A co-produced mixed method evaluation of the NHS Low-Calorie Diet pilot

Learning from staff and service users insights

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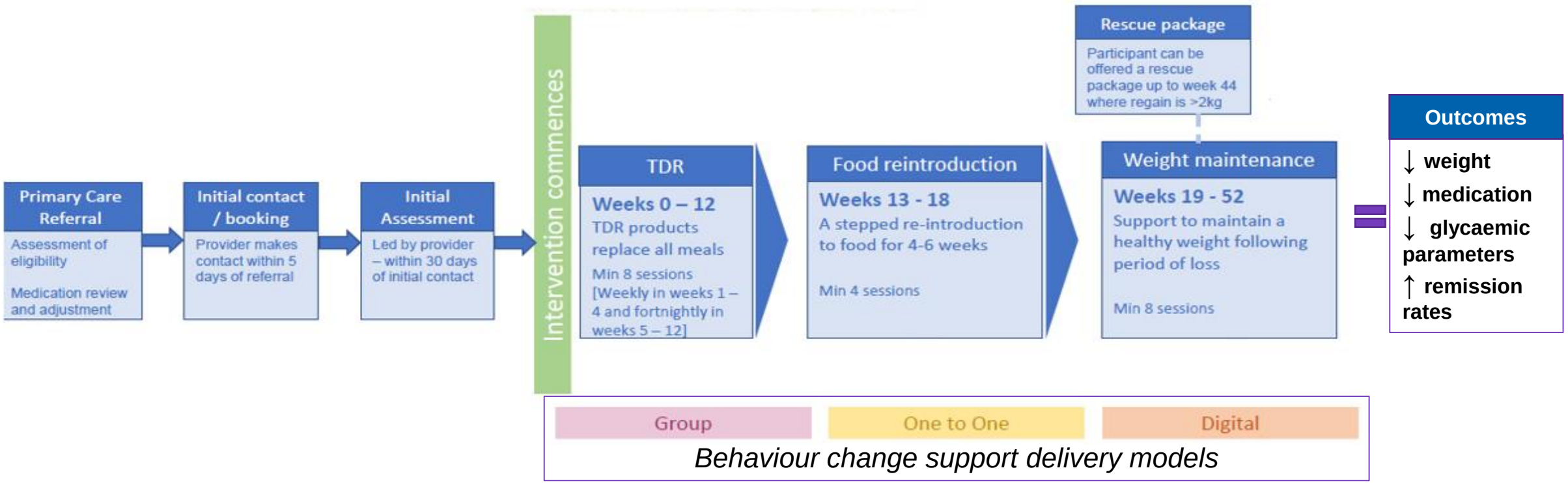
Re:Mission

Background:

- Type 2 diabetes and excess weight prevalence is increasing, and poses a major risk to population wellbeing and the sustainability of the NHS.
- NHS Long Term Plan announced that a low calorie diet programme will be piloted, at scale, from 2020, informed by evidence from the Diabetes Remission Clinical Trial (DiRECT), and the Doctor Referral of Overweight People to Low Energy total diet replacement Treatment (DROPLET) Randomised Control Trials (RCT).
- The resulting NHS Low Calorie Diet programme was a joint initiative between NHS England, Public Health England and Diabetes UK.
- The programme was piloted in two waves: 1 – Sept 2020 (10 ICBs) and 2 – January 2022 (11 ICBs) and tested three different delivery models: one-to-one, digital and group.

An overview of the Low Calorie Diet programme

(now Type 2 Diabetes path to remission programme)



Initial 10 pilot ICS areas (Wave 1) in 2020
Additional 11 ICS areas (Wave 2) in 2022

An overview of the Low Calorie Diet programme

(now Type 2 Diabetes path to remission programme)

Our new patient experience film – please share

https://remission.study/patient-journey

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Study aim:

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

PROTOCOL:
https://fundingawards.nihr.ac.uk/award/NIHR132075
V4 (ARPIL 22)

Study Objectives

1. Assess different providers experiences of the programme, including any barriers and facilitators to implementation across different populations

2. Assess the experiences and attitudes of NHS professionals involved in referring patients and hosting the intervention

3. Assess patients' experiences of the programme: including patients with a range of socio-demographics, and with differing engagement experiences 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.

4. Estimate the long-term cost-effectiveness of each delivery model in terms of cost per quality adjusted life year (QALY), including a cost analysis to enable comparisons with other healthcare resource demands to support commissioning decisions.

5. Assess national roll out through a transferability and policy impact assessment.

6. Integrate findings with the quantitative analyses conducted by NHSE to:

a) examine whether underpinning trial outcomes can be replicated within larger and more diverse populations, and with different providers and behaviour change delivery models;
b) examine how the results impact published cost-effectiveness and support future commissioning;
c) provide a comprehensive understanding of the programme implementation and impact by socio-demographics, delivery model and locality:
d) determine the transferability and policy impact of the programme.

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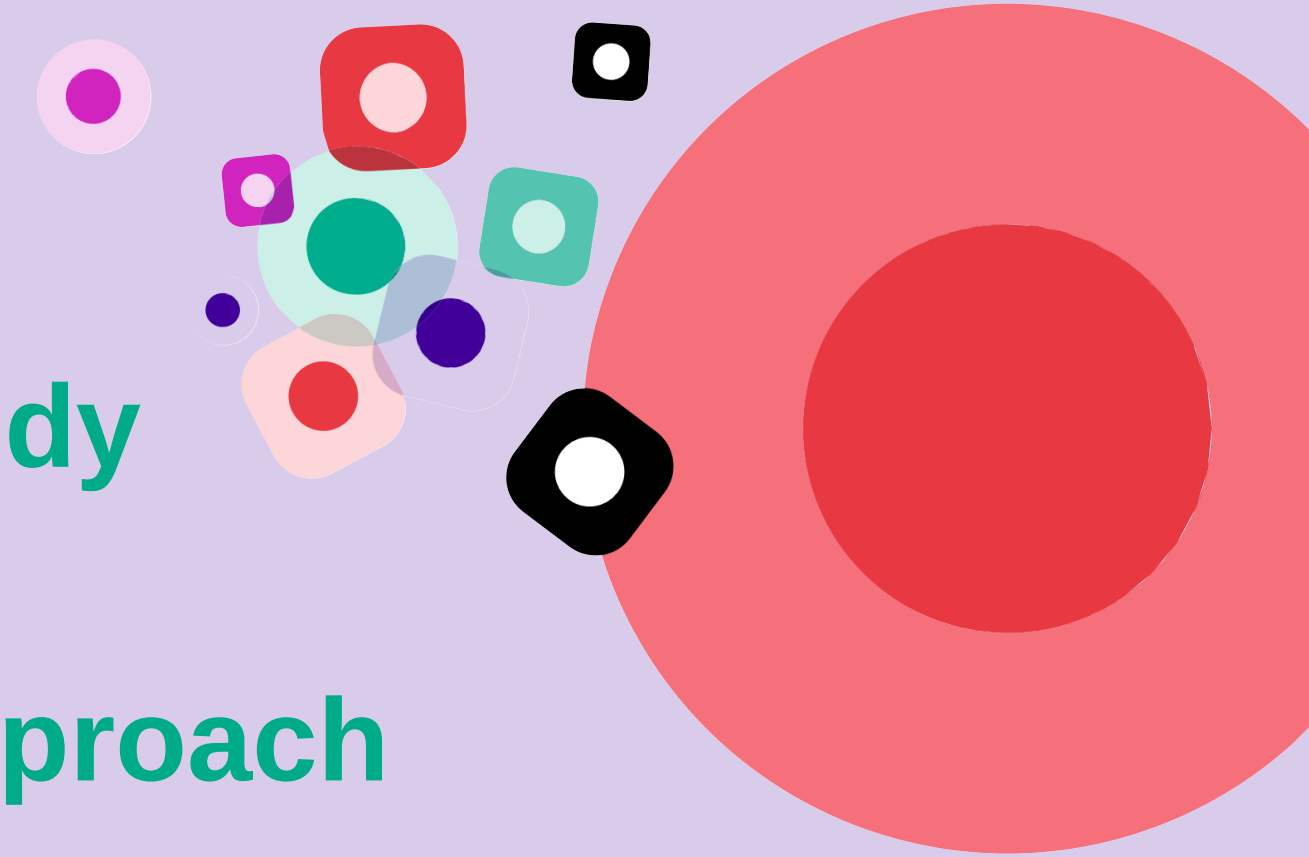
Mixed methods study underpinned by a realist-informed approach



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1) project management and coproduction

2) service fidelity and delivery:

- documentary review;
- session observations;
- thematically analysed semi-structured interviews with NHS staff (n=39);
- focus groups with providers (n=13);
- semi-structured interviews with coaches from/delivering to ethnically diverse populations (n=7).

3) patient experience and inequities:

- cross-sectional and longitudinal service user surveys (n=719),
- semi-structured cross sectional (n=37) & longitudinal (n=30) interviews supported by adapted photovoice.

4) economic evaluation:

- patient-level simulation modelling to estimate the long-term cost-effectiveness (incremental cost QALY) when compared to a counterfactual scenario, and other demands on healthcare resources.

5) transferability assessment:

- semi-structured interviews with NHS staff (n=16) and providers (n=9) in sites involved in wave 2 and analysed according to constructs within the PIET-T (Population, Intervention, Environment, Transfer conceptual model of transferability)

Our learning...

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Service delivery fidelity

- Application and type of behaviour change theory varied across all providers
- Fidelity was demonstrated for most (but not all) of the NHS stipulated service parameters
- Fidelity of BCT delivery for digital delivery models was high.
- Fidelity of BCT delivery for remote 1:1 and group delivery varied
- Facilitators to effective BCT delivery 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.
- Observed variations between providers included: level of cultural adaptation of the programme, discrepancies in advocacy of non-starchy vegetables and physical activity promotion during TDR.

Overall:

+ 1:1 sessions were more successful in their person-centred delivery

+ Skills of, and continuity in, the coaches delivering the sessions had a strong impact on adherence to the service specification.

+ Critical to person-centred delivery were: friendly and accessible communication, ability to provide positive feedback, dedicated efforts to establish build relationships, and peer support.

+ Gaps were identified in the provision of emotional eating and psychological support.

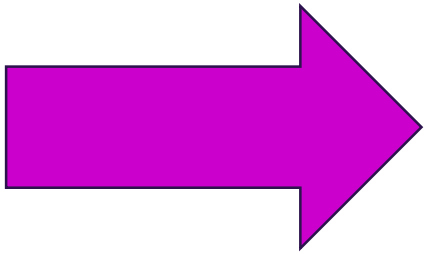
Service provider delivery insights

Facilitators to effective delivery were:

- good internal teamwork,
- trusting coach and service user (SU) relationships,
- a wide choice of TDR products.

Barriers to effective delivery were:

- effectively engaging GP practices and receiving sufficient and appropriate referrals
- supporting service users through challenges to remain compliant (e.g. psychological support needs, multiple life events, busy lifestyles, work & family commitments that revolve around food)
- **digital competency, dietary requirements, taste preferences, needs of the family, and time to attend sessions**
- **ethnicity, culture, language and translation requirements**



<u>When delivery to diverse ethnic groups was explored we found:</u>

- variation in cultural competency of coaches and the potential impact of knowledge gaps on programme.
- a need to adapt systems and processes, and close the gap where needs of service users are not fully met.
- a need to address language barriers, utilise culturally tailored resources, understand diverse cultures, and implement effective cultural tailoring strategies with an understanding of cultural nuances.

NHS delivery staff insights

Staff involved with the referral of patients, and mobilisation of the programme reported on the impact of:

- COVID-19 and primary care capacity and engagement;
- variation in approaches to training, incentivisation and referrals.

Barriers included the complexity of the referral process leading to ineligible referrals and time taken to refer, staff turnover in the local health system and referrer confidence and expertise.

A **key facilitator** to effective mobilisation of the programme was effective collaboration across all stakeholders.

Service user experience: learning from interviews and surveys

REFERRAL

- People were motivated to be referred in order to improve their T2D, weight and health.
- Although most were satisfied with the referral process, some inconsistencies in referral knowledge were highlighted, with more programme information at referral required.

Service user experience: learning from interviews and surveys

THE PROGRAMME

- Concerns were raised by some of our interviewees around the cultural competence of the programme which may explain the reduced uptake and impact across some ethnically diverse communities
- Perceived costs may also have deterred people living in areas of socio-economic deprivation.
- Higher uptake in those who have lived with T2D for longer may also reflect the high motivation to improve health when starting the programme.

Service user experience – KEY LEARNING

- **A good TDR product range is required, and delivery must be frequent**
- **Allowance of supplementary foods** (e.g. non starchy veg)
- **Social impact of TDR should be acknowledged**
- **Variation in cultural competence of programme content and delivery should be addressed**
- **Person-centred delivery and is key and this occurs best 1:1**
- **Increased support and availability of coaches is needed**
- **Additional psychological support needed (and life events accommodated)**
- **Family and peer support is critical**
- **More support around emotional and disordered eating is required**
- **Concern about food re-introduction should be addressed**.
- **Wider benefits of the programme were beyond weight loss were highlighted**

Economic evaluation findings

Patients who chose to spend money on additional resources during the programme, spent an average of £125.99, which included purchasing additional TDR products, recipe books, and extra glucose monitoring strips

The cost of delivering the programme fell in the same range as identified in the DiRECT trial.

Incremental cost per QALY ratio was £13,334, and therefore fell within the the NICE cost-effectiveness (willingness-to-pay) threshold of £20,000 per QALY, and was therefore cost effective.

Cost effectiveness did not vary by ethnicity or area-level deprivation nor in sensitivity analyses, which included (i.) running the model across a range of different time horizons, including 10 years, 15 years, 20 years; and (ii.) altering the intervention costs to reflect possible differences in cost by delivery model

Transferability assessment

- The core elements required to achieve impact, included **confidence in the programme, multi-disciplinary 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 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 highlighted to ensure the needs of individual patients were met.
- Policy implication for wide-spread adoption should include **referral strategies to reach underrepresented groups, a choice of delivery model to optimise uptake, and the provision of timely data from service providers on access and programme benefits.**

Changes to the programme resulting from this study:

1. Increase in variety of TDR products offered (including accommodating intolerances)
2. More frequent TDR delivery – to avoid storage issues and allow product changes
3. Only 1:1 in person or digital delivery (no groups)
4. Service performance and inequalities need to be monitored by providers (including response to service user feedback)
5. Providers are asked to refer back to GP if service users have a suspected eating disorder (development of an eating disorder should be noted as an adverse event)
6. Support for food reintroduction should include healthy dietary plans appropriate and tailored to individual preferences and culinary traditions
7. Additional support sessions have been recommended
8. Planned pauses have been introduced to help mitigate against the significant life events which may impact a service users journey
9. Providers need to provide details on the behaviour change theory used and complete a logic model to demonstrate mechanisms of action for their programme.
10. All providers need to provide peer to peer support groups.

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Study impact

- Finding have informed the development, procurement and delivery of the national roll out of the Low Calorie Diet programme – now called the Type 2 diabetes path to remission programme.
- Findings have made a significant contribution to the evidence base through 23 (further 7 under review) peer review publications and numerous conference presentations.
- Supported 3 staff development and 2 PhD student completions
- Follow on funding applications x3
- Findings have informed a number of patient facing resources including:
  - A short patient journey animation (released April 24)
  - An illustrated patient journal (released April 24)
  - Blogs, patient films, website: www.remission.study

Research recommendations

- Assess the long-term clinical, equity and economic impact of the now nationally available NHS T2D Path to Remission Programme.
- Undertake a quantitative analysis of the costs and health outcomes of the NHS T2D path to remission programme in the post-pandemic environment.
- Research co-development to improve patient completion rates and retention in:
    - younger patient aged 18-39 years,
    - Those from the most deprived quintile,
    - Those with a higher (40+) starting BMI
- Research to understand and improve the reduced weight loss seen Asian and Black patients.
- Examine 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.

THE RE:MISSION TEAM

NHS ENGLAND LOW CALORIE DIET ADVISORY GROUP

NIHR Project Oversight Group:
Dr Adrian Brown - specialist tier 3 dietician; Prof Peter Bower -link to NDPP evaluation; Prof Clare Collins – international dietetic and obesity expert; Prof Jeremy Bray - expert health economist; Prof Simon Coulton - expert statistician; Dr Helen Parretti – GP weight management; Dr David Blane - GP – inequalities; Elizabeth Robertson – diabetes UK, Sarah LeBrocq – Patient Representative, Dr Ollie Mytton – Public Health Consultant

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Project Manager (quant):
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Dr Stuart Flint (2%)
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PG: 14 patient interviews
Scaled insights survey analysis

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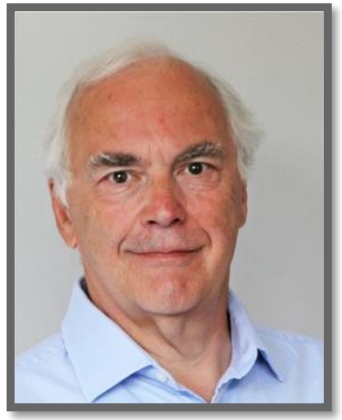
The University of York
University of Leeds
Leeds Beckett University

Our PPIE Team was fundamental to the success of this study: involved from application conception to study dissemination, and everything in between and beyond!







Clare K, Ojo A, Teke J, Willis M, Akhtar G, Clegg B, Goddard C, Freeman C, Drew KJ, Radley D, Homer C, ***Ells*** *LJ (2022) 'Valued and listened to: the collective experience of patient and public involvement in a national evaluation. Perspectives in Public Health 142 (4). pp. 199-201*

THANK YOU

Any questions?

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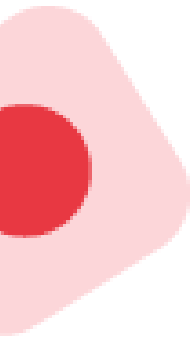

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