Supporting remission of type 2 diabetes in the real world

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The Accelerated Access Review in 2016 highlighted the long pipeline from innovation or inception of research idea to implementation into routine clinical practice, a pipeline often lasting around two decades, and therefore made recommendations to Government on how to accelerate access for NHS patients to innovative medicines, medical technologies, diagnostics and digital products.[1] Following on from this, one of a handful of policy principles that guided actions on the part of the NHS England Diabetes Programme Team was that when high-quality evidence emerged, pathways to implementation should be expedited where possible.

The Long Term Plan for the NHS in England was published in 2019, and set the priorities for the NHS over the next 5-10 years.[2] The lead up to publication provided potential funding opportunities for new programmes that were to be included in the Plan. Among other suggestions, a recently published randomised controlled trial (RCT) formed the basis for a new programme of work suggested for inclusion by the NHS England Diabetes Programme team. The Diabetes Remission Clinical Trial (DiRECT) provided evidence that achievement of remission of type 2 diabetes (T2DM) might be possible for some with recent diagnoses of T2DM – 46% of participants at 12 months in the RCT setting – through total diet replacement (TDR) using a micronutrient-complete but low-energy diet plus behavioural support.[3] The case for inclusion, initially as a pilot, was successfully made.

The DiRECT trial was delivered by healthcare professionals in primary care settings: it demonstrated the efficacy of TDR and behaviour change support compared to usual care in people with T2DM in causing some to achieve T2DM remission.[3] The Doctor Referral of Overweight People to Low Energy total diet replacement Treatment (DROPLET) trial comparing the efficacy of TDR with usual care in adults living with obesity, was published around six months later, and demonstrated that similar weight loss to that seen in the DiRECT trial could be achieved through delivery of similar interventions by commercial providers,[4] providing a potential mechanism for implementation at scale without being limited by healthcare professional workforce availability.

Following principles that had been applied in the development of the NHS Diabetes Prevention Programme,[5] the NHS England Diabetes Programme Team convened an expert advisory group to develop a service specification for delivery of the TDR intervention. The service specification could then be used to run a procurement for third party providers capable of interventional delivery across the country.[6]

The intervention begins with 12 weeks of TDR, followed by 4-6 weeks of food re-introduction, then weight maintenance support for up to 52 weeks. The initial pilot stages of the Programme involved 10 of the 42 geographical NHS administrative areas corresponding to Integrated Care Boards (ICBs) in England, with selection based on expressions of interest. Prior to the COVID-19 pandemic, three different models of delivery had been planned (face-to-face one-to-one, face-to-face group, and digital one-to-one), with each NHS site selecting their delivery model. However, due to constraints relating to the pandemic, launch was delayed by six months to September 2020 and planned face-to-face delivery approaches were changed to remote one-to-one or remote group delivery via video conferencing. The planned digital delivery model, through Apps or websites, remained unchanged. From April 2022, delivery switched to the originally planned delivery methods except for providers delivering the group model, which continued to be delivered remotely until June 2023.

The initial pilot phases of the Programme were able to demonstrate encouraging weight losses for participants, approaching those realised through the RCTs, and justifying further staged roll-out of the Programme.[7] A national procurement exercise has resulted in five providers, each capable of delivering the content of the service specification in any location across the country, being placed on a national framework. Latterly, each local area across England has been supported to run a 'mini-competition' to appoint the provider that best meets their local population needs from the national framework, each provider offering one delivery approach for each specific area. By April 2024, national roll-out across all 42

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ICBs will be complete, so that all areas of England will have access to the programme, enabling national communications to raise awareness amongst general practices who make referrals into the Programme, and among eligible individuals living with T2DM.

From inception, Programme evaluation was planned, with the NHS England Diabetes Programme Team performing the quantitative analyses in-house (monthly participant data feeds allow the team to iterate, respond to and improve the programme almost in real time), and with an NIHR-commissioned independent team, the Re:Mission team,[8] performing the qualitative and cost-effectiveness analyses. This issue of *The British Journal of Diabetes* includes six papers describing the initial qualitative findings of the Re:Mission team. The NHS England team have produced a manuscript describing the initial quantitative analyses of weight changes and remission rates on the Programme, which is currently undergoing peer review and will be published separately.

Of the six papers published in this issue, the first describes the qualitative evaluation methods employed;[9] the second,[10] third[11] and fourth[12] focus respectively on the TDR, food reintroduction and weight maintenance phases of the intervention; the fifth describes the findings of structured interviews with people who did not complete the intervention;[13] and the sixth presents participant experiences of the programme using both quantitative and qualitative data derived from four cross-sectional surveys, and examines differences by sociodemographic characteristics, delivery model and provider.[14]

Valuable learnings from the qualitative findings have already supported, and will continue to support, improvements in the programme, to better meet the needs of participants, as well as referrers, providers and health systems. With full national coverage now almost complete, enabling potential universal access, people living with diabetes, healthcare professionals, commissioners and organisations such as ABCD, PCDS and Diabetes UK can work together to ensure that the option of the NHS Type 2 Diabetes Path to Remission Programme is embedded into, and aligned with, routine T2DM care pathways across England, from the point of diagnosis.

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