acknowledge the impact of social stressors and life events and provide flexibility in session attendance to accommodate this and enhance retention rates.

- Providers inform referrers of service user progress, providing a feedback loop to inform ongoing support for the service user and to increase engagement with referral staff and encourage the successful referral of other patients.
- Providers monitor the use of 'off-programme' TDR products, and support service users to achieve WM without an ongoing reliance on TDR.
- Providers acquire a deeper understanding of culturally specific foods, understanding the cultural influences that affect dietary choices and social support within families and communities of diverse ethnic groups.
- Providers include ongoing continued professional development on cultural competency and health literacy.
- Providers develop language-specific support groups and consider incorporating interpreters into programme delivery.
- Providers ensure ongoing support or signposting is provided for service users who experience mental health concerns, or emotional and disordered eating during WM.
- Providers consider providing more frequent sessions and/or out-of-session support to facilitate adherence and completion of WM.

Impact and learning

Real-world impact

The key real-world impact of this study was that it has informed the national roll-out of the NHS LCD programme, now renamed [with the assistance of the Re:Mission study patient and public involvement (PPI) group] the NHS Type 2 Diabetes Path to Remission Programme.

In addition to four of the research team members (Ells, Evans, Radley and Homer) supporting the national procurement process, the following extracts from the national NHS T2D Path to Remission service specification[21] demonstrate the changes made as a direct result of the learning from this study:

- The provider must offer a variety of TDR products such as soups, shakes and other suitable products. These must include the availability of varied flavours and textures to support service user compliance and retention on the NHS LCD Programme.
- The provider must supply the appropriate TDR products to service users but must not supply any service user with more than a 4-week supply of TDR products at any one time.
- The provider must consider the needs of a variety of potential service users, including offering suitable or alternative TDR products where possible for those with intolerances (e.g. lactose intolerance) which may impact their ability to use certain products.
- It is intended that, within a defined geographical area, a single provider will deliver the NHS LCD Programme by offering to individuals the following choice of delivery models: 1 : 1 face-to-face (the 'Face-to-Face Delivery Model') or 1 : 1 digital support (the 'Digital Delivery Model').
- The provider must monitor service performance and inequalities in outcomes and take appropriate corrective action to improve performance and reduce inequalities accordingly. Specific attention should be given to monitoring and improving performance relating to people with characteristics which have been associated with poorer outcomes in the pilots.
- In addition to the exclusion criteria of anyone with an active eating disorder at referral, if the provider suspects or identifies behaviours that meet the threshold of an eating disorder, the GP practice should be notified, and the service user should be advised to seek care with their GP practice accordingly. In addition, identification of an active eating disorder should be recorded as an adverse event.
- Additional details were added to this statement: the provider must actively encourage and respond to service user feedback. This should be sought on all aspects of the service including the curriculum, programme structure, frequency of support, TDR products, coaching, approach to meeting individual, cultural adaptation, support materials and functionality/usability of any digital tools. The provider must have effective governance processes for collating and actioning such feedback as well as for responding to any complaints.
- Service users must be provided with adequate information about the delivery models to allow for an informed, unrestricted choice about which delivery model would better suit their needs and individual context.
- The provider must ensure that service users receive appropriate advice, tools and support in preparation for the FR phase and the transition to healthy eating. This includes healthy dietary plans appropriate to their preferences and culinary traditions.
- Advice and dietary plans should be tailored to the service users' individual needs, preferences and culinary traditions.
- When the numbers of TDR, FR and WM sessions are described in the specification, the following statement

should be added to encourage additional support: (or more frequently at the discretion of the provider).
- Service users should be made aware of the availability of peer support throughout the intervention. If the service user accepts the offer of peer support, this should be facilitated by the provider.
- Planned pauses: if otherwise at risk of disengagement from the programme due to life circumstances or external factors, a planned pause by a service user of up to 4 weeks can take place during any phase of the programme after the start of the TDR phase. Where a pause is arranged, the provider must share the details of the pause with the service user's GP practice. If the service user is not able to restart the programme within 4 weeks of commencing the pause, the service user should be discharged. If, following discharge, the individual subsequently requests to restart the programme, the provider must inform the individual that they will need to be re-referred by their GP practice. If they had previously commenced the TDR phase of the programme, they should be informed that they will not be accepted on to the programme until a period of 12 months has elapsed since the date that individual was discharged. Where a service user restarts the programme within 4 weeks after an agreed planned pause, the calculation of that service user's progression on the programme, the Milestone 2 Period and the Milestone 3 Period, must not take into account the period of the pause. For example, if a service user commences an agreed planned pause at the end of week 14 and the pause lasts 2 weeks, on restarting the programme, the service user should be treated as starting week 15 of the programme. Where a service user commences an agreed planned pause during a rescue package, the rescue package is treated as having ended on the commencement of the pause.
- The provider should be explicit regarding the behavioural change theory and techniques that are being used, and the expected mechanism of action of their intervention (RA3). The logic model (see *Appendix 4*) was also provided as a template for SPs and assessed in the latest procurement process.

Shared learning

As one of the largest real-world evaluations of a TDR-based LCD approach, learning has been shared internationally, nationally and locally, through the study website (www.remission.study), and presentations at the following events, in addition to the extensive PPI shared learning described below:

International

- European Congress on Obesity (Online) 2021
- The Association for the Study of Obesity Winter School Early Career Research Event 2022
- Royal Society for Public Health Key Note 2022
- UK Congress on Obesity (Lancaster) 2022
- European Congress on Obesity (Dublin) 2023
- European Association for the Study of Obesity Early Career workshop on PPIE 2023
- European Congress on Obesity (Venice) 2024.

National

- Podcast for Leeds Beckett University 2021
- Royal College of Physicians 2021
- Obesity UK Support Group 2021
- Association for the Study of Obesity Webinar 2021
- The UK Society of Behavioural Medicine Early Career Network 2021
- The British Psychological Society Division of Health Psychology Annual Conference 2022
- Self Employed Nutritionists' Support and Enlightenment (Sense) Nutrition group 2022, 2023
- The Association for the Study of Obesity/UK Congress on Obesity Early Career Research Event, 2022
- The UK Society of Behavioural Medicine Annual Scientific Meeting 2023
- Diabetes UK Research Group 2023
- Association of British Clinical Diabetologists webinar (June) and conference (September) 2024
- UK Congress on Obesity, Oxford 2024.

Regional

- Yorkshire Obesity Research Alliance seminar 2021
- Active Lifestyles online cafe (Carnegie School of Sport) 2022
- Active Lifestyles Spring online conference (Carnegie School of Sport) 2023.

Local

- Teesside University researcher presentation 2021
- Carnegie School of Sport Active Lifestyles Cafe 2022
- Leeds Beckett University School of Health seminar 2022
- Leeds NHS Low Calorie Diet group meeting 2022
- Sheffield Hallam University Sport and Physical Activity Research Centre seminar series 2022
- Leeds Beckett University School of Sport postgraduate conference 2023.

This was in addition to: incorporation of learning in both undergraduate and Masters programmes across the schools of health and sport at Leeds Beckett University; a media campaign in April 2024 with the *British Journal of Diabetes* (BJD) to share learning and launch the BJD

special edition for the Re:Mission service user experience papers; and launch of the Re:Mission study service user journey short film, and public-facing evaluation report – delivered through an illustrated online and print journal in April 2024.

Pre-planned activities

Additional upcoming pre-planned activities include:

- Shared learning at the Diabetes UK Conference 2025
- An application to undertake a symposium at the European Congress on Obesity 2025 (as the 2024 conference is not accepting member-led symposia due to venue restrictions)
- Shared learning with Obesity UK members, through a presentation at one of the Autumn/Winter patient groups.

Discussion

The Re:Mission study provides one of the first and largest real-world evaluations of a T2D treatment programme delivered through TDR and behaviour change support using three different commercially provided delivery models. While each of the threaded publications provides a detailed discussion and contextualisation of the reported findings within the current evidence base, here we describe the key overarching findings from the Re:Mission study within the context of the wider literature.

Currently the implementation and delivery of specific TDR remission-focused interventions as part of routine care remain largely under-researched. Therefore, our findings on the effective mobilisation and delivery of the LCD programme provide important new insights. We found that barriers and facilitators to the programme mobilisation aligned across NHS LHS leads and primary care referral staff, who acknowledged the significant impact of the COVID-19 pandemic on resources and staff turnover, a finding which is supported by wider evidence on the impact of COVID-19-related burnout within NHS staff.[22,23] Work with NHS locality staff across WP2 and WP5 also found that local adaptations to referral strategies (such as utilising local population sociodemographic data) were necessary to ensure equitable uptake, and referrals that reflect the local target population, although we were unable to identify a recognised approach or strategy across areas. WP2 also identified a need for ongoing surveillance of referrals, population uptake and outcomes beyond the mobilisation stage to support the continued development and adaptation of the programme and response to local needs. In some areas, a diabetes strategy group of multiple stakeholders existed to support this. Despite an ongoing debate about the use of targeted and universal strategies to address health inequities,[24] proportionate universalism is an example of a policy approach or strategy that would be appropriate for tackling the social gradient in health.

When assessing programme delivery, we identified variability in both the theoretical underpinning of service delivery and a drift in the implementation of fidelity. Interestingly, the provider with the strongest theoretical underpinnings was also found to have the strongest fidelity in their BCT content, while the two providers with the weakest theoretical underpinnings also had the weakest fidelity in their BCT content. This supported the notion that unclear theoretical underpinnings might result in a drift in programme fidelity.[25–27] However, far less drift in the fidelity of the behaviour change was observed for the digital delivery. These findings reflect a similar pattern to the behaviour change fidelity assessment undertaken for the National Diabetes Prevention Programme group and digital delivery (the DIPLOMA study),[27] which is perhaps not surprising given the overlap in SPs across both programmes. This is important as loss of fidelity might impact participants' ability to initiate and sustain behavioural changes and improve their T2D. A recent meta-analysis conducted by our research group identified eight BCTs individually and significantly associated with weight loss following a LCD (RA5). Although the majority of these BCTs were included in the NHS-LCD programme designs, they were not always observed during programme delivery. If BCTs are associated with weight outcomes, it is important that they are delivered with fidelity in order to optimise intervention effects.

When challenges to programme delivery were examined across WP2 and WP3, there was alignment in the findings between SPs and users in the identification of barriers to the programme uptake and engagement. Key learning aligns with the evidence base in demonstrating the importance of patient (service user)-reported outcomes,[28] person-centred care[29] and effective peer support.[30] Ongoing support needs for psychological challenges were also documented. Although baseline assessment (RA12) of well-being scores in service users who completed the evaluation survey reflected the UK population norms,[31] quality-of-life scores were slightly lower than UK population norms.[32] This is an important finding given the DiRECT study[33] found that better baseline quality of life was a predictor of remission at 12 and 24 months, and re-emphasised the need for robust post-intervention follow-up. Unfortunately, a lack of longitudinal survey data prohibited a robust analysis of changes in service users' mental health status over time; however, a recent

systematic review with meta-analysis found no adverse effects of TDR programmes on any mental well-being subdomain.[34] Emotional and disordered eating were also highlighted as an area of concern across the interview and survey data collected. Although we were unable to assess changes in emotional or disordered eating behaviours over time due to insufficient longitudinal data, the baseline prevalence of potential BED diagnosis observed in our survey sample (24%) was over double the rate (11%) reported in the Look AHEAD trial.[35] However, systematic review evidence suggests that severe dietary energy restriction (such as TDR) appears safe and beneficial for people with pre-existing BED under close clinical supervision.[36] This is an important consideration for referral and service delivery staff, as although patients with a diagnosed eating disorder are excluded from the programme, the prevalence of BED is higher in people living with T2D but remains largely under diagnosed.[37]

It is important to acknowledge the impact of the programme in achieving weight loss, and improving glycaemic control for many service users, although the T2D remission rates were lower than those reported in the DiRECT trial.[38] This may be reflective of the anticipated dilution effect when trial evidence is translated into real-world practice,[39] but may also have been impacted by the service users who started and had time to complete the programme with two HbA1c measurements < 48 mmol/mol but were not considered to have achieved remission as they remained on glucose-lowering medication. Nonetheless, the ability to achieve remission has significant benefits, as demonstrated in the recent 12-year data from the Look AHEAD study, which reported a 33% reduction in chronic kidney disease and a 40% lower rate of composite cardiovascular disease measures in patients with evidence of remission.[40] This is in addition to 5-year data from the DiRECT trial which reported 47% fewer serious adverse events in the intervention group compared to the usual care control, driven by reductions in infections and new cancer diagnoses.[20] However, the fact that only 36% of those who were referred and 55% who started the programme completed it suggests this approach may not be acceptable to everyone. MDS data analysed by NHSE also suggest some sociodemographic inequities in uptake and outcomes, which correlates with similar patterns observed in the first cohort analysis of the NHS National Diabetes Prevention Programme.[41]

Although the DiRECT trial was predominantly based on White British adults, recent trial data from Qatar demonstrated 61% remission rates in a cohort of Middle Eastern and North African participants[11] following a similar LCD programme. A further real-world service evaluation[42] demonstrated 78% completion rates, and 66% remission rates within an ethnically diverse UK population. The recent SouTh AsiaN DiaBetes remission feasibility studY (STANDby) trial[8] also assessed the impact and feasibility of TDR-led weight loss in UK-based South Asian adults and demonstrated acceptability of this approach. These findings suggest a need for improved cultural competency of the existing NHS programme, which was a theme drawn out from this evaluation study, with recommendations including culturally tailored resources and language-specific groups, enhanced coach training and a wider range of more culturally tailored TDR products. These findings align with a recent participatory research study among South Asian adults with a lived experience of T2D in Manchester UK, which concluded that TDR in the form of soups and shakes was not acceptable, with a preference for a more culturally tailored low-energy food-based diet.[43] They also align with a systematic review undertaken by the research team (RA18), which concluded that weight management programmes for T2D need to be sensitive to the needs of the population group, and implementable within the community. Recommendations from the review also included consideration of social, habitual, economic and conceptual factors, which include consideration of local ethnic and cultural norms, and community relationships that facilitate the creation of culturally tailored programmes co-designed with target communities.

The cost-effectiveness analyses using short-term follow-up data indicated there is potential for programme to be cost-effective, dependent on assumptions about long-term weight and HbA1c regain trajectories. In contrast to the DiRECT economic analysis,[19] we conclude the programme is unlikely to be cost saving. This difference is likely to be partly due to a smaller observed mean reduction in HbA1c at 12 months, and to our use of a microsimulation model to project long-term outcomes, which differs from the three-state Markov model used in DiRECT. Future economic evaluations would benefit from longer-term follow-up data to determine how long observed weight and HbA1c reductions are maintained among people who have achieved remission at 12 months.

Overall, this study, along with the data on effectiveness from clinical trials, indicates that while LCD can enable some participants to achieve T2D remission, the high incidence of T2D among eligible adults and the low likelihood of LCD being cost saving has the potential to significantly impact NHSE budgets. This is not an unusual conclusion, since it is rare for a new medical treatment for any major chronic disease to be both health-improving and cost saving. Indeed, systematic reviews of novel

healthcare interventions delivered in primary care and the community to promote diet or physical activity[44,45] and other studies that have used UKPDS-OM2 to simulate the cost-effectiveness of interventions,[46–48] have also generally made the same conclusion of cost-effectiveness but not cost saving. Depending on the level of uptake, the LCD budget impact could approach NHSE's budget impact threshold.[49] A useful comparative example is the economic evaluation conducted alongside the DROPLET trial[50] which estimated the long-term outcomes associated with a similar commercially provided TDR-based LCD programme compared with nurse-led behavioural support among eligible participants with or without T2D and a BMI > 30 kg/m^2. The trial had a comparable sample size to DiRECT and used a pre-built simulation model suited to populations without diabetes (PRIMEtime-CE). While there are key differences with our study in terms of the intervention and the comparison group, the study estimated an incremental cost-effectiveness ratio of £12,955 (95% CI: £8082 to £17,827), which is comparable to our study in terms of demonstrating that the intervention improves health but is not cost saving.

Strengths and limitations of the study

While the strengths and limitations of each part of this study are clearly documented within each of the threaded publications, overarching strengths and limitations include the following:

Strengths

- The incorporation of PPI activity at every stage of this study has ensured a person-centred focus throughout.
- Collaboration with Diabetes UK enabled the team to support and incorporate learning from this study, to develop the user experience surveys which are now being used in the national programme to ensure continued monitoring of SP delivery.
- While the independence of this evaluation was paramount, effective coproduction with NHSE was also critical in enabling real-time translation of evidence into practice, which informed the development of the national roll-out prior to the official study end date.
- Effective cross-institutional working has allowed us to pool the breadth of expertise required for this complex real-world evaluation and deliver within a tight time frame and budget.
- The use of real-world data provides evidence of how the intervention works in practice and provides complementary data to the trial evidence but is delivered across the breadth of eligible populations, including the populations who are often under-represented in clinical trials.
- Use of a realist approach pulls together findings from across a complex programme of threaded research to provide a comprehensive insight into the underpinning mechanisms and context that drive the programme outcomes.

Limitations

- Starting the evaluation after the programme had been commissioned led to some limitations such as not being able to observe live staff training which had largely been completed prior to the study commencement.
- There were insufficient data to correlate the fidelity assessment with the clinical outcomes, which would be helpful in informing future service development.
- Given the time taken to acquire and process the NHS data, we are reliant on learning from data from the first cohort of service users who had time to complete the programme. As the data set grows, so will opportunities to expand the analyses.
- Developing relationships with some providers was a challenge, as interest and commitment to the evaluation process varied significantly between providers, despite monthly feedback where data were available.
- Varying levels of provider engagement impacted uptake and engagement in the service user survey (which was reliant on the provider as a gatekeeper for governance and logistical reasons). The longitudinal completions were most significantly impacted which limited the longitudinal analyses we could undertake.
- One provider was unable to take part in the session observations which limited the completeness of our data and the learning from this workstream.
- Data available from this study focused on those referred to the programme; therefore, more data are needed to explore the needs and characteristics of patients who were offered but declined a referral.
- It was challenging to engage NHS staff to take part in the evaluation which took place during the COVID-19 pandemic, which may have impacted the range of staff available to participate.
- As a result of the pandemic, the group and 1 : 1 services had to rapidly convert to remote delivery which may have impacted their delivery plans, and our ability to gain an accurate assessment of differences in costs and effectiveness by delivery model.

- The small number of people completing MyFood24 substantially limited the value of the dietary data intake data.

Other reflections and study learning

Our effective cross-institutional working provided a fantastic opportunity to share expertise, foster cross-university partnerships which have led to other successful funding applications (NHIR Health and Social Care Delivery Research funded complications in excess weight clinic evaluation, and a multiple long-term condition study funded by the Nuffield foundation), and others under development. The study has helped support the career development of our two project PhD students (Evans and Dhir) and Early Career Researchers (Drew and Marwood), and the promotion of three of our senior research staff to reader/associate professor (Matu, Brown and Homer). The study also allowed the development of a close and effective working relationship with the NHSE team, and opportunities such as the involvement of the team in the national procurement process, and the co-development of ongoing research.

Patient and public involvement

Patient and public involvement activity and impact

Our PPI team (Jenny Teke, Abi Ojo, Mike Willis, Gulsoom Akhtar, Clair Goddard, Beth Clegg, led by Ken Clare) represents a range of ages, genders, ethnicities and lived experience of T2D and/or obesity. In the last 6 months, unfortunately, Clair had to resign due to a change in employment, and three new members (Chris, Sarah-Louise and John) joined to bring a lived experience of undertaking the LCD programme, as we work to co-develop a long-term follow-up study (currently under review with Diabetes UK). This study simply would not have been achieved without the PPI team, who played a critical role in every stage of the research. A summary of our PPI activity and impact is summarised in *Table 1*.

Patient and public involvement dissemination and shared learning

Our PPI team played a critical role in the co-development of dissemination materials and were actively involved in the process of sharing learning. These activities are documented in *Table 2*.

TABLE 1 A summary of the Re:Mission PPI activity and impact

PPI activity	Impact
Initial proposal conception and co-development	A successful patient-centred proposal
Biannual PPI meetings	Continuous research co-development and patient-centred focus to research conduct, interpretation and dissemination
PPI WhatsApp group, regular member check-ins, session evaluations and post-session support provided by PPI lead Ken Clare	Highly productive and cohesive group working and very low attrition
PPI data collection training	PPI members took part in the patient interview data collection, which enhanced the patient-centredness of our approach, enriched the study data and contributed to developing participant relationships which resulted in excellent adherence rates
PPI lead Ken Clare represented the group at all internal and external project meetings	PPI activity and input are shared, discussed and actioned during every stage of the research
PPI member co-design and testing of all patient-facing materials	Good study uptake and completion rates
PPI members fed into NIHR reporting	Ensure all PPI activity is documented and shared
PPI co-development of study website: www.remission.study and supporting materials (*Table 2*)	Expanded reach and engagement of the research and study
PPI ongoing research co-development	A new co-developed research proposal and the recruitment of three new PPI team members
PPI involvement in service user interviews at 12, 18 and 52 weeks	Enhanced participant engagement, enriched study data and person-centred focus
PPI-led dissemination and learning (see *Public and patient involvement dissemination and shared learning*)	Significantly enhanced reach and impact of the study

TABLE 2 Patient and public involvement dissemination and shared learning activities and impact

Dissemination and shared learning activities	Outputs and impact
Co-presentation of the Re:Mission study at European Congress on Obesity (ECO) 2021 online and Re:Mission study posters ECO 2022 in Dublin	Shared learning to an international audience, and co-authorship of conference abstracts
Co-presentation of the Re:Mission study posters at the UK Congress on Obesity (UKCO) in Lancaster 2022	Shared learning to a national audience, and co-authorship of conference abstracts
Co-presentation of the Re:Mission study and good practice PPI learning to the sense nutrition professional group in Autumn 2023	Shared learning to a large audience of nutrition professionals
Co-authorship of key patient-orientated papers – see RA10, RA12, RA13, RA19, RA20, RA22	Co-authorship of international peer-reviewed manuscripts, which emphasise the importance of person-centred care
The Re:Mission study PPI group's own peer-reviewed publication (RA1)	PPI-led production and authorship of a peer-reviewed manuscript which shares critical learning from the Re:Mission study PPI activity to an international audience
Co-presentation at the Yorkshire Obesity Research Alliance event	Shared learning and best practice with key policy, practice and public stake-holders across Yorkshire
Presentation of Re:Mission PPI activity by three group members at the ASO webinar: the importance of PPI from a research and public perspective	Shared learning and best practices to key policy-makers and practitioners across the UK
Co-presentation of a PPI workshop to early career researchers (ECR) which used the Re:Mission study as an example of good practice at UKCO 2022 ECR day	Shared learning around the importance of PPI to a national audience of ECR professionals; this included a practical workshop where delegates were supported to develop their own PPI plans
Co-presentation of a PPI workshop to ECR which used the Re:Mission study as an example of good practice for the European Association for the Study of Obesity November 2023	Shared learning around the importance of PPI to an international audience of ECR professionals. This has changed views, perceptions and practice around PPI internationally
PPI-led presentation to the Yorkshire and Humber Clinical Research Network on the Re:Mission study and best practice PPI learning in 2023	Shared learning on the study findings and good PPI practice to a regional diabetes audience
PPI co-development of study website materials: • Participation film • Patient experience blogs • Glossary of terms	Expanded reach and engagement of the research and study. For example, the participant survey video has received 337 views (28 September 2024)
PPI co-development of LCD patient journey film and illustrated patient journal	These materials will be used to help communicate the evaluation findings (patient journal) and patient experience to a wide range of stakeholders which include the general public, GPs, SPs, to raise awareness of the programme and the evaluation findings to the widest possible audience (directly addressing a need arising from the evaluation findings)
Co-presentation of the planned Re:Mission study *British Journal of Diabetes* recorded webinar (March 2024)	This will showcase learning from the patient experience special edition to a national and international audience of diabetes specialists
PPI member chaired the LCD symposium at UKCO 2024	Demonstrates the importance and impact of the voice of lived experience

Equality, diversity and inclusion

Addressing equality, diversity and inclusion (EDI) and real-world learning was at the heart of this study, given the explicit objective to examine the equity impact of the NHS LCD programme and assess the transferability of learning to inform the applicability and development of the national roll-out (WP5).

Understanding our target population demographics and study representation

Type 2 diabetes prevalence remains slightly higher in men, older adults (although more younger people are now being diagnosed), and those of Asian, Chinese, Black African and Black Caribbean ethnicities. It can also be more prevalent in people living in social and economic deprivation.[2,4] This prevalence

pattern is reflected in overweight and obesity, and as both conditions are key inclusion criteria it was critical our study population mirrored the broad and diverse populations who are eligible for the LCD programme, and captured data on those most at risk. We, therefore, took a multifaceted approach to maximise inclusion (described below) and undertook a maximum variation sampling framework in order to ensure representation across gender and age groups, and oversample for those under-represented in the underpinning trial data[7,10] who are living in socioeconomic deprivation and/or from diverse ethnic groups. Any shortfalls in achieving this framework for the longitudinal interviews were made up with the addition of further cross-sectional interviews to ensure lived experiences from across the breadth of eligible populations were captured (see RA20, RA11 and *Appendix 4*).

Overall, the sociodemographic data from the interviews (see *Appendix 4*) and service user survey (see *Appendix 5*) aligned closely to the sociodemographic characteristics of those who were referred to, and started, the NHS LCD programme (see *Appendix 6*). However, additional cross-sectional interviews had to be undertaken to capture experiences across diverse ethnic communities, and recruitment of service users to the participation survey remained lower for diverse ethnic groups. This is therefore an important consideration for future survey research and requires more research coproduction with target communities to co-develop new methods to increase survey uptake.

Our research team and wider involvement

It was critically important that our team represented the diversity of voices to be represented in the study. Therefore, our PPI group included representation from a range of ages, ethnicities (including black and South Asian heritage), genders, socioeconomic status, geographies and comorbidities; this ensured that all our co-development activity represented voices from across our broad and diverse communities that the study would be working with. Our research team also included researchers who represented a range of genders, sexual orientations, ethnicities (including black and South Asian heritage), sociodemographic backgrounds, career stages, ages, experience, skills and expertise. This was important in both the research development and conduct, where researchers and PPI members were matched with the sociodemographics of participants for data collection. We also had a dedicated inequalities lead: Professor Maria Maynard who leads our migrant health research group and extensive EDI activity across the university. Maria ensured an inequalities lens was applied throughout the study.

Our research team included two PhD students (Evans and Dhir) who were supported throughout the study to share their learning at regional, national and international conferences, and professional meetings. These included presentations at the European and UK congresses on obesity, The British Psychological Society and the UK Society of Behavioural Medicine. They also led the authorship of several study publications (RA2, RA3, RA5, RA8, RA11, RA18, RA21) as well as co-authored several other papers. The team also included two early career researchers (Marwood and Drew) who led the authorship of RA6, RA7, RA12, RA16, RA17, and co-authored many of the other study papers. Marwood also took the lead for the associated SWAP study (see *Appendix 1*).

Opportunities to attend conferences, meetings and develop networks were shared across all team members, with an emphasis placed on career development. As such, both doctoral students are continuing post-doctoral work with the team as a direct result of their involvement in the study. Involvement in the study also supported the career progression of Matu, Brown and Homer to reader/associate professor, and Homer taking lead PI for a new NIHR HSDR award to evaluate the NHS complications in excess weight clinics, which directly builds upon the learning and team skills developed in this study.

Inclusive language, terminology and methodology

All our methods and patient-facing materials were co-designed with our diverse PPI group to ensure all materials were understandable, accessible and appropriate to the breadth of our target audience. Where work was undertaken with specific groups where English was not their first language, study materials and data collection were undertaken in the required language through either a formal translator or using the language skills available within the research team. This was particularly important when undertaking research within diverse ethnic communities (with several interviews conducted in Urdu, and a survey completed over the phone in Polish), thus enabling the use of first language and importantly the application of cultural understanding and context. A freephone number was provided to enable participants to receive information about the study and take part verbally to ensure that language and digital literacy/availability were not a barrier to participation, and tablets were provided to all participants taking part in the photovoice and MyFood24 dietary assessment.

Research recommendations

Specific research recommendations are provided within each of the threaded publications, but key overarching areas of future research required to build on learning from this study include the following:

- As this study only provides an evaluation of the initial programme pilot, there is a need to assess the long-term clinical, equity and economic impact of the now nationally available NHS T2D Path to Remission Programme. This research should include qualitative follow-up of diverse lived experiences, and assessment of weight and HbA1c trajectories of participants post 52 weeks (programme end), to determine if, and how rapidly, service users return to their baseline values, in order to further develop the cost-effectiveness models and strategies to prevent weight regain and loss of glycaemic control.
- Further inequalities research is required to further understand and improve:
  - the completion rates and retention in service users aged 18–39 years, in the most deprived quintile, and with a higher (40+) starting BMI, who are currently least likely to complete
  - the reduced weight loss seen by Asian and black service users
  - the pre-referral process, in order to understand the characteristics and support needs of those who were offered but declined a referral to the programme.
- Given this evaluation was undertaken during the COVID-19 pandemic, a quantitative analysis of the costs and health outcomes of the NHS T2D Path to Remission programme in the post-pandemic environment is required. This should include an analysis of changes made to the national roll-out, as well as further analyses linking behaviour change theory and techniques to clinical outcomes, which was not possible in the current study. Evaluation of subsequent years of programme provision is also required to elucidate the impact of changes to the programme specification, made as a result of the findings from the initial evaluation.
- Additional clinical research is required to further understand why some service users do, and some do not, achieve T2D remission.
- Given the prevalence and impact of mental health challenges, and emotional and disordered eating in people seeking weight management support, that were also identified in some service users, further research is required to understand: prevalence rates in this population, how this changes in response to the programme and opportunities to optimise support and outcomes, both during and after programme completion.
- As a result of the observed ongoing reliance on TDR products by some service users, it is important to examine the impact of long-term TDR use, including cost and equity, and the impact on dietary intake, the gut microbiome, and long-term weight and glycaemic control.

Conclusions

Our mixed-methods evaluation, when combined with the findings from the NHS process and clinical data analyses, found that the NHS LCD programme (now NHS T2D Path to Remission) provides a clinically effective and cost-effective programme to support weight loss and glycaemic control in adults with T2D. However, the evaluation also identified some areas for improvement in referral equity, uptake and completion, and fidelity of delivery, which have already informed the development of the programme and the decision to roll out nationally. The findings provide one of the first and largest evaluations of this intervention approach and demonstrate that real-world implementation results can align with those from the underpinning trials, although the ability to monitor long-term impact is now critical.

All study publications are listed in *Box 2*.

Additional information

CRediT contribution statement

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This synopsis should be referenced as follows:
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Patient data statement

This work uses data provided by patients/service users and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that they are stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation

Data-sharing statement

The NDA and MDS data sets may be obtained from a third party but are not publicly available. Authors obtained access to these data sets via Data Processing Agreement with NHSE. The authors are not permitted to share these data. Code books for all anonymised qualitative data are available on request, please contact L.Ells@leedsbeckett.ac.uk for more information.

Ethics statement

Ethics approval for the study was received from:

- Leeds Beckett University LREC references for WP2 (excl NHS interviews): 79441 (initial approval – January 2021), 80438 (updated STAR-LITE – February 2021), 90148 (updated recruitment strategy – November 2021), 93609 (offline observation methods added – February 2022), 106559 (online interviews with coaches added – December 2022), 107887 (added questions to STAR-LITE – January 2023), WP3 additional cross sectional interviews: 99281.

- University of York Department of Health Sciences Research and Ethics committee (HSRGC/2022/537/A) (WP5).

- Health Research Authority approval (West Midlands – Birmingham board) for WP2 NHS interviews and WP3/4 data collection – granted: IRAS project ID 294667; REC reference: 21/WM/0136 (July 2021).

Information governance statement

Leeds Beckett University (sponsor) and collaborating institutes (Universities of Teesside, Lancaster, York, Leeds and Sheffield Hallam) are committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679.

Under the Data Protection legislation, Leeds Beckett University is the Data Controller for the new primary data collection in WP2 and WP3.

Under the Data Protection legislation Leeds Beckett University is the Data Processor for the secondary data analysis in WP3: anonymised MDS data supplied by NHSE, who is the Data Controller for WP3. We processed personal data in accordance with their instructions. The data controller at Leeds Beckett University is the University secretary who can be contacted at: secretary@leedsbeckett.ac.uk You can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here: www.leedsbeckett.ac.uk/our-university/public-information/information-compliance/information-management-and-compliance/

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page. https://doi.org/10.3310/MPRT2139

Primary conflicts of interest: All authors named in this report have been funded by the National Institute for Health and Care Research (Health Services and Delivery Research, NIHR137025 – Evaluation of the NHS England Low-Calorie Diet implementation pilot: a coproduced mixed-method study (apart from Tamara Brown, Jordan R Marwood, Pooja Dhir and Tamla S Evans who were funded by Leeds Beckett University to support this project).

Louisa J Ells has received no other funding for this study but currently holds other NIHR, MRC and Nuffield foundation awards. She is a member of the Office for Life Science and NIHR i4i committee. Louisa is also a study author of the Awareness, Care and Treatment In Obesity maNagement (ACTION) Teens project and the Holbæk Obesity Treatment (HOT) Versus Conventional Obesity Treatment (COT) in Children With Overweight or Obesity trial advisory group member, both of which are funded by Novo Nordisk but LJE role is an independent unfunded external contributor. She is also on the editorial board for the journal *Perspectives in Public Health* and has previously received funding from the World Health Organization, local and central UK government and Scottish Chief Scientist Office.

Tamara Brown has received no other funding for this study but currently holds other NIHR awards and has held Office of Health Improvement and Disparities awards (formerly Public Health England, 2021–2). Tamara Brown has in the past received consultancy fees from the British Dietetic Association (2020) and the European Association for the Study of Obesity (2021). Tamara Brown has an honorary contract (unpaid) with Office for Health Improvement and Disparities 2022–27.

Ken Clare receives funding from NIHR, Obesity UK, and is a member of Patient Advisory Panel Novo Nordisk and Patient Advisory Board Boehringer Ingelheim. He was also on the Association for the Study of Obesity and European Coalition for People living with Obesity boards.

Maria Bryant is the outgoing Chair for the Association for the Study of Obesity.

Duncan Radley also receives funding from the Welsh Government and sits on the editorial board for the journal *Perspectives in Public Health* and organising committee for the Systems Evaluation Network. He was on the advisory group: Towards a Healthy New Towns Guidance: Built Environment, 2017–8, a network member: ESRC Strategic Network, steering committee: NIHR-funded project 'The Kids Will Eat Better study: how can

local authorities improve the efficiency and effectiveness of interventions to address inequality in childhood obesity?', 2020–3, expert advisor: UK Medical Research Council funded project 'Participatory systems mapping approaches in population health research: methods guidance and associated implementation toolkit', 2021–2.

Catherine Homer has received no other funding for this study but currently holds other NIHR awards. She is also on the editorial board for the journal *Perspectives in Public Health*.

Stuart W Flint reports Investigator-led research grants from the National Institute for Health and Care Research, Office of Health Improvement and Disparities, Doncaster Council, West Yorkshire Combined Authority and Novo Nordisk. He also reports support for attending academic meetings from Johnson & Johnson, UK Parliament, Safefood, Novo Nordisk and Devon NHS Integrated Care Service.

Janet E Cade is Honorary Secretary for Association for Nutrition, Chair of Advisory Committee for British Nutrition Foundation, Chair of Board of Directors for Dietary Assessment Ltd.

Chirag Bakhai is a member of the Expert Advisory Group for the NHS Type 2 Diabetes Path to Remission Programme and committee member for the NICE Type 2 Diabetes Guideline Update.

All remaining authors have no disclosures to declare.

Department of Health and Social Care disclaimer

This publication presents independent research commissioned by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, MRC, NIHR Coordinating Centre, the Health and Social Care Delivery Research programme or the Department of Health and Social Care.

This synopsis was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Study registration

This study is registered as NIHR Clinical Research Network Portfolio reference: CPMS ID 49330 and Research registry reference: researchregistry6614.

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Award publications

This synopsis provided an overview of the research award *A coproduced mixed-method evaluation of the NHS England low calorie diet implementation pilot*. Other articles published as part of this thread are:

Clare K, Ojo A, Teke J, Willis M, Akhtar G, Clegg B, *et al*. 'Valued and listened to': the collective experience of patient and public involvement in a national evaluation. *Perspect Public Health* 2022;**142**:199–201. https://doi.org/10.1177/17579139221103184

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Jones S, Brown T, Watson P, Homer C, Freeman C, Bakhai C, Ells L. Commercial provider staff experiences of the NHS Low Calorie Diet Programme pilot: a qualitative exploration of key barriers and facilitators. *BMC Health Serv Res* 2024;**24**:53. https://doi.org/10.1186/s12913-023-10501-y

Evans T, Dhir P, Matu J, Radley D, Hill AJ, Newson L, *et al*. Behaviour change techniques in low-calorie and very low-calorie diet interventions for weight loss: a systematic review with meta-analysis. *Obes Rev* 2025:e13896. https://doi.org/10.1111/obr.13896

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Marwood J, Radley D, Evans T, Matu J, Clare K, Bakhai C, Ells LJ. A cross-sectional analysis of emotional and binge eating in UK adults enrolled on the NHS low-calorie diet pilot for type 2 diabetes. *Clin Obesity* 2025;e70025. https://doi.org/10.1111/cob.70025

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For more information about this research please view the award page (https://fundingawards.nihr.ac.uk/award/NIHR132075)

Additional outputs

Conferences

Oral presentation of study the at the European Congress on Obesity (ECO) online conference (2021).

Oral presentation of the behaviour change work within the Re:Mission study at the British Psychological Society conference (2022).

Poster presentation of the behaviour change work within Re:Mission at UKCO (2022)

Emerging leaning from Re:Mission presented in a poster at UKCO (2022).

Poster presentation on review evidence of T2D and WMS in diverse ethnic groups at UKCO (2022).

Keynote presentation on the Re:Mission study at the Royal Society for Public Health conference – which focused on the importance of coproduction approaches in public health and the importance of this within the Re:Mission study (2022).

Oral presentation on the theoretical underpinnings of the NHS Low-Calorie Diet Programme at the British Psychological Society Division of Health Psychology Annual Conference (2022).

Oral presentation on lessons emerging from studies of dietary control, change and restriction – learning from Re:Mission to the Active Lifestyle Spring online conference (2023).

Poster presentation of the Re:Mission evidence review findings at the European Congress on Obesity (ECO) Conference (2023).

Poster presentation on the observations of service delivery and fidelity of behaviour change techniques Re:Mission at the European Congress on Obesity (ECO) (2024).

Oral presentation on Re:Mission economic analysis at the European Congress on Obesity (ECO) conference (2024).

Oral presentation debate on the benefits of Low Calorie Diet approaches for Type 2 Diabetes, building on learning from the Re:Mission study – ABCD annual conference (2024).

Oral presentations – The Re:Mission study patient perspectives and economic analysis – UK Congress on Obesity (2024).

Seminars, workshops, podcasts and informal presentations and outputs

Webinar (2021) Presentation for the Royal College of Physicians – the presentation was provided as part of CPD accredited webinar specialist series on obesity for the RCP. The series was designed to provide consultants and trainees with the necessary professional knowledge required on the acute medical take.

Podcast for the Leeds Beckett University (15 June 2021) This podcast was disseminated via the Leeds Beckett University social media channels and also feed into the Leeds Beckett University Inclusion, Equality and Inclusion conference Q&A, and has been posted on the Re:Mission study website. The podcast has helped raise awareness of the PPI activity underpinning the Re:Mission study. URL: https://player.captivate.fm/episode/b66828ac-50d3-4ad2-a909-d0463c5f4171

Presentation to the Obesity UK support group (2021) The presentation was about the importance of Patient and Public Involvement and Engagement and how it had been integral in the co-development and conduct of the Re:Mission study.

Blog (2021) Re:Mission study patient and public involvement blog to promote the importance of PPIE in the Re:Mission study, which has been published on the study website. URL: https://remission.study/news/kens-blog

Yorkshire Obesity Research Alliance – A PPIE presentation (2021) The Re:Mission PPI Lead Ken Clare delivered a presentation at YORA to share his experience of PPIE, to encourage more effective PPIE in obesity research across the region. URL: https://drive.google.com/file/d/1zgNYTe3rqmgJI0zamXa5Cv_X-yXqGw-Y/view

Webinar (2021) PPI in the Re:Mission study and the importance of ethnic diversity in research. Re:Mission study PPIE members Jenny Teke and Abi Ojo shared their insights from the Re:Mission study PPIE on the importance of ethnic diversity at the Association for the Study of Obesity – Webinar: The importance ofPatient and Public Involvement from a research and public perspective. This presentation was to raise awareness of the Re:Mission study and share learning from how our ethnically diverse group has helped shape the study. URL: https://aso.org.uk/resource/aso-webinar-importance-public-and-patient-involvement-research-and-public-perspective

Presentation about progress to date to researchers across Teesside University (2021). Researchers from across Teesside University attended. Awareness was raised around the work being carried out and the topic under

evaluation which led to a general discussion of some of the public perceptions of the issues being targeted by this intervention. When colleagues are looking for expertise on the skills employed in this project, they now know who to approach.

Presentation to the UK Society of Behavioural Medicine Early Career Network (2021) Tamla Evans one of the funded Re:Mission PhD students presented at was the UK Society of Behavioural Medicine Early Career Network on 9 December 2021. The presentation was titled 'The NHS low calorie diet programme: theoretical underpinnings and behaviour change fidelity'.

Presentation Carnegie School of Sport Active Lifestyles Café (2022) to share Re:Mission learning at the school of sport lifestyle cafe.

Presentation of the Re:Mission study at Leeds Beckett School of Health seminar (2022).

Presentation – emerging learning from the Re:Mission study presented at the Sheffield Hallam University sport and physical activity research centre seminar series (2022).

Presentation of early Re:mission learning to Leeds LCD group (2022).

Presentation of Re:Mission learning to DUK research group of practitioners, academics and DUK members (2022).

Poster presentation of the Re:Mission systematic review findings at the EASO Winter School ECR event (2022).

Clinical magazine article (NHD) 'Obesity: A multifactorial disease' (2022).

Presentation of the overview and early learning from the Re:mission to the Sense nutrition group (2023).

European association for the study of obesity ECR workshop on good PPIE- sharing learning from the Re:Mission study (2023) URL: www.youtube.com/watch?v=pnKWzm8-jzs

Clinical magazine article about ethnicity and its impact on those living with obesity including barriers to healthy eating, adherence to interventions, nutrition management, communication and recommendations for policy and practice (NHD). 'Obesity and ethnicity' (2023).

Presentation 'Does the design of the NHS Low Calorie Diet Programme have fidelity to the service specification?' at the UK Society of Behavioural Medicine Annual Scientific Meeting (2023).

Presentation to share learning from the Re:Mission study with the Leeds University nutrition group (2024).

Presentation to share Re:Mission study learning with Leeds Beckett University MSc dietetic students (2024).

ABCD webinar – Re:Mission study learning from staff and service user insights from the NHS Low Calorie Diet pilot (2024). URL: https://abcd.care/resource/current/demand-webinar-remission-study-learning-staff-and-service-user-insights-nhs-low

A short highlight notice about the new Path to Remission programme for GP surgeries. URL: https://remission.study/gp-video

A patient experience film – which explains the patient journey through the programme. URL: https://remission.study/patient-journey

An illustrated summary of what we have learnt from the Re:Mission study. URL: https://remission.study/summary

Patient and practice engagement resources

A short highlight notice about the new Path to Remission programme for GP surgeries. URL: https://remission.study/gp-video

A patient experience film – which explains the patient journey through the programme. URL: https://remission.study/patient-journey

An illustrated summary of what we have learnt from the Re:Mission study. URL: https://remission.study/summary

About this synopsis

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List of abbreviations

BCT	Behaviour Change Technique
BED	binge eating disorder
BMI	body mass index
DIRECT	Diabetes Remission Clinical Trial
DROPLET	Doctor Referral of Overweight People to Low Energy total diet replacement Treatment
EDI	equality, diversity and inclusion
FR	food reintroduction
GP	general practice/practitioner
HbA1c	glycated haemoglobin
IA	initial assessment
ICB	Integrated Care Board
LCD	low-calorie diet
LHS	local health system
MDS	minimum data set
MLTC	Multiple Long Terms Conditions
NHSE	National Health Service England
NIHR	National Institute for Health and Care Research
OA	osteoarthritis
PPI	patient and public involvement
QALY	quality-adjusted life-year
RQ	research question
SP	service provider
SWAP	study within a project
T2D	type 2 diabetes
TDR	total diet replacement
UKPDS	United Kingdom Prospective Diabetes Study
WM	weight maintenance
WP	work package

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Appendix 1 Study within a project study report: examining the impact of the NHS Low-Calorie Diet programme on patients with multimorbidity (obesity, type 2 diabetes and osteoarthritis of the hip or knee) IRAS ID: 313211 (HSC REC B)

Background

This 'study within a project' (SWAP) was part of the evaluation of NHS LCD pilot for T2D (NIHR132075). The SWAP was conceived following feedback from our patient advisory group who raised concerns about the impact of coexisting osteoarthritis (OA) and pain on patient experience and success. Joint pain, OA, obesity and T2D are common diseases that frequently coexist as multiple long-term conditions (MLTCs), and many people taking part in the LCD will live with these MLTCs. Importantly, research evidence suggests a bidirectional relationship between weight and pain that may impact weight loss, and that systemic inflammation, found in obesity and diabetes, may be involved in the development and progression of OA pain.[1,2,3,4]

Full methodology for the SWAP is provided in the Re:Mission protocol. The SWAP aimed to recruit a subset of NHS LCD participants who had OA pain to gather their views on the NHS LCD, and to compare their outcomes to participants who did not have OA pain. The study planned to: (1) gather inflammatory biomarker data at baseline and at 6-month follow up, via blood tests taken at participating NHS settings (WP A, n = 100 with OA and n = 100 without OA), and (2) capture the experiences of participants with OA using interviews conducted by trained researchers via Microsoft Teams (Microsoft Corporation, Redmond, WA, US) (WP B, n = 10), to answer the following questions:

- What are the lived experiences of LCD programme participants who have coexisting OA pain?
- What is the relationship between success of the LCD programme and inflammatory biomarkers?
- Can the management of participants on the LCD programme with pre-existing OA pain, be improved?

Study progress

The study was set up within good time, and five sites were recruited to enact the data collection for WP A, as shown in *Table 3*. However, there were significant difficulties with recruitment, which resulted in only 4 of the proposed 200 participants recruited between January and June 2023. Due to the timelines for the rest of the evaluation, and the very slow rate of uptake, the decision was made to terminate the study early, including the planned follow-up blood test for the four patients who had already been recruited.

A summary of the study actions and outcomes undertaken are shown in *Table 4*, and the resulting reflections and lessons learnt are summarised in *Table 5*.

TABLE 3 Study within a project study site recruitment overview

Sites initiated	Patients recruited	Baseline blood collection date
Sheffield Teaching Hospitals NHS Foundation Trust	1	22 February 2023
Leeds Teaching Hospitals NHS Trust	2	28 March 2023 (both)
Hull University Teaching Hospitals Trust	0	–
Gateshead Health NHS	1	27 April 2023
University Hospitals of Morecambe Bay NHS Trust	0	–

TABLE 4 Summary of SWAP study actions and outcomes

Action	Date(s)
Favourable NHS ethics approval received	1 September 2022
Discussing and setting up the study with local sites	February 2022–January 2023
Building relationships with local providers	6 September 2022 onwards
Recruitment commenced	January 2023
Ethical amendment submitted – to provide greater flexibility on the timeline for the baseline visit, and to add additional recruitment avenues to improve uptake (detailed above)	24 March 2023
Ethical approval for additional recruitment activities approved	21 April 2023
Approval for early termination submitted to the REC	27 June 2003
Approval to terminate received from the REC	7 August 2023
Declaration of end of study form submitted to the REC	17 August 2023

REC, Research Ethics Committee.

SWAP references

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TABLE 5 Lessons learnt and reflections for future projects

Problem encountered	Background	Lessons learnt	Recommendations for future mitigation of this problem
Persistent lack of engagement from LCD providers	The study co-ordinator contacted providers via e-mail and held subsequent Teams meetings with each provider individually. In this meeting, the co-ordinator explained the purpose of the study and what was required by providers. This included sending study advertisement materials to LCD service users when they enrolled, as part of a standard e-mail sent to each service user by providers. Despite initial positive discussions and verbal agreement to circulate materials, once recruitment commenced providers disengaged from the recruitment process. For example, one provider refused to circulate study materials once recruitment commenced in their area. This matter was resolved via contacts at the Trust and the senior leadership of the LCD provider, and the provider subsequently engaged well with recruitment. However, the other four providers did not engage well with the process. They were asked to provide updates on how many potential participants they were circulating recruitment materials to; however, they seldom provided this information. This pattern of engagement from providers was mirrored in the main evaluation, which experienced similar difficulties with providers not circulating links for study surveys	Reliance on commercial providers as the only method of recruitment ultimately contributed to the study not being able to recruit a sufficient number of participants Although all providers were contractually mandated to take part in the evaluation, clearer communication from NHSE as to what this was to entail may have helped (although practically challenging in this instance as the SPs were commissioned before the evaluation)	To ensure future recruitment methods are not reliant on commercial providers
Materials for recruitment	Initially participants were sent a participant information sheet (PIS) via e-mail, along with other LCD programme documentation, when they enrolled. The PIS gave a thorough summary of WP A and included an e-mail address and phone number for the OA trials team at Leeds Teaching Hospitals who were managing referrals for WP A. This resulted in three participants signing up for the study	After speaking to one provider, and discussions with the OA trials team at Leeds Teaching Hospitals, suggestions were made to improve the process for participants with the aim of improving recruitment. It was deemed that the initial approach of providing the PIS as an attachment, requiring participants to read to the end, and contact the team to register their interest, provided too many obstacles for participants. Subsequently, an ethical amendment was submitted and accepted which allowed for a brief description of the study and a weblink for participants to submit their details to the OA trials team, who could contact them directly. The full PIS would then be provided to the potential participant This description and link were then subsequently included in the body of the e-mails to participants. The amendment also allowed for the advertisement of the study via the Diabetes UK and social media	Recruitment methods should aim to make it as easy as possible for a potential participant to register their interest in joining a study. For example, the first approach to potential participants should provide brief, easily accessible information and a quick and easy method of signing up for more information
Participant payment	There were no financial incentives offered for WP A, other than the reimbursement of travel expenses	Our patient and public involvement and engagement team suggest that payment to take part may have increased participation, particularly given that each clinical visit will have taken time out of the participant's day	Study participants should be paid for their time at the standard NIHR rate.

This synopsis should be referenced as follows: Ells LJ, Brown T, Matu J, Clare K, Rowlands S, Maynard M, *et al.* Evaluation of the NHS England Low-Calorie Diet implementation pilot: a coproduced mixed-method study. *Health Soc Care Deliv Res* 2025;13(29). https://doi.org/10.3310/MPRT2139

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Appendix 2 Realist information data synthesis framework

Outcomes	Mechanisms	Supporting evidence statements and context
Pre-referral stage		
Identification of patients eligible for LCD	**Individual**	
	All eligible patients are aware of the programme and have a positive perception of it	*Insights from online survey of SUs (RA13)* • Approximately 1 in 10 SUs felt their healthcare practitioner did not have sufficient knowledge of the programme and referral process, and they did not feel listened to and treated with respect *Insights from SUs who did not complete the programme (RA16) and service users interviewed at end of TDR (RA10)* • Patients approached their GP and asked to be referred onto the programme • Patients were motivated to seek referral and happy to be referred, because they wanted to improve their health and understood the impact of their weight on their health • Mental health issues, including anxiety and depression, were common prior to starting the programme • Emotional and disordered eating were raised by patients as issues prior to starting the programme • Patients wanted to be referred to reset their emotional responses to food and come off their diabetes medications *Insights from NHS Referrers (Practice Nurses, General Practitioners, Clinical Pharmacists or Advanced Nurse Practitioners) (RA17)* Not all eligible patients are informed about the programme. Some referrers do not offer referrals to patients they perceive as having barriers to the programme, for example where English is not a person's first language or older adults if it's a remote/technology-assisted programme
	Provider/referrer	
	Referrers have the adaptive capacity, capability, opportunity and motivation to refer equitably and effectively Providers continue to engage with LHE to mobilise the programme	*Insights from commercial provider staff (RA4)* • Providers are dependent on GP practices for referrals • Providers recognised that the eligibility criteria were perceived as unnecessarily limiting by GPs • Providers referred to the need to train GPs in the accurate identification and referral of suitable patients • Providers view patients with disordered eating as 'inappropriate' to refer • Providers are reliant on communication with non-clinical staff (gatekeepers) in GP practices • Providers acknowledged that it took time to build up trust with GPs and for GPs to build confidence in referring patients into the programme, especially when requesting a change in medication • Providers recognised the need for an ongoing process of embedding knowledge and understanding of the programme within GP • Providers can differentiate this programme from other programmes mainly because of the TDR phase • Providers appreciate the higher intensity and longer-term support that the programme offers SUs and being able to follow them on their journey • Providers frame equity as a capacity issue or a lack of need *Insights from Locality Leads (RA6)* • Locality Leads perceive that referrer interest in the programme is vital to their engagement with the programme (referrals are not just about capacity)

Outcomes	Mechanisms	Supporting evidence statements and context
		Insights from NHS Referrers (Practice Nurses, General Practitioners, Clinical Pharmacists or Advanced Nurse Practitioners) (RA17) • Not all referrers had received training about the programme • Not all referrers considered themselves to have sufficient expertise and knowledge of the programme to be able to make referrals • Referrers would have liked more information about the programme including details about the programme phases, the delivery model(s) available in their area, ineligibility criteria and cultural competence of the programme/providers • Referrers, particularly Practice Nurses, would have liked feedback from providers on individual patients journey through the programme so that they could use this knowledge for subsequent referrals (person-centred) • Referrers wanted more support from Locality Leads to refer patients into the programme • Management of referrals is not equity-focused. There was an over-reliance on opportunistic referrals which failed to identify those who are not engaged and potentially more in need of the programme • Referrers highlighted perceived process barriers to referral including additional workload that was time consuming rather than difficult • Referrers perceived deprescribing and lack of confidence in making medication changes as the biggest barrier to referral • Referrers were programme champions and had confidence in the referral process • Referrers acknowledged the high level of commitment required by SUs to undertake the programme, specifically the TDR phase, reporting patients do not want to be on a liquid diet for 12 weeks • Referrers highlight technology and language as significant considerations for referrers when deciding who to refer • Referrers acknowledge that individual patients prefer different models of programme delivery, and the choice of delivery models is important • Having referrers who spoke multiple languages and providers who offer the programme in languages other than English can promote referral and engagement from SUs who speak limited English • Referrers perceive TDR as a barrier to SUs with various cultural food practices *Insights from coaches on programme delivery with minoritised ethnic groups (RA21)* • Providers acknowledged the need for language support in uptake of diverse ethnic populations when providing information about the programme and signing them up *Insights on transferability of the programme (RA15)* • Referrers/locality leads and programme deliverers perceived there to be a strong supporting evidence base (anecdotal and RCT) for the programme • Referral process perceived as complex by locality leads/referrers/programme deliverers, causing bottlenecks in the process leading to disengagement of some referrers • Some referrers perceived eligibility criteria to be too restrictive (e.g. upper age limit of 65) • Referrers/locality leads and programme deliverers perceived a lack of tailoring to some patients needs which reduced accessibility (e.g. non-English speaking, learning disabilities, cultural) • Locality leads and referrers described main barrier to implementation as being securing engagement from GP practices Some locality leads described using a multitude of communication methods to promote interest and knowledge and convening multidisciplinary groups as supporting implementation
	Policy/wider system	
LHE has capacity and resource to proactively support equitable mobilisation		*Insights from commercial providers (RA4)* • Providers reported that locally, to be able to make well-informed decisions, commissioners needed to see and understand how the programme fitted with what else was going on in the area • Not all providers practised targeted recruitment activities with primary care to ensure that it was being offered and accessible to all patients who met the criteria, considering service users' culture, religion or beliefs • Providers acknowledge need for higher volumes of referrals to make the programme cost-effective and attractive to commissioners

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Outcomes	Mechanisms	Supporting evidence statements and context
		Insights from Locality Leads (RA6) • Locality Leads perceive that engagement of GP practices with the programme is dependent on the support from LHE • Locality Leads perceive that many and varied forms of proactive and non-written communication are important between the LHE and referrers to drive referrals to the programme • Locality Leads recognise the importance of communicating with wider stakeholders about the programme and directly with patients • Locality Leads do not always see the need to make training resources available to referrers • Locality Leads agreed that training resources were important to tackle issues with referrals and low engagement with the programme from referrers • Locality Leads do not consistently monitor referrals to ensure equitable distribution of referrals • Locality Leads do not consistently target training of referrers where there is high proportion of eligible patients or low engagement from referrers • Locality Leads perceive barriers to referrals that are process-based (time and complexity and eligibility criteria) and referrer-based (staff turnover, referrers confidence and expertise) • Locality Leads recognise the importance of collaborating with public health colleagues and local stakeholders to deliver the programme effectively (Locality Leads need this support) • Locality Leads perceive it is important for the provider to actively engage with the LHE and to contribute to the training resources (Locality Leads needs this support) Incentives for referral are not used consistently across localities or for the same purpose
Referral stage		
See NHS data summary in *Box 1* and Valabhji *et al.*[17]		
All eligible patients are offered a referral to the programme Demographics of patients referred reflects the sociodemographic of the local population	**Individual** Patients have the capacity, capability, opportunity and motivation to take part in the programme	*Insights from commercial providers (RA4)* • Providers recognise that the main reason for joining the programme might differ between SUs and might be different to the principal aims of diabetes remission and weight (e.g. psychosocial outcomes) *Insights from SUs at 12-weeks (RA10)* SUs exhibited varying levels of understanding regarding the programme. While some had extensive knowledge about it, others had a more ambiguous understanding. Additionally, there were SUs who were under the impression it was as a 12-week course rather than a year-long commitment

Outcomes	Mechanisms	Supporting evidence statements and context
		Insights from online survey of SUs (RA13) • SUs were very motivated to manage their diabetes and lose weight • Approximately 1 in 10 SUs felt their healthcare practitioner did not have sufficient knowledge of the programme and referral process, and they did not feel listened to and treated with respect • Free-text responses when asked things to improve in the referral process reinforced these findings, with 33 SUs stating that referral staff needed to better understand the programme and referral process, providing more information at the point of referral *Insights from SUs during the FR stage (12–18 weeks) (RA22)* • SUs expressed enthusiasm and motivation to participate in the programme. Many perceived it as an opportunity for which they were extremely grateful • SUs with mental health issues referred to the programme without due consideration for their condition and the potential impact the programme could have on their mental health • Health outcomes (present and potential future), no meds, improved QoL main reasons for engagement • Timing of referral important Motivation maintained with personalised support from coach/healthcare provider
	Provider/referrer	
	The referral process needs to be person-centred Referrers have the adaptive capacity, capability, opportunity and motivation to refer effectively and equitably Provider works proactively with referrers to support effective, equitable referral	*Insights from SUs at 12-weeks (RA10)* • The time frames for referrals varied significantly among SUs ranging from a few weeks to a year • Certain self-referred SUs had to exert significant effort to secure a spot in the programme, possibly highlighting inconsistencies in the level of understanding among GPs and diabetes specialist nurses regarding the programme *Insights from SUs who did not complete the programme (RA16)* • Mental health issues, including anxiety and depression, were common prior to starting the programme which patients stated providers were made aware of *Insights from SUs at 52-weeks (RA19)* • Some SUs found that the programme was not aligned with their expectations, feeling they were 'mis-sold' by their referrer. They had anticipated receiving personalised support from medically trained professionals, such as GPs, nutritionists and dietitians, rather than solely relying on the assigned coaches *Insights on transferability of the programme (RA15)* • In the majority of areas sampled, characteristics of the local population did not inform referral strategies
	Policy/wider system	
	LHE develops referral opportunities that are appropriate for local population	*Insights from the economic evaluation (RA14)* • Some SUs were referred more than once and others were not eligible which also impacts on costs *Insights on transferability of the programme (RA15)* In general, locality leads and referrers felt optimistic about the programme and described successful ways of working to reduce pressures on GPs, including the involvement of clinical pharmacists and specialist nurses in the referral process

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Outcomes	Mechanisms	Supporting evidence statements and context
Initial assessment stage (PRE-TDR)		
See NHS data summary in *Box 1* and Valabhji *et al.*[17]		
All SUs start the programme Demographics of person accepting the referral reflects the sociodemographic local population	**Individual** All SUs understand the programme (the programme makes sense to the patient) and any medication changes required The programme is acceptable to the SU	*Insights from online survey of SUs (RA13)* • The majority of SUs (83% to 88%) indicated the information provided by the programme was clear; the programme was easy to incorporate into their lives and helped them achieve their goals *Insights from SUs at 12-weeks (RA10)* • There was inconsistency in the pre-programme assessment process. While some SUs were able to meet (virtually or via a call or watch a pre-recorded video) with the provider before joining to acquire information about the programme, others did not have this opportunity • Not all SUs received course materials/workbooks, etc. before the start of the programme • Most SUs had a basic understanding of the programme and the commitment involved. SUs taking metformin were advised to discontinue its use *Insights from SUs at 52 weeks (RA19)* • SUs experiencing emotional or disordered eating thought that they would be provided with psychological support throughout the programme • SUs would have liked to have been able to access a range of delivery models (i.e. group and 1 : 1 support) *Insights from coaches on programme delivery with minoritised ethnic groups (RA21)* • Preconceptions that SUs from ethnically diverse backgrounds would have difficulty completing the programme due to culture and difference in foods *Insights from the economic evaluation (RA14)* • There was wide variation in terms of the time gaps between the referral dates or dates measurements were taken at referral and when SUs started the programme • There were also some gaps in when the SUs were meant to start the programme and when they actually started (this was possibly due to COVID-19) *Insights on transferability of the programme (RA15)* Referrers/providers perceive that the programme is more acceptable to SUs if the delivery model is appropriate to their personal circumstances and preferences

Outcomes	Mechanisms	Supporting evidence statements and context
	Provider/referrer	
	Provider has the necessary system and processes in place to facilitate successful on boarding/initiation of the programme The IA/on boarding process is person-centred Providers have the adaptive capacity, capability, opportunity and motivation to support SUs and provide a person-centred approach to onboarding	*Insights from online survey of SUs (RA13)* • Ninety per cent SUs 'agreed' or 'strongly agreed' that the SUs doing their initial assessment were helpful and supportive, and that the process gave them an understanding of what to expect on the programme • Free-text responses when asked things to improve in their initial contact with their SPs indicated that some SUs felt the provider needed to provide information earlier, such as their expectations, the possible side effects and when they would start taking the TDR products (*n* = 15); the need for better communication, including clearer and more streamlined information (*n* = 40), and the need to be able to contact the provider (*n* = 40) *Insights from SUs who did not complete the programme (RA16)* • Mental health issues, including anxiety and depression, were common prior to starting the programme which SUs stated providers were made aware of *Insights from cross-sectional analysis of emotional and binge eating (RA12)* • There is a significant proportion of SUs who are accessing routinely commissioned care who may have difficulties with their eating behaviour, or a diagnosable eating disorder • The presence of potential binge eating disorder was seen in 24.3% of the sample Being female and having higher frequency of weight cycling was associated with both emotional and binge eating
12 week TDR stage		
See NHS data summary in *Box 1* and Valabhji *et al.*[17]		
	Individual	
All SUs are able to adhere to TDR phase All SUs successfully complete the TDR stage All SUs lose weight There are no sociodemographic differences in outcomes All SUs reduce levels of HbA1c/improve glycaemic parameters Comorbidities and side effects are monitored	SU has appropriate peer/family support SU understands how to successfully complete TDR stage SUs are able to undertake medication changes and monitor BP/blood glucose and weight SUs develop positive management strategies to undertake the programme	*Insights from commercial provider staff (RA4)* • Providers acknowledge that lack of attention to traditional cultural events such as Ramadan and Christmas, especially during the TDR phase, can create a barrier • Providers view cost of the TDR as a key barrier to uptake • There was variety between providers on choice of products offered to service users • Providers appreciate the 12-week TDR phase is intense and a challenging phase for service users to remain compliant • Barriers faced by service users disproportionately impact SUs from minoritised ethnic groups because of multiple intersecting barriers relating to language, gendered roles and family support and food cultures • The boundaries around medical responsibilities were reported as contested, for example when the provider requests a GP to reduce the patient's medication. Providers perceived that having a Medical Director with appropriate clinical qualifications within the provider organisation was viewed as beneficial

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Outcomes	Mechanisms	Supporting evidence statements and context
		Insights from South Asian SUs experiences (RA11) The SUs described a significant barrier was disliking the taste of the TDR products. This sentiment was compounded by the challenge of refraining from cultural foods and the lack of diverse flavours in the products • There was a tendency among SUs to avoid engaging in social gatherings and familial events during the TDR phase. This avoidance behaviour emerged as a protective mechanism to mitigate exposure to potential dietary temptations and uphold their commitment to the programme • SUs experience of support and their culture were closely intertwined. A lack of encouragement from family and friends during their engagement with the programme was described. This lack of support was sometimes a result of SUs avoidance of social occasions *Insights from programme session observations (RA7)* • Providers gave varying attention to provision of peer and family support. In some cases, this was done well with peer support between group members, or with family members attending the session alongside SUs. However, in other observed sessions, there were often missed opportunities to discuss family support/or barriers to adherence that were not picked up on by the coach • Observations of some sessions documented a disconnect between session content and the stage of programme. For example, for one coach did not mention TDR in several of the TDR stage sessions. There was also variation in the extent to which physical activity was discussed/discouraged in this stage, which may have added confusion for the SUs *Insights from online survey of SUs (RA13)* • Increased support was highlighted by SUs who desired the opportunity to obtain support from their peers • The majority of SUs (83%–88%) indicated the information provided by the programme was clear; the programme was easy to incorporate into their lives and helped them achieve their goals. Further, they felt supported in the programme and had a good relationship with their coach • Perceived negatives of the TDR phase, provided by 43 SUs, were going out socially (n = 23), missing eating (n = 9), hunger (n = 10), the level of determination required (n = 6) and negative side effects (n = 15) • Two hundred and sixty-four SUs rated their TDR products: 63% rated them as 'nice' or 'very nice', 31% as 'ok' and 6% as 'not very nice' or 'horrible'. Of these, 173 SUs provided additional detail on how they felt the TDR products could be improved. A desire for more variety in products was most frequently noted (n = 70), followed by the need to improve flavour/taste and texture (n = 65), with all three of the main TDR products (soups, shakes and ready meals) being referenced. Related to this, 29 SUs felt the products were too sweet or wished more savoury options were available, and 16 SUs wanted solid food options. Eighteen SUs (15 from one SP) also highlighted challenges in obtaining the products advertised on supplier's websites • Increased support was also highlighted by 24 SUs, who desired more support from and availability of their coach

Outcomes	Mechanisms	Supporting evidence statements and context
		Insights from SUs at 12 weeks (RA10) • Peer support varied among the groups, with some being more engaged than others • Some SUs initially did not receive their work booklet or TDR products on time and experienced issues accessing the provider app and modules • There was minimal evidence to suggest that dietary adaptation was culturally adapted or person-centred, except with one provider • Instant changes to weight and blood glucose levels during TDR were reported • Certain SUs reported experiencing side effects, notably bowel irregularity or loose stools, attributed to the TDR products. Regarding acceptability, opinions varied; some SUs found them excessively sweet, while others deemed them enjoyable • SUs could record their measurements in the provider app; however, as the coach lacked access to the app information, they often had to resubmit the information • Monitoring of health outcomes (bloods, side effects of the programme) was not consistently done by primary care during the TDR phase leaving some patients feeling unsupported and concerned • The allowance of supplementary foods supported adherence • Improvement to quality of life, health and weight loss was a motivation to continue the TDR stage • Some SUs received all products at the start of the product, leading to product wastage, storage issues and chances in the taste of products over time • Peer support (where available) through WhatsApp groups or community forums was well received and a source of support outside immediate family and friends • Looking ahead to FR – expectations around meeting weight loss targets and improving blood glucose levels were high, due to the rapid improvements experienced in the first 12 weeks of TDR • Towards the end of the TDR stage, SUs were anxious about losing the control the TDR products gave them as they started to think about reintroducing food • SUs were concerned about the challenges of planning meals for themselves and others around them who may want to eat differently • SUs were considering continued use of TDR products for convenience and to sustain weight loss *Insights from SUs who did not complete the programme (RA16)* • SUs who did not complete the programme said that mental health issues, including anxiety and depression, were common prior to starting the programme and providers were aware of this during the programme • SUs were initially happy to start the programme and the experience of being discharged was framed negatively, with some SUs being discharged by providers against their will, without being presented with an opportunity to continue • SUs who did not complete the programme spoke about a positive impact of the programme • The programme and products were not framed as the defining reasons for withdrawal once SUs started TDR (some SUs continued to use the TDR products after leaving/being withdrawn) from the programme • Mental and physical health challenges and impacted on SUs ability to attend or comply with the programme • Life events and circumstances including bereavement impacted on SUs' ability to attend or comply with the programme • SUs who did not complete the programme perceived a lack of support from the provider *Insights from SUs at 52-weeks (RA19)* • Peer support varied among the groups, with some being more engaged than others • Group peer support and WhatsApp groups were beneficial and most active during TDR but dwindled in other phases of the programme • Instant changes to weight and blood glucose levels during TDR were reported, some of these started to rise by the maintenance phase • Family/social support was received among most SUs • SUs who faced external life events, such as bereavement, did not receive additional support. There was limited flexibility concerning SUs missing sessions, even considering these circumstances

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Outcomes	Mechanisms	Supporting evidence statements and context
		Insights from the economic evaluation (RA14) • There were no significant differences in terms of additional expenditure that SUs incurred during the programme by gender, ethnicity or socioeconomic status • For SUs who did incur additional expenditure during the programme, the average spend was a total of £125.99 over the whole programme. The main component of these additional resources was SUs purchasing their own TDR products, including during the TDR phase • The majority of purchases made during the TDR phase were of extra monitoring strips. SUs who made purchases of monitoring strips spent on average £17.80 during the TDR phase. TDR product purchases were the second most popular purchases made under the TDR phase with 21% of SUs who made purchases reporting to have bought extra TDR products. For those that made purchases of TDR products, they spent an average of £104.50 during the TDR phase. One potential explanation for this is that SUs would have preferred to be given a smaller trial batch that would last about a week, for them to sample the TDR products, i.e. shakes/soups and varied flavours so they could pick what they liked and then purchase more products after that • Despite these additional expenditures, it is likely that on average participants saved money overall during the programme because they were spending less money on their food grocery bills *Insight from digital fidelity (RA9)* • The BCT content of the digital model used in the NHS-LCD programme adhered well to the NHS service specification and providers' plans. It surpassed what has been previously observed in face-to-face services provided through group or one-on-one behavioural support models
	Provider/referrer	
		Insights from SUs at 12 weeks (RA10) • The variation in TDR product availability, with some providers offering a diverse range and others having a limited selection, could potentially impact adherence to the programme • SUs modified the taste of products with spices, non-sugar flavourings and the texture through freezing or baking shakes *Insights from programme session observations (RA7)* • There were some good examples of person-centred delivery across both providers observed • However, some coaches, across both providers, demonstrated less person-centred approaches, including rehearsed and rigid delivery reminiscent of reciting from a script, as well as direct and unempathetic approaches, and the use of academic and non-person-centred language • The coach appeared to be central to person-centred delivery. Maintaining focus on individual goals and discussions proved more challenging in group sessions • One provider gave culturally tailored suggestions for adaptation of TDR products *Insights from SUs who did not complete the programme (RA16)* • Mental health issues, including anxiety and depression, were common prior to starting the programme which SUs stated providers were made aware of *Insights from SUs at 52 weeks (RA19)* • The coach seemed to play a pivotal role in person-centeredness. Some coaches successfully delivered a person-centred approach, while others did not • Certain coaches displayed direct and unempathetic approaches, read from a script and did not attempt to engage the group • Little evidence of cultural adaptions to TDR products *Insights from the economic evaluation (RA14)* • While it is probable that SPs delivered the programme using a face-to-face method would have incurred some additional costs for venues that would not be incurred when using remote delivery, this was not captured in the data shared with us by providers and NHSE, partly because of the predominance of online delivery during the pandemic

Outcomes	Mechanisms	Supporting evidence statements and context
		Insights on transferability of the programme (RA15) • Perceptions of TDR products were generally positive among locality leads/referrers/SPs (with some reporting that some SUs didn't like taste or lack of choice) • Locality leads/referrers/SPs believe TDR phase had high patient compliance due to level of structure it provided, no need to cook and prepare meals and cost savings to SUs • Programme delivers described one-to-one delivery as being flexible in its structure and led by the SU *Insights from coaches on programme delivery with minoritised ethnic groups (RA21)* • Coaches highlighted the challenges experienced when supporting SUs with different ethnicities to their own, in relation to cultural food preferences and considerations associated with their ethnic backgrounds • Some coaches reporting they consider the difference in cultures when delivering the programme and adapt the delivery according to this • Coaches described a sense of responsibility for adapting programme sessions to align with the cultural backgrounds of SUs. Commonly, cultural tailoring was perceived as delivering the content in other languages and providing support and specific resources during Ramadan
	TDR session delivery is person-centred Provider has the necessary system and processes in place to facilitate successful session delivery, support and TDR products/monitoring equipment TDR products work for all SUs (taste acceptable, manage hunger, no or managed side effects) TDR dietary adaptation is person-centred	*Insight from digital fidelity (RA9)* • The BCT content of the digital model used in the NHS-LCD programme adhered well to the NHS service specification and providers' plans. It surpassed what has been previously observed in face-to-face services provided through group or one-on-one behavioural support models • In part, this can be understood through the standardisation of content, which reduces dependence on human delivery. Examining the barriers and facilitators to BCT delivery using group and one-to-one delivery models, our previous work highlighted the influence of both coach-level and programme-level factors on fidelity, including the skill level of the coach in delivering BCTs; session time management; group-based settings sometimes hindering individual engagement with a BCT; and deviations from the session plans

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Outcomes	Mechanisms	Supporting evidence statements and context
FR stage		
See NHS data summary in *Box 1* and Valabhji *et al.*[17]		
All SUs are able to adhere to the FR stage All SUs successfully complete the FR stage (including coming off TDR completely) All SUs retain weight loss There are no sociodemographic differences in outcomes All SUs reduce levels of HbA1c Comorbidities and side effects are monitored	**Individual** Anyone with emotional or disordered eating receives the support needed to undertake new dietary approachSU has appropriate peer/family support SUs are able to buy, store and cook culturally appropriate affordable and healthy foods SUs are able to undertake medication changes and monitor BP/blood glucose and weight SUs have opportunities to be physically active (no cultural, financial or environmental barriers) SU understands how to successfully complete FR stage SUs develop positive management strategies to undertake the FR stage and expectations around weight change	*Insights from South Asian SUs experiences [RA11 – text reproduced from South Asian individuals' experiences on the NHS low-calorie diet programme: a qualitative study in community settings in England, BMJ Open under licence: (cc BY_NC 4.0)]* • SUs described the guidance provided within the programme to be oriented towards a Western diet. The absence of recipes and meal plans tailored to South Asian cuisines and other cultural practices left SUs struggling to effectively apply the programme recommendations to their familiar ethnic foods. SUs reported a sense of responsibility to independently modify recommendations to align with their ethnicity and cultural dietary practices • SUs highlighted the important role of motivation in making dietary changes. These changes encompassed altering portion sizes, reducing the quantity of staple foods, and adopting modified cooking methods • Fellow SUs enrolled in the programme, particularly those who shared the same South Asian ethnicity, emerged as sources of support and encouragement. Reciprocal exchanges of meal ideas and empathetic encouragement were reported *Insights from programme session observations (RA7)* • Although not stipulated in the specification, it was observed that a clear support gap was identified across providers on emotional eating and psychological support, which was often raised by service users but left unaddressed by coaches. It was unclear if this support gap arose from time constraints or insufficient coach training. This observation was important, as the ability to empower SUs for long-term behaviour changes relied on the individual coach's skill set which appeared to be variable • See previous comments on peer and family support. This did not differ across programme stage *Insights from online survey of SUs (RA13)* • Most SUs (84–89%) indicated the information provided by the programme was clear; the programme was easy to incorporate into their lives and helped them achieve their goals. Further, they felt supported in the programme and had a good relationship with their coach • 125 SUs provided information on what they felt the positives were for this phase of the programme. Being able to eat 'real' food was most frequently noted (n = 39), followed by consumption of/appreciation for healthy food (n = 35) and feeling more in control/being more mindful of the food being consumed (n = 34) • Perceived negatives of this phase, provided by 60 SUs, were the need to plan, purchase and prepare food (n = 23); increases in weight/anxiety about weight regain (n = 19); concern about the level of motivation required to stick to the programme (n = 9); anxiety over what food to eat (n = 7); and the amount of support/guidance provided (n = 6) • When asked if they were confident what types of food to reintroduce into their diet, 63 SUs (43% of respondents) indicated 'to some extent' and 8 SUs (5% or respondents) indicated 'no' • SUs were also asked how they felt about any weight change during the FR phase. In general, SUs stated they felt happy, okay or disappointed based on their continued weight loss. However, WM was viewed positively by some and negatively by others

Outcomes	Mechanisms	Supporting evidence statements and context
		Insights from SUs during the FR stage (12–18 weeks) (RA22) • There was minimal provision or support for SUs experiencing mental health issues or struggling with emotional or disordered eating • SUs who faced external life events, such as bereavement, did not receive additional support. There was limited flexibility concerning SUs missing sessions, even considering these circumstances • The process of FR lacked a person-centred approach, with some SUs expressing a desire for personalised meal plans • Health literacy/understanding of diet/meal planning at FR was not consistent • Cultural understanding/information in non-Western diets not accounted for • SUs struggled to make choices and planning for returning to eating meals and craved the structure and control experienced with the TDR products • SUs reported anxiety over returning to poor eating habits and weight regain • SUs who have not met their weight loss targets during TDR were either hopeful they would lose more or reported anxiety over not meeting the targets • SUs required more frequent support than every 2 weeks • SUs were planning to use TDR products long term to manage weight • SUs were increasing their activity levels (through daily life and structured exercise) during FR, which in turn led to improved physical and psychological health *Insights from SUs who did not complete the programme (RA16)* • SUs were initially happy to start the programme and the experience of being discharged was framed negatively with some SUs being discharged by providers against their will, without being presented with an opportunity to continue • SUs who did not complete the programme spoke about a positive impact of the programme • The programme and products were not framed as the defining reasons for withdrawal once SUs started TDR • Mental and physical health challenges and impacted on SUs' ability to attend or comply with the programme • Life events and circumstances including bereavement impacted on SUs' ability to attend or comply with the programme • SUs who did not complete the programme perceived a lack of support from the provider – this was particularly felt during FR where support became infrequent with a lack of clear structure for meal planning *Insights from SUs at 52 weeks (RA19)* • There was minimal provision or support across the programme for SUs experiencing mental health issues or struggling with emotional or disordered eating • SUs who faced external life events, such as bereavement, did not receive additional support. There was limited flexibility across the programme concerning SUs missing sessions, even considering these circumstances • SUs would have liked more support and information during the FR stage, for example, meal planning • SUs felt that extending the duration of the FR stage would have been beneficial. Some reported that the FR stage felt rushed, leaving them feeling unprepared • FR content should be introduced sooner *Insights from the economic evaluation (RA14)* • Although the number was much lower than during the TDR phase, 5.3% of SUs that incurred additional expenditure reported buying TDR products. These represented the highest value items they purchased during this phase, with an average spend of £60 during the FR phase • The most popular purchases made during the FR phase were diet books and cookbooks where 21% and 33% of SUs who made purchases reported to have purchased them. SUs spent on average £18 on cookbooks and diet books • There were also a few SUs that reported to have purchased extra utensils and appliances such as measuring plates and blenders

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Outcomes	Mechanisms	Supporting evidence statements and context
		Insights on transferability of the programme (RA15) • Locality leads/referrers/SPs had concerns that SUs who did not have adequate support at home or low psychological well-being • Locality leads/referrers/SPs perceived that SUs feel disheartened after gaining weight and feel anxious about reintroducing food *Insight from digital fidelity (RA9)* • The BCT content of the digital model used in the NHS-LCD programme adhered well to the NHS service specification and providers' plans. It surpassed what has been previously observed in face-to-face services provided through group or one-on-one behavioural support models
	Provider/referrer	
	FR session delivery is person-centred Provider has the necessary system and processes in place to facilitate successful session delivery, support (to facilitate implementation within everyday life) and TDR products/monitoring equipment	*Insights from coaches on programme delivery with minoritised ethnic groups (RA21)* • Coaches highlighted the challenges experienced when supporting SUs with different ethnicities to their own, in relation to cultural food preferences and considerations associated with their ethnic backgrounds. They discussed limitations in the training they received, including a lack of specific training for working with service users from different ethnic backgrounds and cultures to theirs, and a lack of education about different cultures, multiethnic foods and their impacts on health • Coaches described wanting education and external training from dietitians and health professionals from diverse ethnic backgrounds with an understanding and experience of relevant cultures and lifestyles, to support appreciation and understanding of the nuances within ethnicities • Coaches acknowledged that a deeper understanding of how food and culture intersect could enhance the quality of the service they provide, with some coaches reporting they consider the difference in cultures when delivering the programme and adapt the delivery according to this • Coaches from a White British ethnicity described difficulty in communicating with SUs due to language differences, creating a challenge in building rapport. It was mentioned that, at times, family members were involved as translators to overcome language barriers, and without this the SUs would have faced challenges in understanding the programme's content • Experiences of inadequate resources and uncertainty of resources available such as culturally tailored resources were described, particularly from coaches of White British ethnicity • The relationship with the coach from SUs' perspectives was complex. On one hand, SUs praised the supportive role of coaches, commending their empathy, effective communication and provision of resources. However, a lack of cultural understanding was also described, where coaches occasionally exhibited a lack of understanding regarding South Asian cultural nuances • However, when coaches shared the same cultural background and language, SUs felt they were culturally compatible and this facilitated a more comprehensive understanding of diet and social situations, which enhanced the overall experience. This was resonant in the group whose programme was delivered in Urdu, as these SUs described how helpful it was to have the coaches deliver the programme in the same language and provide tailored information for them *Insights from programme session observations (RA7)* • See previous comments on person-centredness. This did not differ across programme stage *Insights from SUs who did not complete the programme (RA16)* • Mental health issues, including anxiety and depression, were common prior to starting the programme which SUs stated providers were made aware of *Insights from online survey of SUs (RA13)* • Thirty-nine SUs provided additional detail on how they felt this phase of the programme could be improved. Fifteen SUs identified they would have liked additional resources related to meal planning; 13 SUs stated that more support was required from the SP; and 13 suggest a slower transition was required. In a separate question asking SUs how they found the pace of FR, 29 (19% of respondents) indicated they felt it was 'too fast', 120 (76% of respondents) felt it was 'about right', and 8 (5% of respondents) felt it was 'too slow'

Outcomes	Mechanisms	Supporting evidence statements and context
		Insights from SUs during the FR stage (12–18 weeks) (RA22) • The process of FR lacked a person-centred approach, with some SUs expressing a desire for personalised meal plans • FR content lacked cultural adaption • Not all SUs understood the content of the sessions and struggled to implement the diet changes required • 1 : 1 delivery models provided opportunities for asking questions and support understanding, which was lacking in group sessions • Regularity and relationship of coach were important to SUs *Insights from SUs at 52 weeks (RA19)* • The process of FR lacked a person-centred approach, with some SUs expressing a desire for personalised meal plans • In group delivery, there was little evidence of individualised approaches tailored to the needs of SUs • There was minimal provision or support for SUs experiencing mental health issues or struggling with emotional or disordered eating *Insights from coaches on programme delivery with minoritised ethnic groups (RA21)* • Coaches described a sense of responsibility for adapting programme sessions to align with the cultural backgrounds of SUs, despite being unsure on how to culturally tailor • Coaches highlighted the benefit of speaking the same language as SUs and that their personal experiences and cultural understanding enabled them to relate to SUs and build rapport *Insights from the economic evaluation (RA14)* • There were no significant differences in terms of additional expenditure that SUs incurred during the programme by gender, ethnicity, or socioeconomic status *Insights on transferability of the programme (RA15)* • Some programme deliverers felt unable to meet the needs of SUs who requested extra support around meal planning • Programme delivers described one-to-one delivery as being flexible in its structure and led by the SU • When asked about their understanding of behavioural elements, programme deliverers appeared to lack confidence in understanding and application of underpinning programme theory *Insight from digital fidelity (RA9)* • The BCT content of the digital model used in the NHS-LCD programme adhered well to the NHS service specification and providers' plans. It surpassed what has been previously observed in face-to-face services provided through group or one-on-one behavioural support models • In part, this can be understood through the standardisation of content, which reduces dependence on human delivery. Examining the barriers and facilitators to BCT delivery using group and one-to-one delivery models, our previous work highlighted the influence of both coach-level and programme-level factors on fidelity, including the skill level of the coach in delivering BCTs; session time management; group-based settings sometimes hindering individual engagement with a BCT; and deviations from the session plans

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Outcomes	Mechanisms	Supporting evidence statements and context
WM stage		
See NHS data summary in *Box 1* and Valabhji *et al.*[17]		
All SUs complete WM All SUs maintain weight loss All SUs achieve continued improvements in diabetes control (HbA1c)/ improve glycaemic parameters There are no sociodemographic differences in outcomes All SUs are able to sustain behaviour change long term There are no ongoing adverse events (both physical and psychological) SUs are discharged into suitable monitoring and ongoing lifelong person-centred care Programme is cost saving to the individual and to the LHE/NHSE system	**Individual** SU is empowered to become an effective self-manager to maintain long-term behaviour changes SU has appropriate peer/family support SUs are able to buy, store and cook healthy foods SUs have opportunities to be physically active (no cultural, financial or environmental barriers) SUs understand the process for continued monitoring and ongoing support	*Insights from commercial provider staff (RA4)* • Providers focused on SU characteristics and circumstances they perceived as barriers to completing the programme, with individual motivation perceived as the key to programme completion • Providers acknowledge many and varied reasons for non-completion of the programme that relate to the individual. Reasons included psychological reasons, chaotic circumstances, multiple life events, busy lifestyles, work commitments that revolve around food, SUs with larger families, SUs who do not work but have a lot of 'thinking time', living with severe depression and other health issues, having a lot going on at home, mental traumas and mindset • Providers focused on SU characteristics and circumstances they perceived as barriers to completing the programme, with individual motivation perceived as the key to programme completion • Providers acknowledge many and varied reasons for non-completion of the programme that relate to the individual. Reasons included psychological reasons, chaotic circumstances, multiple life events, busy lifestyles, work commitments that revolve around food, SUs with larger families, SUs who do not work but have a lot of 'thinking time', living with severe depression and other health issues, having a lot going on at home, mental traumas, and mindset

Outcomes	Mechanisms	Supporting evidence statements and context
		Insights from South Asian SUs experiences (RA11) • SUs described the guidance provided within the programme to be oriented towards a Western diet. The absence of recipes and meal plans tailored to South Asian cuisines and other cultural practices left SUs struggling to effectively apply the programme recommendations to their familiar ethnic foods. SUs reported a sense of responsibility to independently modify recommendations to align with their ethnicity and cultural dietary practices • SUs highlighted the important role of motivation in making dietary changes. These changes encompassed altering portion sizes, reducing the quantity of staple foods and adopting modified cooking methods • Fellow SUs enrolled in the programme, particularly those who shared the same South Asian ethnicity, emerged as sources of support and encouragement. Reciprocal exchanges of meal ideas and empathetic encouragement were reported *Insights from programme session observations (RA7)* • See previous comments on peer and family support. This did not differ across programme stage *Insights from online survey of SUs (RA13)* • Seventy-three SUs answered Likert scale response questions related to their WM phase. The majority of SUs (82–88%) indicated a positive experience. However, approximately one in five SUs felt they did not have enough support to maintain the lifestyle changes and that the programme did not support them to achieve their goals • Forty-six SUs provided information on how they felt about any weight change during the WM phase. Forty SUs indicated they were happy with their weight change, 13 stated they were disappointed and 4 indicated they were okay *Insights from SUs during the FR stage (12–18 weeks) (RA22)* • There was minimal provision or support for SUs experiencing mental health issues or struggling with emotional or disordered eating • Many SUs implemented behaviour changes and engaged in increased physical activity • While some SUs experienced weight reduction and successfully sustained the achieved weight loss, others exhibited fluctuations in their weight over time • Peer support exhibited a decline during the weight management phase *Insights from SUs who did not complete the programme (RA16)* • SUs were initially happy to start the programme and the experience of being discharged was framed negatively with some SUs being discharged by providers against their will, without being presented with an opportunity to continue • SUs who did not complete the programme spoke about a positive impact of the programme • The programme and products were not framed as the defining reasons for withdrawal once SUs started TDR • Mental and physical health challenges impacted on SUs' ability to attend or comply with the programme • Life events and circumstances including bereavement impacted on SUs' ability to attend or comply with the programme • SUs who did not complete the programme perceived a lack of support from the provider

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Outcomes	Mechanisms	Supporting evidence statements and context
		Insights from SUs at 52-weeks (RA19) • There was minimal provision or support for SUs experiencing mental health issues or struggling with emotional or disordered eating • SUs seeking emotional or disordered eating support did not receive the necessary assistance, leaving them to navigate new dietary approaches alone. Coping independently, some managed well, while others faced challenges due to the lack of consideration for external life events and a perceived absence of timely support • Many SUs implemented behaviour changes and engaged in increased physical activity • While some SUs experienced weight reduction and successfully sustained the achieved weight loss, others exhibited fluctuations in their weight over time and some were seeking further weight loss post programme • Some participants had returned to elevated glycaemia • Peer support exhibited a decline during the weight management phase • Some SUs felt well equipped to maintain longer-term behaviour changes • Some SUs did not feel that their needs were met around requested extra support around meal planning • The transition from fortnightly to monthly session durations left some SUs feeling unsupported • Some SUs thought they should have been automatically offered the rescue package but found themselves in a situation where they had to take the initiative to request it, whereas others were encouraged to take it • Some SUs (9 out of 25) reported using TDR products to replace at least one meal per day, during WM for convenience and structure and suggested that they will use these indefinitely • Some SUs continue to monitor their glucose levels post programme, reflecting a commitment to ongoing health tracking • Reported outcomes beyond weight and glycaemia were extremely important to SUs and included improved appearance, daily physical functioning and improved social relationships • SUs reported benefits on the health of family and friends *Insights from the economic evaluation* (to note: the number of SUs who reported any expenditure varies by item and phase) (RA14) • The majority of purchases (28%) made under the WM phase were on extra monitoring strips, with an average spend of £17.25 among those who reported making these purchases. • Fourteen per cent of SUs reported to have purchased TDR products during WM phase, with an average spend of £125. This was higher than the average expenditures on TDR products during the TDR phase *Insights on transferability of the programme (RA15)* • Locality leads/referrers/SPs had concerns that SUs who did not have adequate support at home or low psychological well-being • Locality leads/referrers/SPs perceived that SUs feel disheartened after gaining weight and feel anxious about reintroducing food *Insight from digital fidelity (RA9)* • The BCT content of the digital model used in the NHS-LCD programme adhered well to the NHS service specification and providers' plans. It surpassed what has been previously observed in face-to-face services provided through group or one-on-one behavioural support models

Outcomes	Mechanisms	Supporting evidence statements and context
	Provider/referrer WM session delivery is person-centred Provider has the necessary system and processes in place to facilitate successful session delivery, support and monitoring equipment All SUs eligible for a rescue package receive it. Provider informs referrer of SU progress continued feedback loop to inform ongoing support for the individual and successful referrals of other patients Anyone with emotional or disordered eating receives the support needed to undertake new dietary approach Long-term sustainable dietary management is person-centred	*Insights from commercial provider staff (RA4)* • There is a tension between providers and referrers over responsibility for retention • Providers believe GPs should not refer SUs with mental health issues related to food, such as disordered eating *Insights from coaches on programme delivery with minoritised ethnic groups (RA21)* • Coaches highlighted the challenges experienced when supporting SUs with different ethnicities to their own, in relation to cultural food preferences and considerations associated with their ethnic backgrounds. They discussed limitations in the training they received, including a lack of specific training for working with SUs from different ethnic backgrounds and cultures to theirs, and a lack of education about different cultures, multiethnic foods and their impacts on health • Coaches described wanting education and external training from dietitians and health professionals from diverse ethnic backgrounds with an understanding and experience of relevant cultures and lifestyles, to support appreciation and understanding of the nuances within ethnicities • Coaches acknowledged that a deeper understanding of how food and culture intersect could enhance the quality of the service they provide, with some coaches reporting they consider the difference in cultures when delivering the programme and adapt the delivery according to this • Coaches from a White British ethnicity described difficulty in communicating with SUs due to language differences, creating a challenge in building rapport. It was mentioned that, at times, family members were involved as translators to overcome language barriers, and without this the SUs would have faced challenges in understanding the programme's content • Experiences of inadequate resources and uncertainty of resources available such as culturally tailored resources were described, particularly from coaches of White British ethnicity • The relationship with the coach from SUs' perspectives was complex. On one hand, SUs praised the supportive role of coaches, commending their empathy, effective communication and provision of resources. However, a lack of cultural understanding was also described, where coaches occasionally exhibited a lack of understanding regarding South Asian cultural nuances • However, when coaches shared the same cultural background and language, SUs felt they were culturally compatible and this facilitated a more comprehensive understanding of diet and social situations, which enhanced the overall experience. This was resonant in the group whose programme was delivered in Urdu, as these SUs described how helpful it was to have the coaches deliver the programme in the same language and provide tailored information for them *Insights from an examination of underpinning theory (RA2)* • All four providers mentioned theory at least once within their designs or staff training documents, only one provider evidenced all BCTs being linked to theory and/or constructs (through construction of a logic model). Two providers linked some but not all BCTs to theory, and one provided no evidence of theory use in their programme design, aside from inclusion in a staff training slide. Delivery methods and materials might enhance or dilute fidelity, most notably the fidelity in delivery of techniques such as goal setting, action planning and problem solving, which were key for enhancing self-regulatory skills in the logic model (i.e. expected mechanisms) *Insights from documentary review of programme specification (RA3)* • Programmes featured large variations in the use of specific BCTs, as well as variations in their intended dose. The provider with the strongest theoretical underpinnings was also found to have the strongest fidelity in their BCT content, while the two providers with the weakest theoretical underpinnings were also identified as having the weakest fidelity in their BCT content. Without a clear underpinning programme theory describing how providers programmes expect to produce behavioural changes and health outcomes, justification for the BCTs selected is unclear and may result in a drift in the fidelity of programme delivery *Insights from BCT delivery (RA8)* • Fidelity in the delivery of BCTs across two providers commissioned to deliver face-to-face NHS-LCD programmes across England was 55% (range = 33–70%), thus indicating low-to-moderate fidelity during the delivery phase of the NHS-LCD and variation in the fidelity of programmes being delivered across England

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Outcomes	Mechanisms	Supporting evidence statements and context
		Insights from programme session observations (RA7) • See previous comments on person-centredness. This did not differ across programme stage • Session observations did not indicate that emotional and/or disordered eating was discussed, and there were no alternative approaches offered to SUs *Insights from cross-sectional analysis of emotional and binge eating (RA12)* • Recommendation that SUs should have ongoing monitoring of their emotional/disordered eating behaviour to determine if this changes over time *Insights from SUs who did not complete the programme (RA16)* • Mental health issues, including anxiety and depression, were common prior to starting the programme which SUs stated providers were made aware of *Insights from SUs at 52-weeks (RA19)* • Coach continuity was identified as a significant challenge, with some groups experiencing a rotation of four different coaches. This posed difficulties in establishing rapport, as coaches occasionally repeated content from the previous session and displayed a lack of engagement by not actively involving SUs through questions or breakout room interactions • Challenges arose when reaching out to the provider outside of sessions, as calls were directed to a call centre not consistently staffed by individuals with adequate training, often resulting in unresolved queries and a lack of follow-up • Instances were reported where SUs, after notifying the provider about missing a session, felt inundated with inappropriate calls, pressuring them to submit measurements • Provider challenges included difficulty accessing measurements and information entered by SUs in the app, leading to the inconvenience of double submissions for SUs (into the app and over the phone to coaches) • Not all referrers had detailed knowledge of the programme and SUs sometimes had to navigate their GP practice and provider *Insights from the economic evaluation (RA14)* • SPs who delivered the programme using the face-to-face method reported to have incurred extra costs for venues that are not incurred by remote delivery *Insights on transferability of the programme (RA15)* • Some programme deliverers felt unable to meet the needs of SUs who requested extra support around meal planning • Programme delivers described one-to-one delivery as being flexible in its structure and led by the SU • Programme deliverers appeared to lack confidence in understanding and application of underpinning programme theory *Insights from AI analysis (RA23)* • Three key personality clusters predict motivation to continue on the programme • Cluster 1 – characterised by attributes: responsible, level-headed and moderate in most other personality types. High in conscientiousness, self-efficacy and dutifulness. Low in neuroticism • Cluster 2 – characterised by attributes: high anxiety, disorganised, vulnerability and neuroticism. Low in self-discipline, orderliness, conscientiousness, self-efficacy and dutifulness • Cluster 3 – characterised by attributes: high in orderliness and conscientious. Low in work-orientated and dutifulness – not very driven or loyal Personality rather than demographic characteristics determines motivation to continue the programme

Outcomes	Mechanisms	Supporting evidence statements and context
		Insight from digital fidelity (RA9) • The BCT content of the digital model used in the NHS-LCD programme adhered well to the NHS service specification and providers' plans. It surpassed what has been previously observed in face-to-face services provided through group or one-on-one behavioural support models • In part, this can be understood through the standardisation of content, which reduces dependence on human delivery. Examining the barriers and facilitators to BCT delivery using group and one-to-one delivery models, our previous work highlighted the influence of both coach-level and programme-level factors on fidelity, including the skill level of the coach in delivering BCTs; session time management; group-based settings sometimes hindering individual engagement with a BCT; and deviations from the session plans
	Policy/wider system	
	Policy-makers and commissioners have data (outcomes, cost and service user experience) to commission a diabetes service appropriate for the population	*Insights from the economic evaluation (RA14)* • After 1 year, the mean weight loss in our sample (n = 838) is 9.86 kg. After 1 year, the mean reduction in HbA1c (%) in our sample is 0.24. Both the mean weight and HbA1c reductions are higher among white SUs (0.28% and 10.7 kg) than among minoritised ethnic groups (0.11% and 7.37 kg); and mean HbA1c reductions are higher among SUs living in the most deprived areas compared to the least deprived areas. Differences in mean weight reduction by area-level deprivation were less pronounced From the perspective of NHSE using short-term follow-up data we calculate there is potential for programme to be cost-effective, dependent on assumptions about long-term weight and HbA1c regain trajectories. More rapid weight and HbA1c trajectories would mean the intervention is less cost-effective. Our study indicates that the programme could be cost-effective against a £20,000/QALY threshold if weight and HbA1c trajectories remain below those in the counterfactual scenario for at least 6–7 years (£19,759.80/QALY assuming 7 years) and against a £30,000/QALY threshold if those trajectories remain apart for 4–5 years (£27,625.99/QALY assuming 5 years). When adopting the societal perspective, the LCD intervention is highly likely to be cost-effective (and cost saving in most scenarios) due primarily to the money SUs are likely to save on their usual grocery shopping. However, it is unlikely that these cost savings would (or should) be factored into healthcare decision-making

SU, service users.

This synopsis should be referenced as follows: Ells LJ, Brown T, Matu J, Clare K, Rowlands S, Maynard M, *et al.* Evaluation of the NHS England Low-Calorie Diet implementation pilot: a coproduced mixed-method study. *Health Soc Care Deliv Res* 2025;**13**(29). https://doi.org/10.3310/MPRT2139

Appendix 3 Interview participant dietary data analysis

Dietary data from the interview participants who took part in the MyFood24 diary assessment data are presented in *Tables 6–8*.

TABLE 6 Energy, macronutrient, fruit and vegetable intake/day at weeks 12, 18 and 52

Nutrient	Week 12 (*n* = 16)	Week 18 (*n* = 11)	Week 52 (*n* = 8)	*p*-value (Friedman's test)
Energy (kcal)	843.5 (308.7)	1075.2 (481.5)	1346.1 (537.5)	0.091
Energy (KJ)	3545.2 (1293.6)	4510.7 (2011.3)	5643.4 (2244.7)	N/A
Fat (g)	22.9 (14.4)	41.0 (26.8)	53.9 (34.7)	0.015[a]
Saturated fatty acid (g)	4.4 (3.7)	12.6 (9.3)	17.7 (12.8)	0.074
Carbohydrate (g)	94.5 (40.9)	118.5 (51.7)	141.2 (66.4)	0.472
Sugars (g)	60.8 (40.4)	47.9 (23.5)	49.1 (34.9)	0.819
NSP fibre (g)	5.3 (4.8)	2.2 (3.4)	2.1 (3.2)	0.319
Association of Official Analytical Chemists fibre (g)	12.9 (8.3)	17.6 (9.6)	17.1 (8.9)	0.472
Protein (g)	58.8 (27.5)	51.7 (27.8)	62.0 (25.9)	0.779
Sodium (mg)	1283.3 (738.3)	1345.1 (693.0)	1770.6 (1122.7)	0.472
Vegetable (g)	26.5 (50.2)	195.9 (144.1)	215 (3)	0.057
Fruit (g)	126.2 (221.5)	117.7 (66.4)	129.4 (177.6)	0.936

N/A, not applicable; NSP, non-starch polysaccharides.
a *p*-value refers to difference in intake over time (weeks 12, 18 and 52; $p < 0.05$), by repeated measures with Friedman's test.

Note
Values reported as mean (standard deviation).

- There was a significant increase in fat intake from week 12 to week 52. This may be due to reduction in the consumption of the meal replacement products after week 12 and preference for standard foods such as nuts and seeds products (see *Table 8*).
- Fibre intake was generally below recommendation.
- Sodium intake, although increased, did not exceed the daily limit of 2.5 g.
- Daily energy intake increased but was less than current recommendations for adult males/females.
- Free sugars intakes, although decreased over time, exceeded the 30 g/day limit for adults especially at week 12.
- Fruit and vegetables intake was less than the NHS recommended 5 a day recommendation (i.e. about 80 g x 5 = 400 g.

TABLE 7 Micronutrient intake/day at weeks 12, 18 and 52

Micronutrient	RNI (male/female)	Week 12 (*n* = 16)	Week 18 (*n* = 11)	Week 52 (*n* = 8)	*p*-value[a]
Vitamin D (µg)	10	7.5 (5.2)	1.1 (2.1)	0.1 (0.4)	0.060
Vitamin E (mg)	4/3	18.8 (13.4)	2.2 (3.6)	1.2 (2.8)	0.057
Thiamine (mg)	1.0/0.8	2.6 (1.5)	1.3 (0.7)	0.9 (0.4)	0.050
Vitamin B12 (µg)	1.5	4.9 (2.9)	5.0 (6.4)	2.8 (1.9)	0.472
Folate (µg)	200	318.6 (192.5)	322.1 (231.5)	257.3 (95.3)	0.779
Beta carotene (µg)	700/600[b]	856.8 (1695.1)	3146.1 (3091.6)	2388.4 (1888.4)	0.607
Iodine (µg)	140	200.2 (128.6)	124.5 (321.6)	5.5 (12.1)	0.076
Selenium (µg)	75/60	76.4 (55.9)	8.4 (14.1)	7.1 (13.1)	0.076
Zinc (mg)	9.5/7.0	12.5 (6.6)	8.4 (6.1)	8.5 (5.2)	0.368
Copper (mg)	1.2	2.3 (1.5)	1.4 (0.8)	1.4 (0.8)	0.472
Iron (mg)	8.7/14.8	17.2 (9.4)	10.4 (6.7)	9.5 (4.5)	0.135
Magnesium (mg)	300/270	411.7 (228.1)	314.9 (173.4)	281.5 (115.7)	0.472
Calcium (mg)	700	1209.5 (624.9)	627.3 (287.3)	805.2 (543.8)	0.174
Potassium (mg)	3500	2820.0 (1474.8)	2125.9 (644.6)	2022.8 (782.1)	1.000

RNI, Reference Nutrient Intake.
a *p*-value refers to difference in intake over time (weeks 12, 18 and 52; $p < 0.05$), by repeated measures with Friedman's test.
b RNI for Vitamin A.

Notes
There was no significant difference in the micronutrient intake of participants.
Values reported as mean (standard deviation).
Apart from beta carotene, the above micronutrient composition of the diets reduced after week 12. In addition, micronutrient levels were below the RNI by week 52, except for vitamin B12, beta carotene, folate, copper, iron (for males) and calcium.
Only two participants reported taking supplements and this was vitamin D with calcium.

TABLE 8 Popularly consumed foods/beverages at weeks 12, 18 and 52

Meal event	Week 12	Week 18	Week 52
Breakfast	Optifast shake, porridge, water, wholemeal bread, all bran cereal, scrambled egg, lean pork bacon	Porridge, coffee (with and without milk), water, mixed seeds, mixed nuts, fruit, breakfast cereal	Porridge, cereal (e.g. muesli), cooked breakfast (e.g. fired/boiled egg, mushroom), bread, coffee, tea
Lunch	Optifast soup, water, meal replacement bar or powder reconstituted with water	Meal replacement bar, soup, vegetables with protein (e.g. skinless chicken, prawn, turkey, egg), salad, wholemeal/pita bread, cheese	Rice, potato, bread, mixed vegetables/lentils, chicken, Tuna, cheese
Evening meal	Optifast meal bars, Optifast shake, spaghetti bolognese, chilli with beans, water, curry made with pulses, steamed vegetables	Mixed vegetables, potato/rice, skinless chicken, Salmon	Mixed vegetables, lentils, potato, pasta, rice, chicken/vegetable curry
Drink	Water, tea/coffee with and without semi-skimmed milk (no sugar), sugar free fruit squash, juice drink, diet fizzy drink	Tea/coffee (with and without milk), water and diet fizzy drink	Water, tea, coffee (e.g. latte, cappuccino, expresso), milk, wine, diet fizzy drink
Snack	Fruit and nut cereal bar, Optifast meal bars, Optifast shake/soup, nuts, fruit and vegetables	Protein/nutrition bar, fruit	Yogurt, fruit, biscuit

Notes
Consumption of meal replacement bars/shakes reduced after week 12.
Starchy foods and milk-based coffee drinks were commonly consumed at week 52 compared to weeks 12 and 18.

Appendix 4 National Health Service Low-Calorie Diet logic model

The logic model generated for the LCD programme is shown in *Figure 3*.

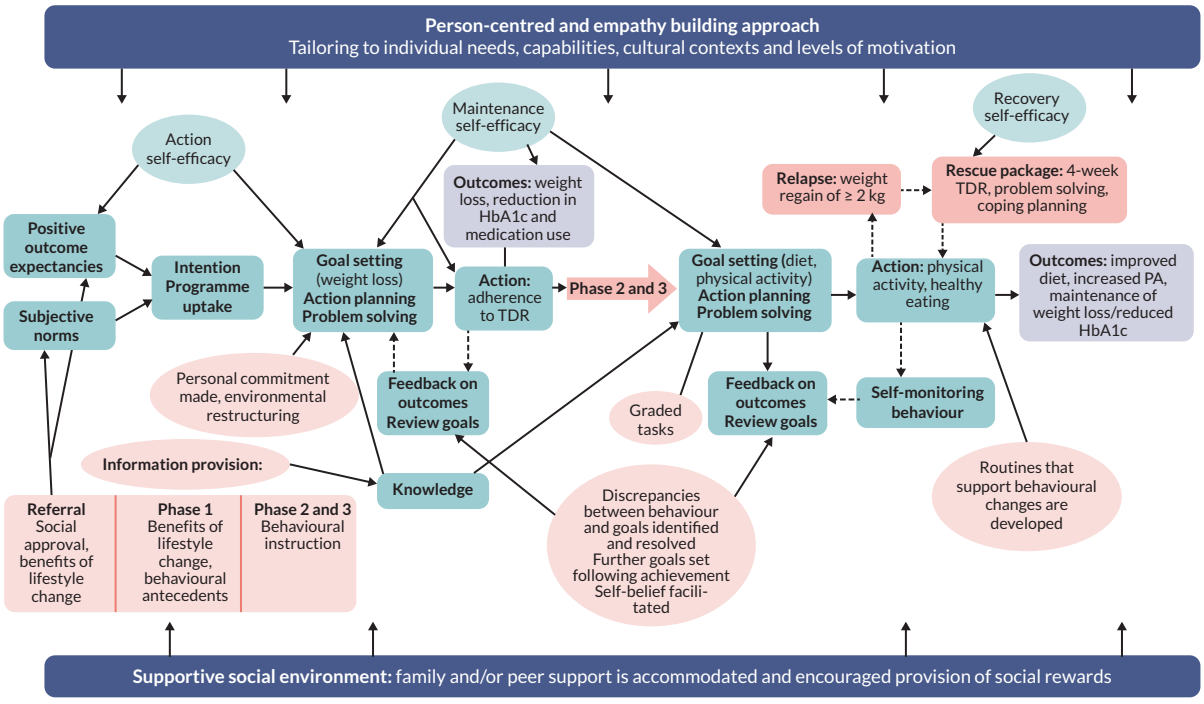

FIGURE 3 A logic model of the NHS LCD programme. PA, physical activity.

Appendix 5 Service user interviewee characteristics

The sociodemographic characteristics of the Re:Mission study service user interviewee's are shown in *Table 9*.

TABLE 9 Sociodemographic characteristics of interviewee's

Participant characteristics' summary		12 weeks Number of participants (*n* = 30)	18 weeks Number of participants (*n* = 28)	52 weeks Number of participants (*n* = 25)	Cross-sectional Number of participants (*n* = 15)	Withdrawal Number of participants (*n* = 10)
Gender	Males	12 (40%)	11 (40%)	9 (36%)	6 (40%)	4 (40%)
	Females	18 (60%)	17 (60%)	16 (64%)	9 (60%)	6 (60%)
Age	30–34	1 (3%)	1 (4%)	1 (4%)	0 (0%)	0 (0%)
	35–39	4 (13%)	3 (11%)	2 (8%)	2 (13%)	1 (10%)
	40–44	3 (10%)	3 (11%)	3 (12%)	2 (13%)	5 (50%)
	45–49	3 (10%)	3 (11%)	1 (4%)	2 (13%)	1 (10%)
	50–54	6 (20%)	6 (21%)	6 (24%)	2 (13%)	1 (10%)
	55–59	5 (17%)	4 (14%)	4 (16%)	3 (20%)	1 (10%)
	60–65	8 (27%)	8 (28%)	8 (32%)	4 (27%)	1 (10%)
Provider	SP1	1 (3%)	1 (4%)	1 (4%)	1 (7%)	2 (20%)
	SP2	19 (63%)	18 (64%)	18 (72%)	5 (33%)	5 (50%)
	SP3	7 (23%)	7 (25%)	5 (20%)	3 (20%)	1 (10%)
	SP4	1 (3%)	1 (4%)	1 (4%)	4 (27%)	1 (10%)
	SP5	2 (7%)	1 (4%)	0 (0%)	2 (13%)	0 (0%)
	SP6	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (10%)
Delivery model	Face-to-face 1 : 1	3 (10%)	1 (4%)	0 (0%)	2 (13%)	0 (0%)
	Remote 1 : 1	2 (7%)	2 (7%)	2 (8%)	4 (27%)	3 (30%)
	Remote group	22 (73%)	22 (78%)	20 (80%)	6 (40%)	6 (60%)
	Digital	3 (10%)	3 (11%)	3 (12%)	3 (20%)	1 (10%)

continued

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TABLE 9 Sociodemographic characteristics of interviewee's (*continued*)

Participant characteristics' summary		12 weeks Number of participants (*n* = 30)	18 weeks Number of participants (*n* = 28)	52 weeks Number of participants (*n* = 25)	Cross-sectional Number of participants (*n* = 15)	Withdrawal Number of participants (*n* = 10)
Ethnic group[a]	White British or White mixed British	25 (83%)	23 (82%)	21 (84%)	10 (66%)	8 (80%)
	Asian/Asian British	3 (10%)	3 (11%)	2 (8%)	0 (0%)	0 (0%)
	Black/African/Caribbean/ Black British	1 (3%)	1 (4%)	1 (4%)	2 (13%)	1 (10%)
	Mixed or multiple ethnic group	1 (3%)	1 (4%)	1 (4%)	1 (7%)	0 (0%)
	Other ethnic group	0 (0%)	0 (0%)	0 (0%)	1 (7%)	0 (0%)
	Prefer not to say	0 (%)	0 (0%)	0 (0%)	1 (7%)	1 (10%)
IMD quintiles[b]	1	11 (37%)	11 (39%)	10 (40%)	2 (13%)	2 (20%)
	2	4 (13%)	4 (14%)	4 (16%)	3 (20%)	3 (30%)
	3	6 (20%)	5 (18%)	4 (16%)	3 (20%)	4 (40%)
	4	3 (10%)	3 (11%)	2 (8%)	4 (27%)	0 (0%)
	5	6 (20%)	5 (18%)	5 (20%)	3 (20%)	1 (10%)

IMD, Index of Multiple Deprivation.
a The ethnic group classification as used by the Office for National Statistics in the 2021 Census.
b The IMD score is as absolute measure of deprivation that allows for Lower Super Output Areas (LSOAs) in England to be ranked and subsequently classified into five quintile bands. Quintile 1 is the 20% most deprived LSOAs in England, while quintile 5 is the 20% least deprived LSOAs.

Appendix 6 Participant characteristics for the service user survey

The sociodemographic characteristics of the service users who took part in the Re:Mission study service user survey are shown in *Table 10*.

TABLE 10 Sociodemographic characteristics for service user survey participants

	Survey			
	Baseline (*N* = 580)	12 weeks (*N* = 220)	18 weeks (*N* = 138)	52 weeks (*N* = 69)
Sex				
Male	39%	43%	44%	54%
Female	61%	57%	56%	46%
Ethnicity				
White	80%	84%	88%	83%
Other ethnic group	20%	16%	12%	17%
IMD quintile[a]				
1	29%	26%	23%	33%
2	22%	19%	19%	10%
3	16%	23%	20%	19%
4	15%	14%	20%	19%
5	17%	19%	18%	19%
Age				
< 39	15%	12%	7%	10%
40–49	27%	21%	25%	17%
50–59	39%	40%	44%	39%
60+	19%	28%	24%	33%

IMD, Index of Multiple Deprivation.
a The IMD score is as absolute measure of deprivation that allows for Lower Super Output Areas (LSOAs) in England to be ranked and subsequently classified into five quintile bands. Quintile 1 is the 20% most deprived LSOAs in England, while quintile 5 is the 20% least deprived LSOAs.

TABLE 11 Distribution of participants by delivery model

	Survey			
Delivery model	**Baseline**	**12-week**	**18-week**	**52-week**
Group	405 (56%)	155 (58%)	81 (48%)	34 (44%)
1:1	191 (27%)	51 (19%)	45 (27%)	23 (29%)
Digital	123 (17%)	63 (23%)	41 (25%)	21 (27%)