

## **The Re:Mission study. Evaluating the NHS Low Calorie Diet pilot - an overview of service user data collection methods**

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# The Re:Mission study. Evaluating the NHS Low Calorie Diet pilot - an overview of service user data collection methods

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## Abstract

**Introduction:** The National Health Service (NHS) Low Calorie Diet (LCD) pilot programme aimed to support people with type 2 diabetes (T2DM) to lose weight, reduce glycaemia and potentially achieve T2DM remission using total diet replacement alongside behaviour change support. The Re:Mission study seeks 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. This article presents an overview of the methods used in the Re:Mission study.

**Methods and analysis:** A mixed method approach was used to draw together service user insights from across longitudinal and cross-sectional online surveys and semi-structured interviews supported by a modified photovoice technique. Insights were captured from active service users across the three phases of the programme (total diet replacement, food reintroduction and maintenance) in addition to those discharged prematurely. Survey data were analysed using descriptive statistics and qualitative data were thematically analysed and interpreted through a realist informed lens to understand which aspects of the service work and do not work, for whom, in what context and why.

**Results:** Results from the study are presented elsewhere, with recommendations for policy practice and research.

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**Key words:** type 2 diabetes, obesity, Low Calorie Diet, qualitative, longitudinal, weight maintenance, Re:Mission study

## Background

Type 2 diabetes (T2DM) is now one of the leading causes of global deaths;<sup>1</sup> it affects 4.3 million people across the UK.<sup>2</sup> More than a quarter of adults in England live with obesity,<sup>3</sup> which is the most significant modifiable risk factor for developing T2DM.<sup>4,5</sup> However, obesity and T2DM do not affect all populations equally, with prevalence of both conditions increasing with age and area-level deprivation, and ethnicity. For Black and South Asian ethnicity, body mass index (BMI) >23 kg/m<sup>2</sup> indicates increased risk of T2DM and BMI >27.5 kg/m<sup>2</sup> indicates high risk of T2DM; comparable values of BMI for White ethnicity are >25 kg/m<sup>2</sup> and >30 kg/m<sup>2</sup>, respectively.<sup>6</sup>

Modelled projections indicate that health service and wider societal costs associated with obesity and diabetes will escalate dramatically unless urgent action is taken.<sup>7</sup> The NHS Long Term Plan therefore pledged to provide a targeted support offer and access to weight management services for people with a diagnosis of T2DM and a BMI of  $\geq 30$  kg/m<sup>2</sup> (adjusted appropriately for ethnicity),<sup>8</sup> with the aim of significantly improving health, reducing health inequalities and cutting associated costs.

Systematic review and trial evidence has shown that a Low Calorie Diet (LCD) achieved through Total Diet Replacement (TDR) can lead to clinically significant weight loss and improvements in glycaemia, with some people achieving remission of T2DM.<sup>9-18</sup> Based on evidence from the two large UK trials (DiRECT and DROPLET),<sup>15,16</sup> a commitment was made by the NHS in England to pilot a LCD programme for people living with T2DM and overweight/obesity, offering TDR alongside behaviour change support. Given the large scale of such an intervention, a comprehensive evaluation of the translation and implementation of this intervention into real-world practice was critical.

## The NHS LCD programme

In 2020, NHS England commissioned the LCD programme. It was piloted initially in 10 socio-demographically diverse sites across England (wave 1), with a further 11 sites added in 2022 (wave 2). NHS England provided a standard service specification,<sup>19</sup> which was delivered by a range of commercial service providers. In brief, the programme included 12 weeks of total diet replacement and 4-6 weeks of food reintroduction, followed by weight maintenance support until the end of the programme (52 weeks). Behaviour change support was

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delivered via one of three delivery models: one-to-one, group or digital delivery via an App (each site was allocated one delivery model and selected a provider through a commercial procurement process). As the programme was launched during the COVID-19 pandemic, one-to-one and group support were initially delivered remotely, with in-person delivery starting in 2022. Eligibility criteria included: age of 18-65 years, T2DM diagnosed within the previous six years and BMI  $\geq 27\text{kg/m}^2$  (adjusted to  $\geq 25\text{kg/m}^2$  for Black, Asian and other minority ethnic groups).<sup>20</sup>

### The Re:Mission study

The Re:Mission study aimed to deliver a coproduced, comprehensive qualitative and economic evaluation of the NHS LCD pilot, to be integrated with the NHS England quantitative analyses and 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.<sup>21</sup> This special issue provides insights from the patient perspective, derived from the longitudinal and cross-sectional service user surveys and qualitative interviews, to address the following research questions:

- To what extent is the content of the NHS LCD programme understood and applied by service users?
- How do socio-demographic characteristics and service delivery model impact service user experience?
- Which aspects of the service work and do not work, for whom, in what context and why?
- How can the service be improved in the future, to enhance service user experience and ensure any inequities are addressed?

This article details the methodological approach taken using the Consolidated criteria for reporting qualitative research COREQ guidelines.<sup>22</sup> Findings from the studies detailed within this paper are reported elsewhere in this issue.<sup>23-27</sup>

### Methods

The research team used a patient-centred framework aligned to the eight principles of patient-centred care,<sup>28</sup> working in coproduction with NHS England, the national LCD advisory group, and our public and patient involvement and engagement (PPIE) group (representing voices of lived experience from across our broad and diverse communities).<sup>29</sup> The Re:Mission study was underpinned by a realist informed approach, to help provide research-informed theories to determine how and why outcomes may differ for different people. The concept of realist evaluation has been summarised as: 'what works for whom in what circumstances and in what respects, and how?'.<sup>30</sup> Three different methodologies were used to inform the service user insight work: cross-sectional, longitudinal and withdrawing participant (service user) surveys and interviews.

### Participant surveys

A short (~20 minute) online participant survey was codesigned and piloted with service users, to capture participant experience and outcomes during each stage of the programme (baseline,

end of TDR, end of food reintroduction, end of maintenance and withdrawal); and to assess how these may differ by socio-demographics and delivery model. The data from each survey were anonymously linked (via a unique referral ID) to the sociodemographic, process and clinical outcomes data collected by NHS England as part of the LCD programme minimum dataset. Participants could complete the survey longitudinally (linked via unique referral ID) or cross-sectionally at any time point. Due to COVID-19 restrictions, the survey was made available via a secure encrypted online survey platform [Qualtrics, Provo, UT], with an option to complete over the phone (using a freephone number) in a language of choice, to ensure that language, literacy or IT accessibility were not barriers to participation. Invitations to participate in each survey was sent via LCD service providers at the relevant timepoint. Data analysis and findings from the survey are available.<sup>26</sup> All participants were invited to opt into a prize draw to win one of four £50 gift vouchers drawn at the end of each year.

### Participant interviews

#### *Data collection methods*

Semi-structured interview schedules were codesigned and piloted with our PPIE group to gather in-depth participant insights across the programme stages. Participants were recruited to interview either on expressing an interest in the participant survey or on responding to an invitation sent via their service provider. Participants were invited to interview based on maximum variation sampling,<sup>31</sup> to gain representation from across different socio-demographic and service delivery models.

Three subsets of interviews were completed:

- 1) longitudinal, with a retention rate of 83%. The same participants were interviewed at the end of total diet replacement (12 weeks, n=30), end of food reintroduction (18 weeks, n=28) and end of weight maintenance (52 weeks, n=25);
- 2) cross-sectional, in order to capture insights from any socio-demographic groups or delivery models underrepresented in the longitudinal interviews. Participants were interviewed at 24 weeks (n=15);
- 3) withdrawal (n=10) to capture insights from participants who withdrew or were prematurely discharged from the programme.

Overall n=55 participants were interviewed in the study. Thirty participants were recruited to longitudinal interviews. The retention rate was 83%: 12 weeks (n=30), 18 weeks (n=28) and 52 weeks (n=25). Additional participants (n=15) were recruited to cross-sectional interviews and interviewed once at 24 weeks into their LCD programme journey. A further group of participants (n=10) were interviewed as they withdrew or were discharged prematurely from the LCD programme. All participants were previously unknown to the interviewers and were offered a £20 gift voucher as a thank you for their time after each interview.

Longitudinal interview data were collected between February 2022 and September 2023. The interview lasted between 38 and 105 minutes. Two researchers (KD, CH) conducted the longitudinal interviews. All participants were asked if they

consented for one of the PPIE team to co-interview. The interviews were led by the researcher, with the PPIE member asking follow-up questions and prompts. Eleven interviews were co-led by a researcher and a member of the PPIE team.

Cross-sectional interview data were collected between May 2022 and July 2023. The interview lasted between 40 and 67 minutes, and was led by two researchers (KK and CF). Withdrawal interview data were collected between June 2022 and June 2023 by KD; the interview lasted between 60 and 110 minutes.

Longitudinal interviews also included photo elicitation techniques: participants were offered a free tablet device, sent prior to interview, to take photographs, films or audio recordings which were shared with the researcher at the interview. Prior to the interview taking place, a photo prompt sheet which aligned to the interview schedule (and included safety guidance), was shared with all participants who agreed to take part in this element of data collection (n=21).

### Data analysis

Interviews were conducted and recorded online using Microsoft Teams, transcribed verbatim and subjected to thematic analysis.<sup>32</sup> NVivo software (QS International Pty Ltd. Version 12) was used to assist the storing and organising of the data for all interviews. Longitudinal: 12-, 18- and 52-week data analysis was led by KK and CH. To inform the analysis process researchers (CH, KD, TB, KK, JM, SR) each familiarised themselves with transcripts from 12-week interviews that varied by delivery model, age and gender of service user and engagement with photo elicitation. A preliminary list of codes was identified by each researcher using the interview schedule as a deductive framework. Following a meeting to discuss the codes and agree an initial framework, each researcher inductively coded five transcripts which added codes to the initial list. This stage included a focus on the narrative that accompanied any images and recording, and a prompt marked to share the associated image with the team during the meetings. Researchers met again to discuss any additional codes. CH and KK revised the coding framework and used a sample of transcripts to check for additional meanings that were not initially included. KK performed the analysis with CH checking a sample of interviews.

Week 18 interviews were read multiple times by KK and were inductively and deductively analysed using the framework from week 12 and the interview schedules. CH read a sample of transcripts of the 18-week transcripts to check with the framework. KK coded the transcripts with the final framework. Analysis for the 52-week data followed the same process as 12-week data, with TB, JM, KK and CH each reading a sample of four transcripts which were coded against the 12- and 18-week frameworks. Any new codes were added and following discussion a revised 52-week framework was developed. KK then coded the transcripts.

Cross-sectional analysis was led by KK, who read all transcripts multiple times before conducting the thematic analysis. CH read a sample of transcripts to check for alternative meanings in the data. Themes were identified, defined, and consolidated into clusters to reveal higher-level patterns. The



### Key messages

- ▲ Trials show that Low Calorie Diets achieved through Total Diet Replacement can lead to significant weight loss and reduced glycemia, This study evaluates the translation and implementation into real world practice.
- ▲ Surveys and interviews with service users undertaken using a realist lens explored which aspects of the service work and do not work for whom in what context and why.

data was combined with the longitudinal data using NVivo software (QS International Pty Ltd. Version 12).

Withdrawal data analysis was led by KD, who read all transcripts multiple times before conducting the thematic analysis. CH read a sample of transcripts to check for alternative meanings in the data.

### Results and dissemination

The findings from the study, with recommendations for policy, practice and research, are presented elsewhere: total diet replacement phase;<sup>23</sup> food reintroduction phase;<sup>24</sup> weight maintenance phase;<sup>25</sup> interviews with individuals who withdrew;<sup>27</sup> and the participant experiences survey.<sup>26</sup>

In addition there will be dissemination through a series of peer-reviewed publications, national and international conference presentations, alongside public facing blogs and vlogs on the Re:Mission study website,<sup>33</sup> accompanied by an illustrated journal-style summary of the final report and a short film documenting service user journeys through the photovoice materials.

Insights from the study have already informed the national roll out and new specification of the programme (now called the NHS Type 2 Diabetes Path to Remission Programme) and will continue to provide critical learning to inform ongoing service improvements.



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