Early findings from the NHS Type 2 Diabetes Path to Remission Programme: a prospective evaluation of real-world implementation

Jonathan Valabhji, Tessa Gorton, Emma Barron, Soraya Safazadeh, Fiona Earnshaw, Clare Helm, Martin Virr, John Kernan, Shaun Crowe, Paul Aveyard, John Wilding, Tony Willis, Louisa Ells, Simon O'Neill, Elizabeth Robertson, Susan Jebb, Roy Taylor, Chirag Bakhai

Summary

Background Randomised controlled trials have shown that total diet replacement (TDR) can lead to remission of type 2 diabetes. In 2019, the English National Health Service (NHS) committed to establishing a TDR-based interventional programme delivered at scale within real-world environments; development followed of the NHS Type 2 Diabetes Path to Remission (T2DR) programme, a 12-month behavioural intervention to support weight loss involving an initial 3-month period of TDR. We assessed remission of type 2 diabetes for programme participants.

Methods In this national prospective service evaluation of programme implementation, people in England aged 18–65 years and diagnosed with type 2 diabetes in the last 6 years were referred to the programme between programme launch on Sept 1, 2020, and Dec 31, 2022. Programme data were linked to the National Diabetes Audit to ascertain HbA_{1c} measurements and glucose-lowering medication prescriptions. The primary outcome was remission of type 2 diabetes at 1 year, defined as two HbA_{1c} measurements of less than 48 mmol/mol recorded at least 3 months apart with no glucose-lowering medications prescribed from 3 months before the first HbA_{1c} measurement, and the second HbA_{1c} measurement recorded 11–15 months after the programme start date. Outcomes were assessed in two ways: for all participants who started TDR on the 12-month programme before January, 2022, for whom there were no missing data; and for all participants who started TDR on the 12-month programme before January, 2022, and had completed the programme (ie, had a valid weight recorded at month 12) by Dec 31, 2022, for whom there were no missing data.

Findings Between Sept 1, 2020, and Dec 31, 2022, 7540 people were referred to the programme; of those, 1740 started TDR before January, 2022, and therefore had a full 12-month opportunity to undertake the programme by the time of data extraction at the end of December, 2022. Of those who started TDR before January, 2022, 960 (55%) completed the programme (defined as having a weight recorded at 12 months). The mean weight loss for the 1710 participants who started the programme before January, 2022 and had no missing data was 8·3% (95% CI 7·9–8·6) or 9·4 kg (8·9–9·8), and the mean weight loss for the 945 participants who completed the programme and had no missing data was 9·3% (8·8–9·8) or 10·3 kg (9·7–10·9). For the subgroup of 710 (42%) of 1710 participants who started the programme before January, 2022, and also had two HbA_{1c} measurements recorded, 190 (27%) had remission, with mean weight loss of 13·4% (12·3–14·5) or 14·8 kg (13·4–16·3). Of the 945 participants who completed the programme, 450 (48%) had two HbA_{1c} measurements recorded; of these, 145 (32%) had remission, with mean weight loss of 14·4% (13·2–15·5) or 15·9 kg (14·3–17·4).

Interpretation Findings from the NHS T2DR programme show that remission of type 2 diabetes is possible outside of research settings, through at-scale service delivery. However, the rate of remission achieved is lower and the ascertainment of data is more limited with implementation in the real world than in randomised controlled trial settings.

Funding None.

Introduction

The increasing prevalence of type 2 diabetes poses risks to the wellbeing of individuals and the health of populations, representing a major burden on health-care services. Until recently, type 2 diabetes had been considered a lifelong progressive condition. Elucidation of the potentially reversible nature of type 2 diabetes was achieved by documenting the underlying pathophysiological processes before and after dietary weight loss.[1–3] Subsequent randomised controlled trials have shown that total diet replacement (TDR) using a micronutrient-complete but low-energy diet, typically in the form of soups and shakes, can lead to marked weight loss and long-term maintenance of remission of diabetes,[4,5] and has been shown to be an acceptable treatment option for some people with type 2 diabetes.[6,7] It is unclear, however, whether such interventions can be successfully delivered at scale in real-world settings.

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Prevention and Long Term Conditions Programme, Medical Directorate, NHS England, London, UK (Prof J Valabhji MD, T Gorton BSc, E Barron MSc, S Safazadeh MSc, F Earnshaw PhD, C Helm BSc, M Virr BA, J Kernan BSc, S Crowe BA, C Bakhai MBA); **Department of Metabolism, Digestion and Reproduction, Faculty of Medicine, Imperial College London, London, UK** (Prof J Valabhji, E Barron); **Chelsea and Westminster Hospital NHS Foundation Trust, London, UK** (Prof J Valabhji, E Barron); **Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, UK** (Prof P Aveyard PhD, Prof S Jebb PhD); **Institute of Life Course and Medical Sciences, University of Liverpool, Liverpool, UK** (Prof J Wilding MD); **NHS North West London ICB, London, UK** (T Willis PhD); **Obesity Institute, School of Health, Leeds Beckett University, Leeds, UK** (Prof L Ells PhD); **Diabetes UK, London, UK** (S O'Neill RN, E Robertson PhD); **Magnetic Resonance Centre, Translational and Clinical Research Institute, University of Newcastle, Newcastle, UK** (Prof R Taylor MD); **NHS Bedfordshire, Luton and Milton Keynes ICB, Luton, UK** (C Bakhai)

Correspondence to: Prof Jonathan Valabhji, Department of Metabolism, Digestion and Reproduction, Faculty of Medicine, Chelsea and Westminster Hospital Campus, Imperial College London, London SW10 9NH, UK **j.valabhji@imperial.ac.uk**

Research in context

Evidence before this study

Randomised controlled trials have shown that total diet replacement (TDR) using a micronutrient-complete but low-energy diet, typically in the form of soups and shakes, can lead to marked weight loss and remission of type 2 diabetes. The Diabetes Remission Clinical Trial (DiRECT) reported a 12-month mean weight loss of 10·0 kg in the intervention group, with 68 (46%) of 149 intervention participants reaching remission at 12 months and 53 (36%) at 24 months, whereas the Diabetes Intervention Accentuating Diet and Enhancing Metabolism (DIADEM-I) trial reported a 12-month mean weight loss of 12·0 kg in the intervention group and remission in 43 (61%) of 70 participants at 12 months. Remission has also been shown in 44% of participants at 12 months in a randomised controlled trial of people of East Asian ethnicity following weight loss from intermittent fasting diets of around 9% from baseline.

Added value of this study

To our knowledge, this is the first study to show that remission of type 2 diabetes can be achieved through at-scale delivery outside of a research setting. We assessed data from the first 7540 people referred into the English National Health Service (NHS) Type 2 Diabetes Path to Remission Programme (T2DR). For those who had a full 12-month opportunity to undertake the programme and had two subsequent HbA_{1c} measurements recorded, 27% had remission with a mean HbA_{1c} reduction of 12·0 mmol/mol and a mean weight loss of 13·4% or 14·8 kg.

Implications of all the available evidence

Remission rates on the NHS T2DR programme were somewhat lower than those seen in randomised controlled trials. Our results complement the clinical efficacy findings from randomised controlled trial settings, providing important evidence on the clinical effectiveness of the TDR approach when delivered at scale in real-world settings. We also assess the effect of the programme by dimensions of inequalities, data that have not been available from the randomised controlled trials that have been performed. Our findings can support better informed policy decisions regarding the TDR approach in terms of operational effectiveness and effect on population health.

The Diabetes Remission Clinical Trial (DiRECT), delivered by health-care professionals in primary care settings, compared the effectiveness of TDR and behaviour change support, alongside withdrawal of antihypertensive and glucose-lowering medication, with usual care in 298 people with type 2 diabetes.[4] At 12 months, the adjusted mean difference showed 8·8 kg (95% CI 10·3–7·3) greater weight loss in the intervention group compared with the control group, with 46% of the intervention group showing remission.[4] The Doctor Referral of Overweight People to Low Energy Total Diet Replacement Treatment (DROPLET) randomised controlled trial compared the effectiveness and safety of a TDR programme with usual care in 278 adults living with obesity,[5] delivered by commercial providers rather than primary-care health-care professionals. At 12 months, intention-to-treat analysis showed similar absolute weight loss to DiRECT and 7·2 kg (95% CI 4·9–9·4) greater weight loss in the intervention group compared with the control group.

In 2020, the English National Health Service (NHS) established the Low-Calorie Diet Programme, which was subsequently renamed the Type 2 Diabetes Path to Remission (T2DR) programme based on service user feedback, to support weight loss and maintenance, reduction in glucose-lowering medication, and potential remission of type 2 diabetes. The programme draws upon the evidence from the DiRECT and DROPLET randomised controlled trials, implementing a low-energy TDR intervention through at-scale service delivery, outside the controlled environment of a clinical trial.

Using data from the first 2 years of the programme, we aimed to assess whether interventions delivered at scale through commercial providers could lead to remission of type 2 diabetes. These quantitative analyses will be complemented by subsequent independent qualitative and economic evaluations of the programme, commissioned by the National Institute for Health and Care Research (NIHR).[8]

Methods

Study design

In this prospective service evaluation of a real-world implementation of TDR, we assessed the effectiveness of the NHS T2DR programme in England using prospectively collected national service-level data relating to all those referred to the programme from its launch on Sept 1, 2020, to Dec 31, 2022.

The programme was delivered according to a national service specification by one of six service providers selected through a national, competitive, open procurement process. The specification was developed by an expert reference group,[9] building on the evidence of the DiRECT and DROPLET randomised controlled trials and guidance published by the National Institute for Health and Care Excellence.[4,5,10–13]

Ten geographical areas corresponding to Integrated Care Boards (ICBs), administrative footprints within the NHS in England of which there are 42 in total, were initially selected based on an expression of interest process. In January, 2022, an additional 11 ICBs were added. A full list of participating areas can be found in the appendix (p 1). Each area was served by one of six providers and offered one delivery approach. By April 1, 2024, the NHS T2DR programme had been made available in all 42 ICBs in England.

Each provider delivered the programme following the national service specification of TDR, food reintroduction, and weight maintenance, with a minimum of 20 sessions

See Online for appendix

(eight while on TDR, four in food reintroduction, and eight in the weight maintenance phase) and a total programme duration of 12 months. The TDR phase was for 12 weeks with a total daily calorie intake of around 800–900 kcal, comprised of nutritionally formulated products such as soups, shakes, and bars, alongside weekly coaching sessions for the first 4 weeks and fortnightly sessions for the subsequent 8 weeks. This was followed by a period of food reintroduction for 4–6 weeks, featuring at least four coaching sessions, focusing on transitioning from TDR to a healthy balanced diet and setting individualised targets for energy intake and weight. The final phase of the programme, titled weight maintenance, supported attainment of these goals alongside monthly coaching sessions directed at behaviour change and encouragement of physical activity.

Before the COVID-19 pandemic, face-to-face one-to-one and group approaches and digital one-to-one approaches had been planned, with each NHS T2DR site selecting their delivery model. However, due to constraints relating to the pandemic, planned face-to-face delivery approaches changed to remote one-to-one or group delivery via videoconferencing. The planned digital delivery model, through apps or websites, remained unchanged. From April, 2022, delivery switched to the originally planned delivery methods with the exception of providers delivering the group model, which continued to be delivered remotely until June, 2023.

Participants

The identification and referral of suitable individuals to the NHS T2DR programme was undertaken by general practices in primary care. Individuals were eligible if they were aged 18–65 years (the upper threshold aligned with DiRECT), diagnosed with type 2 diabetes within the last 6 years,[2,3] and had a BMI of 27 kg/m² or more if from a White ethnic group, adjusted to 25 kg/m² or more for Black, Asian, Mixed, and Other ethnic groups. The most recent HbA_{1c} measurement, taken within the last 12 months, was required to be 43–87 mmol/mol if the individual was on glucose-lowering medication, or 48–87 mmol/mol otherwise. A full list of eligibility criteria can be found in the appendix (pp 2–3). Individuals referred by general practices were invited by providers to attend an individual assessment to verify eligibility, receive further details of the programme, determine whether they wished to continue, and, if they did, agree a TDR start date.

Delivery of the intervention was by health coaches, although some providers used dietitians. Although medical responsibility remained with the general practice at all times, each provider had a medical director for the health coaches to access clinical advice as necessary. At the end of the 12-month programme, or earlier if a participant dropped out, participants were discharged to the care of their general practice.

Data sources

All providers were contractually required to collect a minimum dataset capturing demographic and clinical information for all individuals referred to the programme. Age, sex, postcode, baseline bodyweight, baseline HbA_{1c}, height, ethnicity, medications taken at referral, and number of years since diagnosis of diabetes were recorded at receipt of referral. Bodyweight was recorded at each session attended, self-reported for remote and digital deliveries or collected by the provider for in-person sessions. Previous experience in implementing the NHS Diabetes Prevention Programme in England,[14] which had revealed problematic performance for point-of-care HbA_{1c} testing while on the programme, alongside additional expense, leading to its removal from the programme specification, informed the decision not to require T2DR providers to monitor HbA_{1c}. Instead, HbA_{1c} data would be extracted from primary care records through the National Diabetes Audit (NDA); it was recommended that general practice check HbA_{1c} twice for participants during the 12-month programme, at 6 months and 12 months after the programme start. The NDA also extracted data on prescriptions of glucose-lowering medication during programme attendance and following discharge from the programme, in order to ascertain remission of type 2 diabetes at 12 months. The NDA has collated data on people with diabetes registered with general practices in England since 2003, with almost complete practice participation in recent years (98% in 2021/22).[15] The NDA was linked to the minimum dataset by pseudo-NHS number (a unique patient identifier that does not reveal the individual's identity).

To fulfil its statutory duties, NHS England requires access to and linkage of various pseudonymised national datasets, in line with the requirements of the General Data Protection Regulation. The legal basis for the NDA data collection and linkage is a direction from the Department of Health and Social Care to NHS England according to section 254 of the Health and Social Care Act for England 2012. Data are not extracted if the person has withdrawn their permission for their record to be used for secondary analyses, which applies to approximately 2·6% of records.

Outcomes

The primary outcome was remission of type 2 diabetes at 12 months for those who started TDR before January, 2022, and therefore had a full 12-month opportunity to undertake the programme by time of data extraction at the end of December, 2022. Secondary outcomes were the percentage change in bodyweight and change in bodyweight (kg) at 12 months, the proportions of participants who achieved a weight loss of at least 10% and of at least 15% at 12 months, and the proportion who completed the programme. For participants who had two HbA_{1c} measurements recorded at least 3 months apart, with the second 11–15 months after the programme start,

the change in HbA_{1c} between referral and the most recent test recorded was also calculated.

Remission of type 2 diabetes at 12 months was defined as two HbA_{1c} measurements less than 48 mmol/mol recorded at least 3 months apart, with no glucose-lowering medications prescribed from 3 months before the first HbA_{1c} measurement, and the second HbA_{1c} measurement recorded 11–15 months after the programme start.[16] Participants who completed the programme were defined as those who started TDR before January, 2022, and also had a valid weight measurement recorded within 21 days of month 12 (364 days) indicating that they were still participating in the programme at that time. Completion rates were calculated with the number of people who started TDR and had a full 12-month opportunity to undertake the programme as the denominator. The baseline measurement was defined as the weight reported within 7 days of the TDR start date. Where multiple weights were recorded within the same interval from the TDR start or programme end date, the minimum weight was chosen. Weight changes greater than 5 SDs from the mean and recorded weights of less than 35 kg or more than 300 kg were deemed erroneous and excluded from analyses.

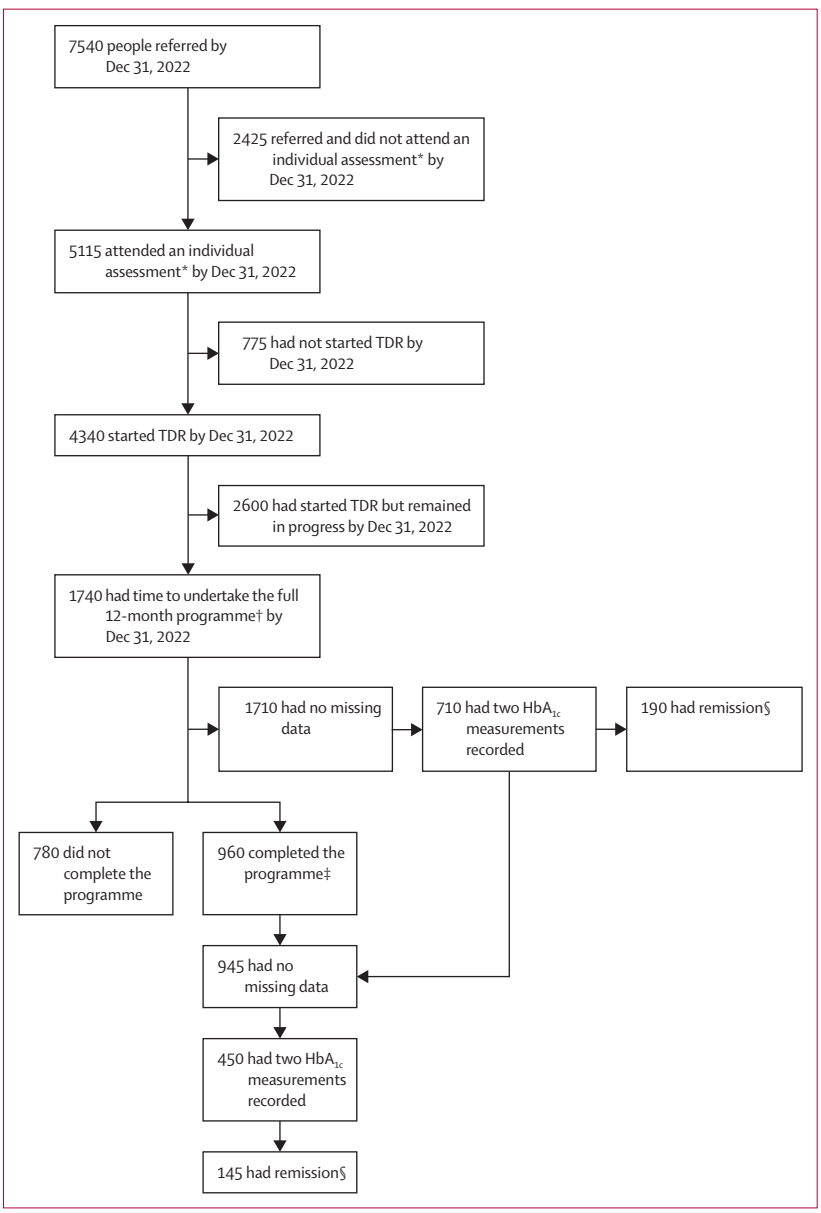

Figure: **Trial profile**
All numbers have been rounded to the nearest 5 to protect participant confidentiality. TDR=total diet replacement. *Individuals referred to the programme are required to attend an individual assessment to verify eligibility, receive further details of the programme, determine whether they wish to continue, and, if they do, agree a TDR start date. †Individuals who started TDR before January, 2022, and therefore had a full 12-month opportunity to undertake the programme by time of data extraction on Dec 31, 2022. ‡Participants who had undertaken the programme and had a valid weight measurement within 21 days of month 12 (364 days) indicating that they were still participating in the programme at that time. §Remission of type 2 diabetes at 12 months was defined as two HbA_{1c} measurements lower than 48 mmol/mol recorded at least 3 months apart, with no glucose-lowering medications prescribed from 3 months before the first HbA_{1c} measurement, and the second HbA_{1c} measurement recorded 11–15 months after the programme start.

Outcomes were assessed in two ways: for all participants who started TDR on the 12-month programme before January, 2022, and had completed the programme (ie, had a valid weight recorded at month 12) for whom there were no missing data for age, sex, ethnicity, deprivation, duration of diabetes, baseline HbA_{1c},baseline BMI, provider, delivery method, or weight (at baseline and month 12); and for all participants who started TDR on the 12-month programme before January, 2022, irrespective of whether or not they fulfilled the criteria for completion, for whom there were no missing data for age, sex, ethnicity, deprivation, duration of diabetes, baseline HbA_{1c}, baseline BMI, provider, delivery method, or weight (at baseline). Where no weight was recorded at month 12, the last weight recorded before withdrawal from the programme was used.

Covariates

Demographic factors (age, sex, ethnicity, and socioeconomic status), clinical factors (duration of diabetes, baseline HbA_{1c}, and baseline BMI) and programme factors (provider and delivery method), all of which were provided by general practice at time of referral, were identified as potential outcome moderators. Sex was recorded as male, female, or indeterminate, as provided by general practice at time of referral. Age was grouped as 18 to <40, 40 to <50, or 50 to 65 years, and self-reported ethnicity as White, Asian, Black, Mixed, or Other. Socioeconomic status was measured using the Index of Multiple Deprivation quintiles associated with the Lower Super Output Area derived from participant home postcode.[17] The number of years since diabetes diagnosis was grouped into less than 1 year, 1 to <4 years, and 4 to 6 years. BMI was calculated from the weight and height submitted on referral and grouped into bands of 25 to <30, 30 to <40, and 40 or more kg/m^2. All variables also include an unknown category where either the person declined to provide the relevant information or a value was not recorded.

Statistical analysis

Multivariable regression models were used to assess whether changes in outcomes were associated with demographic, clinical, or programme factors (linear regression to assess percentage weight change and logistic regression to assess changes in programme uptake, completion of the programme, and remission at 12 months). We considered the causal relationships between each primary exposure (age, sex, ethnicity, deprivation, baseline referral HbA_{1c}, baseline BMI, duration of diabetes, programme provider, and delivery method) and outcome of interest, and differentiated potential confounding variables from potential mediating variables. For example, in assessing the association between ethnicity and the four outcomes of interest, we did not adjust for deprivation, as we considered it to be a plausible partial mediator on the causal pathway. A full description of all confounding variables and mediators for each primary exposure and outcome is in the appendix (pp 4–7). We ran regression models for each primary exposure and outcome of interest, first unadjusted to give crude results, and then adjusted for confounders to give adjusted results. We checked assumptions for linear and logistic regressions, including no multicollinearity, that residuals for linear regression were normally distributed, and that they were not heteroskedastic. We found the assumptions to be acceptable.

We undertook sensitivity analyses assessing different timings of the second HbA_{1c} measurement (month 12 to month 13, month 12 to month 14, month 12 to month 15, month 11 to month 13, and 21 days before to 21 days after month 12) in order to determine remission. We defined statistical significance as p value of less than 0·05 and set CIs at 95%. We analysed all data using Stata version 16. We rounded all data between 1 and 7 to 5, and all other figures to the nearest 5, to protect participant confidentiality.

Role of the funding source

There was no funding source for this study.

Results

Between Sept 1, 2020, and Dec 31, 2022, 7540 people with type 2 diabetes were referred to the NHS T2DR programme. Of those, 5115 (68%) attended an individual assessment and 4340 (58%) started TDR. Restricting to the 6115 people referred up to Sept 1, 2022, to give people sufficient time to have started the programme by Dec 31, 2022, 4585 (75%) attended an individual assessment and 4160 (68%) started TDR. Of the 1740 participants who started TDR before January, 2022, and therefore had a full 12-month opportunity to undertake the programme by time of data extraction at the end of December, 2022, 960 (55%) completed the 12-month programme (figure).

Characteristics of participants at each stage in the programme are shown in table 1. 3240 (43%) of the 7540 people referred were men; the mean age was 50 years

	Referrals (n=7540)	Attended individual assessment* (n=5115)	Started TDR (n=4340)	Undertook the programme† (n=1740)	Completed the programme‡ (n=960)
Age group, years					
18 to <40	1270 (17%)	910 (18%)	795 (18%)	315 (18%)	135 (14%)
40 to <50	2115 (28%)	1420 (28%)	1220 (28%)	500 (29%)	250 (26%)
50 to 65	4145 (55%)	2780 (54%)	2330 (54%)	925 (53%)	575 (60%)
Unknown	15 (<1%)	5 (<1%)	0	0	0
Sex					
Female	4295 (57%)	2965 (58%)	2525 (58%)	980 (56%)	540 (56%)
Male	3240 (43%)	2145 (42%)	1815 (42%)	760 (44%)	420 (44%)
Unknown	5 (<1%)	5 (<1%)	5 (<1%)	5 (<1%)	5 (1%)
Ethnic group					
Asian	1395 (19%)	860 (17%)	725 (17%)	280 (16%)	160 (17%)
Black	600 (8%)	405 (8%)	345 (8%)	115 (7%)	65 (7%)
Mixed	235 (3%)	195 (4%)	175 (4%)	70 (4%)	35 (4%)
Other	110 (1%)	60 (1%)	45 (1%)	20 (1%)	15 (2%)
White	4820 (64%)	3535 (69%)	3005 (69%)	1245 (72%)	680 (71%)
Unknown	385 (5%)	55 (1%)	45 (1%)	10 (1%)	5 (1%)
Deprivation quintile					
IMD 1 (most deprived)	1935 (26%)	1265 (25%)	1020 (24%)	370 (21%)	195 (20%)
IMD 2	1775 (24%)	1130 (22%)	960 (22%)	345 (20%)	185 (19%)
IMD 3	1495 (20%)	1035 (20%)	885 (20%)	345 (20%)	165 (17%)
IMD 4	1295 (17%)	915 (18%)	795 (18%)	345 (20%)	195 (20%)
IMD 5 (least deprived)	1040 (14%)	770 (15%)	680 (16%)	335 (19%)	215 (22%)
Unknown	5 (<1%)	0	0	0	0
Duration of diabetes, years					
<1	3575 (47%)	2380 (47%)	1980 (46%)	740 (43%)	405 (42%)
1 to <4	1855 (25%)	1265 (25%)	1090 (25%)	440 (25%)	240 (25%)
4 to 6	2085 (28%)	1470 (29%)	1270 (29%)	560 (32%)	315 (33%)
Unknown	30 (<1%)	0	0	0	0
Baseline BMI, kg/m²					
25 to <30	980 (13%)	560 (11%)	465 (11%)	170 (10%)	115 (12%)
30 to <40	3965 (53%)	2730 (53%)	2315 (53%)	935 (54%)	540 (56%)
≥40	2560 (34%)	1820 (36%)	1560 (36%)	630 (36%)	305 (32%)
Unknown	35 (<1%)	5 (<1%)	5 (<1%)	0	0
Baseline HbA_{1c}, mmol/mol					
43 to <53	2880 (38%)	1945 (38%)	1635 (38%)	610 (35%)	340 (35%)
53 to <64	2570 (34%)	1750 (34%)	1485 (34%)	600 (34%)	335 (35%)
64 to <75	1215 (16%)	855 (17%)	730 (17%)	310 (18%)	165 (17%)
75 to 87	855 (11%)	570 (11%)	490 (11%)	220 (13%)	120 (13%)
Unknown	25 (<1%)	5 (<1%)	0	0	0
Provider					
ABL	140 (2%)	90 (2%)	55 (1%)	0	0
Liva	100 (1%)	80 (2%)	35 (1%)	0	0
Momenta	1045 (14%)	850 (17%)	595 (14%)	190 (11%)	90 (9%)
Oviva	2170 (29%)	1600 (31%)	1455 (34%)	715 (41%)	370 (39%)
Reed	480 (6%)	400 (8%)	345 (8%)	190 (11%)	100 (10%)
Xyla	3605 (48%)	2095 (41%)	1855 (43%)	650 (37%)	405 (42%)

(Table 1 continues on next page)

	Referrals (n=7540)	Attended individual assessment* (n=5115)	Started TDR (n=4340)	Undertook the programme† (n=1740)	Completed the programme‡ (n=960)
(Continued from previous page)					
Delivery method					
Digital	2320 (31%)	1685 (33%)	1560 (36%)	820 (47%)	440 (46%)
In-person 1:1	1010 (13%)	565 (11%)	410 (9%)	0	0
In-person group	645 (9%)	395 (8%)	250 (6%)	0	0
Remote 1:1	605 (8%)	515 (10%)	490 (11%)	345 (20%)	190 (20%)
Remote group	2960 (39%)	1950 (38%)	1635 (38%)	570 (33%)	330 (34%)

Data are n (%). All numbers have been rounded to the nearest 5 to protect patient confidentiality. TDR=total diet replacement. IMD=Index of Multiple Deprivation. *Individuals referred to the programme are required to attend an individual assessment to verify eligibility, receive further details of the programme, determine whether they wish to continue, and, if they do, agree a TDR start date. †Individuals who started TDR before January, 2022, and therefore had a full 12-month opportunity to undertake the programme by time of data extraction on Dec 31, 2022. ‡Participants who had undertaken the programme and had a valid weight measurement within 21 days of month 12 (364 days) indicating that they were still participating in the programme at that time.

Table 1: **Participant characteristics at each stage of the programme**

(SD 10); and 4820 (64%) were of White ethnicity, 1395 (19%) Asian, 600 (8%) Black, 235 (3%) Mixed, and 110 (1%) Other. A higher proportion of people were referred from the most deprived quintile (1935 [26%]) compared with the least deprived quintile (1040 [14%]), and 3575 (47%) had been diagnosed with diabetes less than 1 year before referral. At referral, the mean weight was 109·2 kg (SD 24·8), the mean BMI was 38·0 kg/m² (7·8), and the mean HbA_{1c} was 58·5 mmol/mol (10·8). Higher HbA_{1c} was associated with greater duration of diabetes (appendix p 8). Of the 7540 people referred, 2585 (34%) were not taking glucose-lowering medication, 3760 (50%) were taking one glucose-lowering medication, and 1195 (16%) were taking two or more. The most common glucose-lowering medication taken at referral was metformin (4615 [61%]), followed by SGLT2 inhibitors (780 [10%]) and DPP4 inhibitors (355 [5%]; appendix p 9). Ethnicity data were missing for 385 (5%) participant records; for all other variables recorded at baseline, less than 1% of data were missing (table 1). For all those referred up to Sept 1, 2022, and who therefore had sufficient time to reach TDR by Dec 31, 2022, regression analyses indicated that younger people, those diagnosed with diabetes 4–6 years before referral, those of Mixed ethnicity, and those from less deprived backgrounds were more likely to start TDR, whereas men, older people, those with a BMI in the range 25 to <30 kg/m² (overweight), and those of Asian, Black, or Other ethnicity were less likely (appendix pp 10–11).

Univariate analyses of primary and secondary outcomes for those with no missing data who started TDR before January, 2022, and therefore had a full 12-month opportunity to undertake the programme by time of data extraction on Dec 31, 2022, are shown in tables 2 and 3 and the appendix (pp 12–15). Of the 1740 participants who started TDR before January, 2022, 1710 (98%) had no missing data. Of those, 1435 (84%) were active on programme at the end of the TDR phase (month 3), 1350 (79%) were still active at the end of the food reintroduction phase (month 5), and 945 (55%) completed the programme (appendix p 16). The mean time on the programme was 8 months (SD 4). Logistic regression analysis showed that, compared with those aged 40 to <50 years, participants aged 18 to <40 years were less likely to complete the programme, whereas participants aged 50 to 65 were more likely (appendix pp 17–18). Participants in the least deprived quintile were more likely to complete the programme than those in the most deprived quintile, and participants with a BMI of 40 kg/m² or higher were less likely to complete than those with a BMI of 30 to <40 kg/m², whereas those with a BMI of 25 to <30 kg/m² were more likely. There were statistically significant differences in completion rates by provider but no differences by delivery method, baseline HbA_{1c}, sex, duration of diabetes, or ethnicity.

For participants who started TDR before January, 2022, and had no missing data, the mean baseline weight was 110·1 kg with a mean weight change of –8·3% (95% CI –8·6 to –7·9) or –9·4 kg (–9·8 to –8·9); 590 (35%) participants lost 10% or more of their baseline weight and 270 (16%) lost 15% or more of their baseline weight (table 2). Weight loss increased with number of months of the programme attended until month 5 (the end of the food reintroduction phase), after which there were no significant changes (appendix p 19). Linear regression analysis showed that participants of Asian, Black, and Mixed ethnicities lost significantly lower percentages of their baseline weight compared with those of White ethnicity, and those with BMI of 40 kg/m² or higher lost significantly greater percentages of their baseline weight compared with those with BMI of 30 to <40 kg/m². There were differences in percentage weight change by provider and delivery method (appendix pp 20–21).

Remission status and HbA_{1c} change were assessed for a subgroup of 710 (42%) participants who had started TDR before January, 2022, and had two HbA_{1c} measurements recorded in the NDA at the applicable timepoints. Comparing the characteristics of those with two recorded HbA_{1c} measurements to those without, there were greater proportions of participants aged 50–65 years, women, and participants of White ethnicity, and a lower proportion of those referred within 1 year of diagnosis. However, proportions were broadly similar across deprivation quintiles, by baseline BMI and by baseline HbA1c (appendix p 22). The overall mean weight change in this subgroup was similar to that for the overall group who had started TDR before January, 2022 (–9·3 kg *vs* –9·4 kg; appendix p 23 and table 2).

Of these individuals who had two HbA_{1c} measurements recorded, 250 (35%) had both HbA_{1c} measurements less than 48 mmol/mol, with 190 (27%) meeting the definition of remission (both HbA_{1c} measurements <48 mmol/mol and no glucose-lowering medications prescribed from 3 months before the first HbA_{1c} measurement). Of the 60 participants with two HbA_{1c} measurements less than

	n	Mean baseline weight, kg	Mean percentage weight change, %	Mean weight change, kg	Number losing 10% of baseline weight	Number losing 15% of baseline weight
Total	1710	110·1	−8·3% (−8·6 to −7·9)	−9·4 (−9·8 to −8·9)	590 (35%)	270 (16%)
Age group, years						
18 to <40	310	114·9	−7·1% (−7·9 to −6·3)	−8·5 (−9·6 to −7·4)	85 (27%)	40 (13%)
40 to <50	485	111·9	−8·0% (−8·7 to −7·4)	−9·2 (−10·0 to −8·4)	165 (34%)	75 (15%)
50 to 65	915	107·6	−8·8% (−9·3 to −8·3)	−9·7 (−10·3 to −9·1)	340 (37%)	155 (17%)
Sex						
Female	965	104·8	−8·0% (−8·5 to −7·6)	−8·6 (−9·1 to −8·1)	320 (33%)	145 (15%)
Male	745	117·0	−8·6% (−9·1 to −8·1)	−10·3 (−11·0 to −9·6)	265 (36%)	125 (17%)
Ethnic group						
Asian	280	97·3	−6·3% (−7·1 to −5·5)	−6·2 (−7·1 to −5·4)	65 (23%)	25 (9%)
Black	110	106·5	−6·7% (−7·8 to −5·6)	−7·2 (−8·5 to −5·9)	25 (23%)	10 (9%)
Mixed	70	103·9	−6·8% (−8·0 to −5·6)	−7·1 (−8·5 to −5·8)	20 (29%)	5 (7%)
Other	20	99·6	−6·0% (−9·0 to −3·0)	−6·0 (−9·0 to −3·0)	5 (25%)	5 (25%)
White	1230	113·9	−9·0% (−9·4 to −8·6)	−10·4 (−11·0 to −9·9)	475 (39%)	225 (18%)
Deprivation quintile						
IMD 1 (most deprived)	365	112·5	−7·8% (−8·5 to −7·1)	−9·0 (−10·0 to −8·1)	115 (32%)	50 (14%)
IMD 2	340	110·7	−8·2% (−9·0 to −7·5)	−9·4 (−10·4 to −8·5)	115 (34%)	60 (18%)
IMD 3	335	110·3	−8·4% (−9·1 to −7·6)	−9·4 (−10·4 to −8·4)	120 (36%)	50 (15%)
IMD 4	335	108·5	−7·9% (−8·7 to −7·1)	−8·8 (−9·8 to −7·9)	110 (33%)	50 (15%)
IMD 5 (least deprived)	330	108·4	−9·1% (−10·0 to −8·3)	−10·1 (−11·2 to −9·1)	125 (38%)	60 (18%)
Duration of diabetes, years						
<1	725	112·5	−8·4% (−8·9 to −7·8)	−9·7 (−10·4 to −9·0)	255 (35%)	120 (17%)
1 to <4	435	111·9	−8·0% (−8·7 to −7·3)	−9·2 (−10·1 to −8·3)	145 (33%)	60 (14%)
4 to 6	545	105·6	−8·3% (−8·9 to −7·8)	−9·0 (−9·8 to −8·3)	190 (35%)	90 (17%)
Baseline BMI, kg/m²						
25 to <30	165	82·2	−7·6% (−8·6 to −6·6)	−6·3 (−7·2 to −5·5)	45 (27%)	20 (12%)
30 to <40	925	100·6	−7·9% (−8·4 to −7·5)	−8·1 (−8·6 to −7·6)	300 (32%)	125 (14%)
≥40	620	131·9	−8·9% (−9·6 to −8·3)	−12·0 (−12·9 to −11·1)	240 (39%)	125 (20%)
Baseline HbA_{1c}, mmol/mol						
43 to <53	600	108·6	−8·5% (−9·1 to −7·8)	−9·4 (−10·2 to −8·7)	215 (36%)	100 (17%)
53 to <64	590	110·9	−8·6% (−9·2 to −8·0)	−9·8 (−10·6 to −9·0)	210 (36%)	105 (18%)
64 to <75	305	109·6	−7·5% (−8·3 to −6·8)	−8·4 (−9·3 to −7·6)	95 (31%)	35 (11%)
75 to 87	215	113·2	−8·0% (−8·9 to −7·0)	−9·1 (−10·3 to −8·0)	70 (33%)	30 (14%)
Provider						
Momenta	185	106·5	−7·5% (−8·4 to −6·6)	−8·1 (−9·3 to −7·0)	60 (32%)	25 (14%)
Oviva	695	110·9	−8·7% (−9·3 to −8·1)	−9·8 (−10·5 to −9·1)	255 (37%)	125 (18%)
Reed	190	116·5	−9·7% (−10·7 to −8·8)	−11·7 (−12·9 to −10·4)	75 (39%)	35 (18%)
Xyla	640	108·4	−7·7% (−8·2 to −7·1)	−8·5 (−9·2 to −7·9)	200 (31%)	85 (13%)
Delivery method						
Digital	800	110·6	−8·5% (−9·0 to −7·9)	−9·6 (−10·3 to −8·9)	290 (36%)	140 (18%)
Remote 1:1	340	113·1	−9·0% (−9·7 to −8·3)	−10·5 (−11·4 to −9·6)	115 (34%)	60 (18%)
Remote group	565	107·6	−7·5% (−8·1 to −7·0)	−8·3 (−9·0 to −7·6)	185 (33%)	70 (12%)

Data are mean (95% CI) or n (%). All numbers have been rounded to the nearest 5 to protect participant confidentiality. Included individuals are those with no missing data who started total diet replacement before January, 2022, and therefore had a full 12-month opportunity to undertake the programme by time of data extraction on Dec 31, 2022. IMD=Index of Multiple Deprivation.

Table 2: **Mean weight change at 12 months—univariate analysis**

48 mmol/mol but not considered to have had remission, 50 (83%) remained on metformin, of whom 25 (50%) had an HbA_{1c} measurement less than 42 mmol/mol (appendix p 24). The distribution of the most recent HbA_{1c} measurement for those who had remission can be found in the appendix (p 25). Univariate analyses of those who had remission compared with those who did not are shown in the appendix (pp 26–27). Higher remission rates were associated with greater weight loss (appendix p 28). Logistic regression analysis showed that participants referred more than 1 year after diagnosis were less likely to have remission compared with those who were referred

	Undertook the programme*				Completed the programme†			
	Total	Participants with two HbA_{1c} tests	Participants with two HbA_{1c} tests <48 mmol/mol	Participants who had remission‡	Total	Participants with two HbA_{1c} tests	Participants with two HbA_{1c} tests <48 mmol/mol	Participants who had remission‡
Overall	1710	710 (42%)	250 (35%)	190 (27%)	945	450 (48%)	185 (41%)	145 (32%)
Age group, years								
18 to <40	310	110 (35%)	35 (32%)	25 (23%)	135	60 (44%)	20 (33%)	15 (25%)
40 to <50	485	180 (37%)	60 (33%)	50 (28%)	245	110 (45%)	45 (41%)	40 (36%)
50 to 65	915	415 (45%)	155 (37%)	115 (28%)	570	280 (49%)	120 (43%)	90 (32%)
Sex								
Female	965	420 (44%)	145 (35%)	110 (26%)	535	275 (51%)	105 (38%)	80 (29%)
Male	745	290 (39%)	105 (36%)	80 (28%)	410	180 (44%)	80 (44%)	65 (36%)
Ethnic group								
Asian	280	105 (38%)	30 (29%)	20 (19%)	155	70 (45%)	25 (36%)	15 (21%)
Black	110	40 (36%)	5 (13%)	5 (13%)	65	30 (46%)	5 (17%)	5 (17%)
Mixed	70	25 (36%)	10 (40%)	10 (40%)	35	15 (43%)	5 (33%)	5 (33%)
Other	20	5 (25%)	5 (100%)	5 (100%)	15	5 (33%)	5 (100%)	5 (100%)
White	1230	530 (43%)	200 (38%)	155 (29%)	675	335 (50%)	150 (45%)	120 (36%)
Deprivation quintile								
IMD 1 (most deprived)	365	145 (40%)	45 (31%)	30 (21%)	190	85 (45%)	35 (41%)	25 (29%)
IMD 2	340	140 (41%)	45 (32%)	35 (25%)	185	85 (46%)	30 (35%)	25 (29%)
IMD 3	335	150 (45%)	45 (30%)	35 (23%)	165	90 (55%)	35 (39%)	30 (33%)
IMD 4	335	155 (46%)	65 (42%)	45 (29%)	190	100 (53%)	45 (45%)	35 (35%)
IMD 5 (least deprived)	330	125 (38%)	55 (44%)	40 (32%)	215	95 (44%)	45 (47%)	35 (37%)
Duration of diabetes, years								
<1	725	275 (38%)	135 (49%)	105 (38%)	395	170 (43%)	95 (56%)	75 (44%)
1 to <4	435	185 (43%)	50 (27%)	40 (22%)	235	120 (51%)	40 (33%)	35 (29%)
4 to 6	545	250 (46%)	60 (24%)	45 (18%)	310	160 (52%)	50 (31%)	35 (22%)
Baseline BMI, kg/m^2								
25 to <30	165	70 (42%)	20 (29%)	20 (29%)	110	55 (50%)	20 (36%)	15 (27%)
30 to <40	925	390 (42%)	140 (36%)	110 (28%)	535	260 (49%)	110 (42%)	85 (33%)
≥40	620	250 (40%)	90 (36%)	65 (26%)	300	140 (47%)	60 (43%)	45 (32%)
Baseline HbA_{1c}, mmol/mol								
43 to <53	600	245 (41%)	135 (55%)	110 (45%)	340	160 (47%)	100 (63%)	85 (53%)
53 to <64	590	240 (41%)	80 (33%)	60 (25%)	330	145 (44%)	60 (41%)	45 (31%)
64 to <75	305	135 (44%)	20 (15%)	10 (7%)	160	85 (53%)	20 (24%)	10 (12%)
75 to 87	215	90 (42%)	15 (17%)	10 (11%)	115	60 (52%)	10 (17%)	5 (8%)
Provider								
Momenta	185	55 (30%)	20 (36%)	15 (27%)	85	30 (35%)	10 (33%)	10 (33%)
Oviva	695	335 (48%)	130 (39%)	100 (30%)	360	215 (60%)	105 (49%)	80 (37%)
Reed	190	80 (42%)	25 (31%)	25 (31%)	100	45 (45%)	20 (44%)	20 (44%)
Xyla	640	235 (37%)	75 (32%)	50 (21%)	400	160 (40%)	55 (34%)	35 (22%)
Delivery method								
Digital	800	365 (46%)	140 (38%)	110 (30%)	430	240 (56%)	110 (46%)	85 (35%)
Remote 1:1	340	140 (41%)	45 (32%)	40 (29%)	190	80 (42%)	30 (38%)	30 (38%)
Remote group	565	205 (36%)	65 (32%)	45 (22%)	325	130 (40%)	45 (35%)	30 (23%)

Data are n or n (%). All numbers have been rounded to the nearest 5 to protect participant confidentiality. IMD=Index of Multiple Deprivation. *Individuals who started total diet replacement before January, 2022, and therefore had a full 12-month opportunity to undertake the programme by time of data extraction on Dec 31, 2022. †Participants who had undertaken the programme and had a valid weight measurement within 21 days of month 12 (364 days) indicating that they were still participating in the programme at that time. ‡Remission of type 2 diabetes at 12 months was defined as two HbA_{1c} measurements of less than 48 mmol/mol recorded at least 3 months apart, with no glucose-lowering medications prescribed from 3 months before the first HbA_{1c} measurement, and the second HbA_{1c} measurement recorded 11–15 months after the programme start.

Table 3: **Remission rates at 12 months for participants with two HbA_{1c} tests recorded**

within 1 year of diagnosis, and that those with lower baseline HbA_{1c} were more likely to have remission compared with those with higher baseline HbA_{1c}. There were differences in remission by provider and delivery method (appendix pp 29–30). Of those who had remission, the mean change in HbA_{1c} was –12·0 mmol/mol (95% CI –13·4 to –10·7; appendix p 31) and the mean weight change was –13·4% (–14·5 to –12·3) or –14·8 kg (–16·3 to –13·4; appendix p 32), with 130 (68%) of participants losing 10% or more of their baseline weight and 75 (39%) losing 15% or more of their baseline weight.

For the 945 participants who completed the programme with no missing data, the mean baseline weight was 107·1 kg with a mean weight change of –9·3% (95% CI –9·8 to –8·8) or –10·3 kg (–10·9 to –9·7); 395 (42%) lost 10% or more of their baseline weight and 190 (20%) lost 15% or more of their baseline weight (appendix pp 12–13). 450 (48%) participants had two HbA_{1c} measurements recorded, with 185 (41%) having both measurements less than 48 mmol/mol and 145 (32%) meeting the definition of remission (table 3). Of those who had remission, the mean change in HbA_{1c} was –12·6 mmol/mol (–14·2 to –11·1; appendix p 31) with a mean weight change of –14·4% (–15·5 to –13·2) or –15·9 kg (–17·4 to –14·3; appendix p 32); 110 (76%) of participants lost 10% or more of their baseline weight and 65 (45%) lost 15% or more of their baseline weight.

Sensitivity analyses showed no substantive changes in the percentage of participants who had remission (appendix p 33).

Discussion

Our findings show that the mean weight loss for those who undertook the NHS T2DR programme, whether or not they completed it, was 8·3% or 9·4 kg, increasing to 9·3% or 10·3 kg for the subgroup who completed the programme. For those with two HbA_{1c} measurements recorded at the applicable timepoints, 27% of participants who undertook the programme and 32% of the subgroup who completed the programme had remission of type 2 diabetes at 12 months, showing that people with type 2 diabetes can reach remission with this approach outside of research settings. For participants who had remission, mean weight losses were 13·4% or 14·8 kg for those who undertook the programme and 14·4% or 15·9 kg for the subgroup who completed it. The likelihood of reaching remission was greater for those with greater weight loss, those within 1 year of diagnosis, and those with lower baseline HbA_{1c} values.

The weight loss recorded by the NHS T2DR programme is similar to that reported in a systematic review of randomised controlled trials using very low-energy diets for the management of weight loss,[18] which found a mean weight loss of 10·3 kg at 12 months. The DiRECT trial[4] reported a mean weight loss of 10·0 kg in the intervention group at 12 months, and the Diabetes Intervention Accentuating Diet and Enhancing Metabolism (DIADEM-I) trial[19] reported a mean weight loss of 12·0 kg in the intervention group at 12 months. In the DROPLET trial,[5] a similar intervention in a population of people living with obesity, mean weight loss at 12 months was 10·7 kg; 45% of participants in the intervention group lost 10% or more of their baseline weight and 22% lost 15% or more of their baseline weight at 12 months. A randomised controlled trial of intermittent fasting in China[20] reported a mean weight loss of 5·9 kg in the intervention group at 12 months, which was 9% of the baseline weight.

The primary aim of the T2DR programme is diabetes remission. However, for people living with excess weight, any weight loss is likely to be beneficial and to reduce cardiometabolic risk factors. In addition, the 5-year data from DiRECT[21] reported 47% fewer serious adverse events in the weight loss group than in the control group managed according to usual care guidelines, driven mainly by a decrease in number of infections of all types and fewer new cancer diagnoses. In the Look AHEAD study,[22] participants with evidence of remission had a 33% lower rate of chronic kidney disease and 40% lower rate of cardiovascular disease at 12 years.

In the DiRECT trial,[4,23] diabetes remission was seen in 46% of participants at 12 months and 36% at 24 months, whereas in the DIADEM-I trial,[19] diabetes remission was reached in 61% of participants in the intervention group. The randomised controlled trial of intermittent fasting in China[20] showed diabetes remission in 44% of participants in the intervention group. Remission rates on the NHS T2DR programme were somewhat lower than those seen in the randomised controlled trials. This might reflect the context of the real-world delivery compared with that of a clinical trial, with a more diverse population group and different baseline characteristics. Notably, 17% of participants who undertook the programme with two HbA_{1c} measurements less than 48 mmol/mol were not considered to have reached remission as they remained on metformin, and half of these participants had an HbA_{1c} measurement less than 42 mmol/mol. It is likely that some of these participants would have satisfied the definition of remission had they not been prescribed metformin, and this might have contributed to the lower rate of remission observed compared with the clinical trials. Although we did not collect data concerning the reasons for ongoing prescription of glucose-lowering medication in those with HbA_{1c} measurements well below 48 mmol/mol, they might include reluctance among health-care professionals and people with diabetes to discontinue medication, and the potential benefits of ongoing medication use taking clinical priority over the potential for formal recognition of remission. However, it is also possible that the weight loss calculated for those who withdrew from the programme was an overestimate because the last weight recorded before withdrawal was used. It is possible that these individuals could have experienced reduced weight loss or even weight gain after the discontinuation of weight

maintenance support. This might explain the lower remission rate observed compared with the clinical trials.

Of those who started the programme, 960 (55%) completed it. However, this figure does not take into account those who were referred to the programme and never started TDR. It also does not take into account those who were offered the programme in general practices but declined the referral. The programme and intervention, therefore, are clearly not acceptable to everybody and must be considered as just one treatment pathway in a portfolio of potential options for weight loss, including other dietary strategies, pharmacotherapy, and bariatric surgery. Of those who started TDR, 84% completed the main interventional element of the programme (the 3-month TDR phase), with a further 30% of these withdrawing before the end of the 12 months. Work from the NIHR-commissioned independent qualitative evaluation of the programme has suggested a variety of reasons for participants' early withdrawal, including psychological reasons, multiple life events, living with severe depression, and other health issues.[24] Participant feedback gathered by the independent evaluation has also highlighted that programme support might have been overly tailored to Western diets and cultural norms.[25] Our own study also showed statistically significant differences in outcomes by provider and delivery method. However, overall uptake and completion rates were similar to those seen in other large-scale NHS lifestyle intervention programmes.[26]

Weight loss in the T2DR programme was statistically significantly lower in participants of Asian and Black ethnicities compared with those of White ethnicity, although we were unable to establish a statistically significant difference in remission rates. The STANDby[27] trial assessed the effect of TDR in people with type 2 diabetes of South Asian ethnicity and reported a considerably lower mean absolute weight loss of 7·2 kg or 7·7% of baseline bodyweight, with the remission rate similar to that seen in DiRECT at 38%.

Although individuals from more deprived areas were more likely to be referred into the programme, their completion rates were lower; however, we were unable to establish statistically significant differences in their weight loss or remission rates. Indeed, lower completion rates have been, and remain, features of those from more deprived areas participating in the NHS Diabetes Prevention Programme.[26]

A previous study[28] found that people with type 2 diabetes formally recorded with a diagnostic code of remission in the NDA were less likely to receive diabetes care processes compared with those without such coding. This suggests that recognition of remission of type 2 diabetes affects the likelihood of being offered, or accepting, routine monitoring, despite a high risk of redeveloping hyperglycaemia. Given that a notable proportion of participants in the NHS T2DR programme appear to be reaching remission, there is an onus on policy makers, local health-care economies, service providers, and health-care professionals to support ongoing provision of monitoring and avoid any unintended adverse consequences associated with remission. To this end, guidance for general practices referring to the T2DR programme states that ongoing review and monitoring should be offered to those reaching remission in line with usual care for people with type 2 diabetes.

A major strength of this study is its size, including data on the largest group of people referred to a diabetes remission programme to date. There are also, however, some limitations. The study uses observational data with no control group. For those on remote and digital deliveries, weights were self-reported and there is a tendency for weights to be underreported by this method.[29,30] We were only able to calculate remission for 42% of participants who undertook the programme using HbA_{1c} measurements and prescribing data from the NDA. It is possible that these individuals constitute a sample in which some bias is present, particularly due to the lower proportions of people with a shorter duration of diabetes. The lower limit of BMI reflected that of the evidence base at outset, and recent data show 70% remission at 1 year from intervention in a group with BMI 21–27 kg/m².[31] It should also be acknowledged that for policy makers to make informed decisions around interventional clinical and cost effectiveness, effect on population health, affordability, and value for health systems and the populations that they serve, they need some indication as to the effectiveness of interventions when implemented in the real world. It is well recognised that effect sizes can be attenuated when pragmatic interventional implementation within the real world is compared with interventional testing in randomised controlled trial settings. Similarly, it is also inevitable that ascertainment of data will be poorer.[32]

To conclude, we report that, of participants who undertook the NHS T2DR programme and had two HbA_{1c} measurements available at the applicable timepoints, 27% had remission with a mean HbA_{1c} change of –12·0 mmol/mol and mean weight change of –13·4% or –14·8 kg, showing that remission is possible outside of research settings through at-scale delivery, although the rate of remission is less than those reported in randomised controlled trial settings. The evolution of the programme is iterative, and the results of these analyses have informed a new programme specification[9] now available across the whole of England. Future analyses will continue to monitor remission rates in addition to mortality and complication rates.

Contributors

JV, CB, RT, and SJ conceived the study. TG, EB, FE, and SS managed the data and carried out the statistical analysis. TG accessed and verified the data. All authors collaborated in interpretation of the results and drafting of the manuscript. TG, EB, FE, SS, and JV had full access to the data in the study. JV had final responsibility for the decision to submit for publication.

Declaration of interests

JV reports being the National Clinical Director for Diabetes and Obesity at NHS England from April, 2013, to September, 2023. EB and JV report

funding from CW+, the official charity of Chelsea and Westminster Hospital NHS Foundation Trust. CB reports being an adviser to the NHS Diabetes Programme. RT reports funding for educational lectures by Novo Nordisk, Janssen, and Novartis; and being an advisor to Fast800. SJ and PA report donation of total diet replacement products by Nestlé to support NHS treatment in a separate trial of total diet replacement for treating non-alcoholic fatty disease. LE reports funding from NIHR and the UK Medical Research Council; and being part of the ACTION Teens authorship and HOT trial in Denmark. JW reports consultancy or advisory board work contracted via the University of Liverpool (no personal payment) for Altimmune, AstraZeneca, Boehringer Ingelheim, Cytoki, Lilly, Napp, Novo Nordisk, Menarini, Pfizer, Rhythm Pharmaceuticals, Sanofi, Saniona, Tern, Shionogi, and YSOPIA; research grants for clinical trials from AstraZeneca and Novo Nordisk; personal honoraria or lecture fees from AstraZeneca, Boehringer Ingelheim, Medscape, Napp, Novo Nordisk, and Rhythm Pharmaceuticals; being former president of the World Obesity Federation; membership of the Association for the Study of Obesity, Diabetes UK, the European Association for the Study of Diabetes, the American Diabetes Association, the Society for Endocrinology, and the Rank Prize Funds Nutrition Committee; and being national lead for the Metabolic and Endocrine Speciality Group of the UK NIHR Clinical Research Network. All other authors declare no competing interests.

Data sharing

Data from the National Diabetes Audit can be requested through the NHS England Data Access Request Service process at https://digital.nhs.uk/services/data-access-request-service-dars.

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