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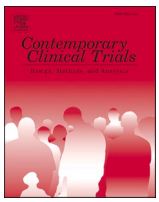

Testing a New Diabetes Adaptive Weight management Network (NewDAWN): A protocol for a randomised controlled trial☆

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ABSTRACT

Background: The NHS Path to Remission (PtR) offers a total diet replacement (TDR) programme to help people newly-diagnosed with type 2 diabetes (T2D) lose weight. It is very effective for people who participate, but most eligible people do not take part.

Aim: To assess whether offering a range of weight loss programmes can increase uptake of, and persistence with, weight loss and lead to a higher proportion of the population achieving remission of T2D compared with offering PtR only.

Method: 1788 people diagnosed with T2D in the last six years, who are willing to try to lose weight to achieve remission, will be recruited via GP practices and randomised to the NewDAWN service or PtR. Outcomes (weight, height, HbA1c, medications, BP, CVD risk score, PAID, EQ-5D, healthcare resource use) will be assessed at baseline and 12 months, with diabetes remission at 12 months as the primary outcome. An internal pilot assessment will follow 150 participants for 16 weeks to determine whether to progress using pre-specified criteria based on fidelity of programme delivery, adherence to the programme and change in weight. The decision will be reviewed by an external programme steering committee who will also advise on any other considerations they deem material to the likely successful completion of the full trial. A process evaluation will assess fidelity of delivery and collect both staff and participant feedback on the NewDAWN service to improve the effectiveness of implementation. The costs of NewDAWN and lifetime cost-effectiveness of the service will also be determined.

ISRCTN Registration: 11090437

1. Background

Research shows that for people with overweight, type 2 diabetes (T2D) can be put into remission with intensive weight loss [1]. A total diet replacement programme (TDR) is the most effective dietary intervention known to achieve remission. In the DiRECT trial, 149 people recently diagnosed with T2D who lost 10 kg on average had almost a 50 % chance of remission [2]. The NHS offers this programme ("Path to Remission" (PtR)) to eligible patients recently diagnosed with T2D. It is the only programme available within the NHS with the explicit goal of achieving remission. Although early evidence of effectiveness is promising, only a minority of eligible patients commence the programme [2].

☆ In April 2025, this trial was terminated because it was not possible to recruit patients at an acceptable rate. The barriers faced were: trial eligibility criteria, workforce capacity and capability, 'competition' with the established PtR pathway, changes in NHS structures and complex lines of responsibility and decision-making, which, in combination proved insurmoutable. It was also difficult to make full use of nationally available weight-loss programmes because of complex referral pathways. A full report will be available in the NIHR Library.

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Emerging data also suggests people from minority ethnic groups, and areas of higher deprivation may be less likely to take up the offer of remission, and lose less weight on the PtR programme compared to people of White ethnicity and from areas of lower deprivation [3].

The DiRECT trial showed that weight loss was the only meaningful predictor of remission. Consequently, any programme that achieves successful weight loss is likely to increase remission rates if offered to people with T2D. Many people perceive that offering a choice of weight loss programmes would enable patients to select a treatment likely to be effective for them. However, a systematic review found that choice per se did not lead to greater weight loss [4].

NewDAWN, a New Diabetes Adaptive Weight management Network, is a complex intervention in which participants are offered the opportunity to try several weight loss programmes (including PtR) sequentially through supported self-experimentation, to identify which may be most suitable for them. It is grounded in evidence that people are more willing to attempt a new weight loss method for a defined period ahead of review, rather than feel they are committing indefinitely [5], and qualitative research suggests that people find weight-loss interventions more acceptable than they imagine prior to participation [6,7]. Therefore, offering people a short "trial" may encourage more people to take up the offer of weight loss programmes.

In addition, empirical evidence suggests that people frame their ability to lose weight or make other behavioural changes as a matter of willpower [8,9]. Theory suggests that the failure of an attempt to lose weight may be seen as a catastrophic collapse of willpower and undermine subsequent attempts to re-engage in weight loss. Reframing "I failed to lose weight" (perceived as a failure of willpower) to "a treatment failure" (the treatment wasn't right for me) may support continued motivation to engage in subsequent weight-loss attempts [10].

We hypothesise that by offering a range of alternative treatment approaches, we can (i) increase the proportion of patients who are willing to initiate any weight loss attempt, (ii) retain people for whom PtR is unacceptable or unsuitable by offering an alternative programme and (iii) increase rates of remission from type 2 diabetes.

2. Aim

To test in a randomised controlled trial, whether a programme that supports people to experiment with a sequence of weight loss programmes aimed at T2D remission is more successful than the current best care offered in the PtR programme (Table 1).

3. Methods

3.1. Design and setting

The study will take place in general practices in the UK. It is a randomised, two-arm parallel-group, open-label, superiority trial (Flowchart 1). We will conduct an internal pilot assessment of the first 150 participants at 16 weeks (Table 1) to assess whether the intervention can be delivered as planned, increases uptake of referral to a diabetes remission programme (whether PtR in the control group, or any of the four programmes available on NewDAWN), supports more people to remain in a remission programme, and achieve greater weight loss at 16 weeks than the control. If it meets pre-specified progression criteria, and if an independent steering committee and funding body agree that the trial has a reasonable chance of successful completion, we will continue the trial with T2D remission at 1 year as the primary outcome (Table 1).

3.2. Patient and public involvement (PPI)

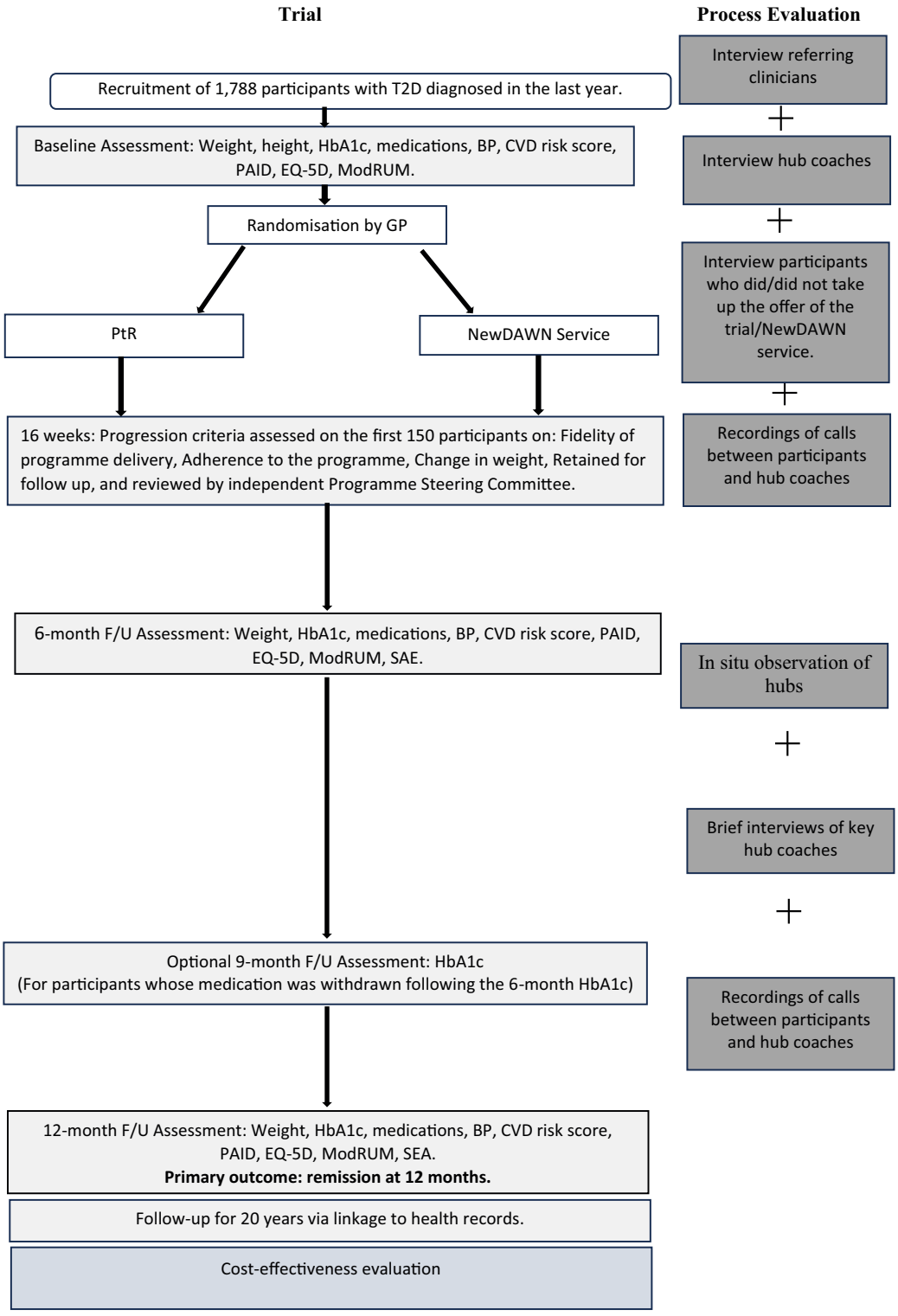
The trial has adhered to the principles of INCLUDE guidance throughout the design process to support recruitment of under-represented populations including those from ethnic minorities, across the socioeconomic spectrum and those with lower health literacy to ensure the findings will be generalizable. INCLUDE is a framework from the National Institute for Health and Care Research (NIHR) to improve inclusion of under-served groups in clinical research [11]. The NewDAWN service was designed following extensive development work including qualitative interviews with a purposive and diverse group of people living with T2D, and a discrete choice experiment (DCE) to understand factors affecting uptake of weight management programmes [12]. People living with T2D shaped the interview questions, and the DCE. One of the co-investigators on the NewDAWN team is an expert by experience, and conducted qualitative interviews and analysis. A Patient Advisory Group (PAG) comprising 10 individuals with T2D will meet every 6 months to assess progress, including recruitment, data collection and results, and feedback on the study. Our patient co-applicant co-leads this group with NG.

Table 1
Outcome measures for the NewDAWN trial.

Internal Pilot Only		
Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure
To assess the potential for a successful definitive trial of the NewDAWN intervention	Progression criteria traffic light system on the first 150 participants. Criteria including: Fidelity of programme delivery Adherence to the programme* Change in weight Retained for follow up	16 weeks after randomisation; reviewed by independent Programme Steering Committee

Main Trial		
Primary objective	Outcome measures	Timepoint(s) of evaluation of this outcome measure
To determine the rate of type 2 diabetes remission for people with newly diagnosed T2D who are overweight in the NewDAWN service compared with the current NHS standard care (PtR)	Type 2 diabetes remission, defined as HbA1c < 48 mmol/mol for at least 3 months while off diabetes medication.	12 months after randomisation
Secondary objectives		
To compare the effect of the NewDAWN service vs NHS standard care on weight	Weight change in participants from baseline	12 months after randomisation
To compare the effect of the NewDAWN service vs NHS standard care on glycaemic control	Change in concentration of HbA1c in blood samples from participants from baseline	12 months after randomisation
To compare the effect of the NewDAWN service vs NHS standard care on lipid profile	Change in lipid profile (Ratio of total cholesterol/ HDL) in blood samples from participants from baseline	12 months after randomisation
To compare the effect of the NewDAWN service vs NHS standard care on cardiometabolic risk	Change in QRISK2 score or SMART score obtained from participants from baseline	12 months after randomisation
To compare the effect of the NewDAWN service vs NHS standard care on blood pressure	Change in systolic and diastolic blood pressure in participants from baseline	12 months after randomisation
To compare the effect of the NewDAWN service vs NHS standard care on quality of life	Change in Problem areas in diabetes (PAID) score and EQ-5D 5 L score from baseline	12 months after randomisation

* "Programme" means PtR in the control group or on any of the four available weight loss programmes within the NewDAWN service.



Flowchart 1. Overview of clinical trial including process and cost-effectiveness evaluation.

3.3. Participant flow

3.3.1. Recruitment

The study will recruit GP practices via National Institute for Health Research (NIHR) supported Clinical Research Networks (CRN) (or equivalent bodies in the devolved nations) in the UK. We will ask CRNs (or equivalent) to prioritise recruitment of practices in areas of higher deprivation and with a greater proportion of people from minority ethnic groups. Throughout recruitment, the study team will track data on the ethnicity of enrolling participants and IMD data for practices who agree to recruit, using guidance from Diabetes UK [13].

We will enrol adults with T2D diagnosed in the last six years, who meet the ethnicity-specific BMI cut-offs and who may benefit from achieving remission. The inclusion and exclusion criteria are as follows:

Inclusion criteria

- Participant is willing and able to give informed consent for participation in the study
- Adults (aged 18 to 65 years) with type 2 diabetes diagnosed in the past six years
- A BMI of at least 25 kg/m2 (or 27 kg/m2 where individuals are from White ethnic groups) and who may benefit from achieving remission.
- For patients on diabetes medication, current HbA1c ≥43 mmol/mol, if not on diabetes medication, current HbA1c ≥ 48 mmol/mol
- Able to attend baseline visits, adhere to intervention and follow-up appointments
- Participant is registered at a GP practice that is open for recruitment
- Participant is willing to be randomised to either treatment option

Exclusion criteria

- Currently diagnosed with type 2 diabetes but who are in remission
- People currently following the Path to Remission programme, or who have previously followed this programme
- Currently using insulin injections
- GLP1-agonists or SGLT2 inhibitors started in the 3 months prior to study enrolment
- Currently taking an SGLT2 inhibitor for an indication other than type 2 diabetes
- Diagnosed with a known eating disorder for whom the programme could be unsafe or require extensive monitoring to ensure safety
- People who are pregnant or planning pregnancy
- People who are breastfeeding
- Diagnosed with a recent myocardial infarction or stroke in the past six months, uncontrolled cardiac conduction abnormalities e.g. long QT syndrome
- Diagnosed with maculopathy or proliferative retinopathy
- Severe liver impairment, severe renal impairment (eGRF <30) or porphyria
- People with HbA1c ≥ 87 mmol/mol
- Current substance misuse disorder
- Has had or is awaiting bariatric surgery
- People with significant life-limiting illnesses that mean that remission is unlikely to improve health (severe cardiac failure, palliatively treated cancer, dementia), other current severe illness or planned major surgery that means that following a weight loss programme would not be possible.
- People taking part in other research that would compromise either their participation in NewDAWN or the other research study/ies that they are participating in.
- Living in the same household as a NewDAWN participant
- Has read the protocol or trial registration document

GP practice staff will invite potentially eligible patients by letter, text message, or phone call to attend a recruitment appointment. The letter will be accompanied by the participant information sheet (PIS). This appointment may be at their usual GP practice with a member of practice staff or via telephone call with either practice staff or a member of the research team, depending on patient and practice preference. This recruitment appointment aims to recruit trial participants by discussing the nature of the trial and presenting the benefits of remission. Recruiting staff (and the PIS) will not reveal the two interventions to participants, only that they are both weight loss programmes. The aim is to enrol participants who are willing to consider support for weight loss. The trial will succeed in meeting its goals of achieving greater population remission rates if the population enrolled are not confined to those committed to trying a TDR, which would be the case if the nature of the weight loss support was discussed plainly. People keen to take part will be invited to be consented at the practice, and eligibility will be confirmed.

3.3.2. Baseline assessment

At baseline assessment (which could immediately follow the consent meeting or occur later) participants' weight, height, and blood pressure will be recorded. Participants will be asked to complete the PAID [14] and EQ-5D [15] questionnaires electronically and a blood sample will be taken for measurement of HbA1c, lipid profile, and - in people with established cardiovascular disease – C-reactive protein (CRP) to allow calculation of risk of future cardiovascular events [16]. At this appointment, participants will complete the ModRUM questionnaire [17] and a health resource use questionnaire to measure healthcare usage.

All participants in the pilot intervention will be sent a set of scales at the baseline visit if they do not have any.

3.3.3. Randomisation

Eligible participants that complete the baseline assessment will be individually randomised, by the GP practice or a member of the research team, on a 1:1 basis to referral to either the PtR programme or to the NewDAWN service. We will randomise using a permuted blocks algorithm with varying block size, stratified by general practice. Randomisation will be carried out using a web-based validated, secure randomisation system, Sortition, developed by the Oxford Primary Care Clinical Trials Unit.

3.3.4. Blinding

This is an open-label study in which participants, clinicians, and trial staff will know the allocation of the participant. We consider the risk of bias to be low and the trial statistician(s) will remain blinded to treatment allocation when performing the final analysis.

3.3.5. Description of study intervention: NewDAWN service

Participants randomised to the intervention arm will be referred by the GP practice to the NewDAWN service. The service is delivered via "hubs" which are staffed by trained health coaches. The hub coaches will discuss the concept of self-experimentation, and finding the programme that works for them through this process (Schematic 1). Participants who agree to start the NewDAWN service will be able to try up to four weight loss programmes (Table 2). They will be encouraged to try the programmes in order of average effectiveness for weight loss (Schematic 1). They will be offered each programme for an initial two-week period, after which the hub coach will contact them in a pre-arranged call to review their progress. If the programme is working, they will stay on the programme, and the coach will contact them at four-weekly intervals up to 3 times. If the programme is not working, the participant will be able to try the next most effective programme, again for a two-week trial period, after which the follow-up schedule remains the same. Participants can switch to a new programme at any follow-up call, except the final 4-week follow-up. The decision on whether the programme is working or not will be made using the "Continue or switch" protocol (supplementary data).

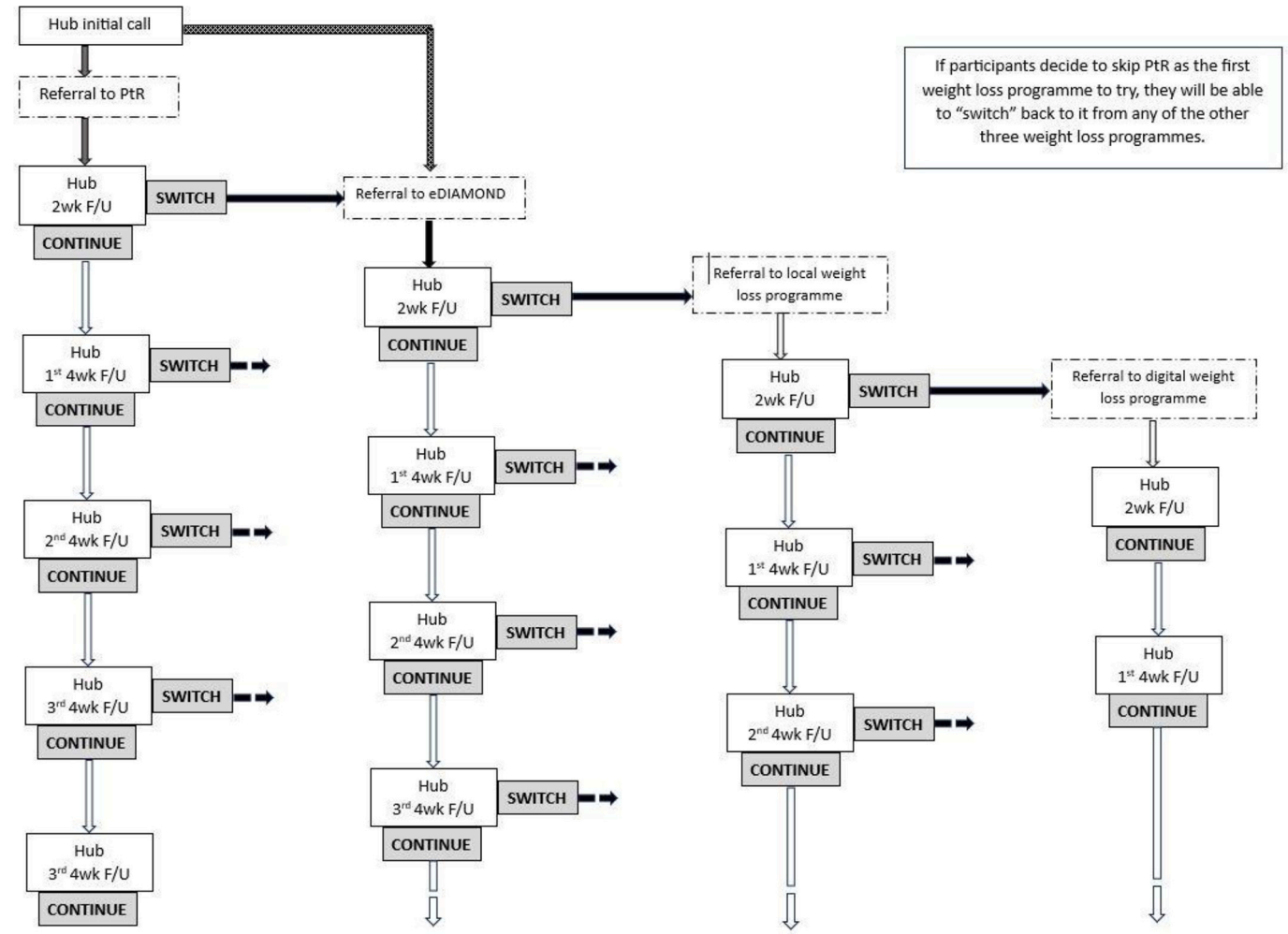
If participants decline PtR initially, they will be allowed to switch back 'up' to PtR after trying one or more of the other weight loss programmes. Participants will be allowed to switch up to three times. After this, they will be encouraged to stay on their current programme. Participants will not be re-referred to a programme they have previously tried as part of NewDAWN.

With data collected during the process of evaluation, the 'Continue or Switch' protocol will be reviewed throughout the pilot and on progression to the main trial.

Participants in the intervention arm that do not have scales at home will be sent a set by the research team to self-monitor their weight. Participants will be asked to weigh themselves weekly, including on the day of their follow-up call.

3.3.6. Hub coach training and aide-memoire

The NewDAWN hub coaches are generalist health coaches who have



Schematic 1. A schematic of the NewDAWN service. Participants will be able to try up to 4 weight loss programmes. They will receive follow-up calls with the hub coach approximately 2 weeks after beginning a weight loss programme, and then 3 × 4-weekly follow-ups if they continue with the programme. They will have the opportunity to switch to the next programme up to and including the second 4-week follow-up. If participants switch programmes, the follow-up schedule (a 2-weekly follow-up and then 3 × 4-weekly follow-ups) begins again.
Key:

All participants will be encouraged to try PtR as the first programme in the service. However, if participants are adamant they do not want to try it, they will be referred to DIAMOND as the first programme. Participants who "skip" PtR as the first programme will be able to switch to PtR at any F/U in the service.

If participants are meeting their weight loss target, and are willing/keen to continue, they will continue with their current programme, and continue to receive 3 x 4 weekly calls.

If participants are not meeting their weight loss target, and/or are not willing/keen to continue, they will switch to the next programme in the service.

a level 3 qualification in health improvement/nutrition or similar, and have received additional training in behaviour change from Reed Wellbeing. They will also receive a half-day training session on 1) T2D and remission 2) weight loss management principles and 3) specific behavioural techniques [5] to encourage engagement and persistence with weight loss attempts. To guide the delivery of hub coach support, we developed an aide-memoire to highlight key behavioural techniques and phrases based on the extant literature [24,25] and our pre-pilot qualitative work and with input from our patient expert.

3.3.7. Diabetes and blood pressure medications

Prior to referral to the NewDAWN service, participants will undergo a medication review by a prescribing clinician at their practice, focussing on any medications for diabetes or blood pressure. If medications changes are required, the clinician will discuss potential changes with the participant.

For the weight loss programmes that recommend <1000 kcal per day (PtR and DIAMOND) we will follow the standard NHS England protocol [26] for diabetes and blood pressure medication withdrawal, namely stopping all medications used to control glycaemia (for people taking 1 or 2 medications) and stopping one blood pressure medication (for participants whose blood pressure is well controlled at baseline) on day 1 of the diet. Further adjustments can be made as necessary at the 6-month follow-up visit or if self-monitoring data or symptoms prompts them to seek a GP review. If a participant stops the diet before the end of the programme, they will be advised to resume all previous diabetes and

Table 2
The four weight loss programmes on offer in NewDAWN. Participants will be encouraged to try the programmes in order of weight loss effectiveness observed in the literature.

Order	Programme		Mean weight loss based on literature	Expected/ Typical Key Features
1	Path to Remission*	Total diet replacement (TDR), approximately 800 kcal for 12 weeks, with food reintroduction up to one year.	10 kg [2,18]	Marked energy restriction. Meal replacement, 1:1 intervention, can be digital or face-to-face.
2	DIAMOND**	A low energy (850 kcal), low-carbohydrate diet for 12 weeks, followed by low-carbohydrate weight maintenance diet support up to 20 weeks.	10 kg [19]	Marked energy restriction. Low-carbohydrate diet, 1:1 digital intervention.
3	Commercial or local authority programme***	Structured programme, typically 12 weeks, focussed on energy reduction and increasing physical activity.	4-5 kg [20,21]	Moderate energy-restriction. Group-based, can be digital or face-to-face.
4	Locally available programme, potentially on a digital platform ***	Range of options including referrals to leisure centres, locally available programmes or to NHS web-based resources	2-3 kg [22,23]	Moderate energy restriction

* PtR will be delivered by a provider contracted by the NHS (where available) or by a provider contracted by the research team for the duration of the study.
** DIAMOND will be delivered by a provider contracted by the research team for the duration of the study.
*** The third and fourth programmes may differ depending on which integrated care system (ICS) participants are recruited from as local services vary.

blood pressure medications. A member of the GP practice staff will advise participants on the medication changes. When programmes are agreed between the coach and participant, the coach will inform the participant that they may need to adjust their medication following an agreed plan with their GP, and this will be reinforced on enrolment into the weight loss programme by the coaches.

For less intensive programmes where the energy intake is >1000 kcal and/or weight loss based on published data is expected to be an average of <1 kg per week, we will follow principles in line with NICE guidance (NG28) [27] for medication adjustment. If a participant has suboptimal glucose control (HbA1c of ≥58 mmol/mol (7.5 %)) they will be advised to stay on their diabetes medications until their 6-month follow-up visit unless self-monitoring data or symptoms prompts them to seek a GP review. If they have good glucose control of HbA1c < 58 mmol/mol (7.5 %) they will be advised to remove diabetes medications that increase the risk of hypoglycaemia (e.g., sulphonylureas) and stay on their other diabetes medications until their 6-month follow-up unless self-monitoring data or symptoms prompts GP review. Likewise, participants will be advised to continue their blood pressure medications until their next review.

3.4. Description of comparator: usual care arm (NHS PtR programme)

Patients randomised to the Path to Remission (PtR) programme will be referred by the practice to either the current NHS PtR pathway (where this programme is available) or PtR delivered by a provider contracted by the research team for the duration of the study. In each case, the provider will explain the programme and the participant will choose whether to enrol. This is the current 'best care' for people newly diagnosed with T2D.

This programme has a 12-week intensive weight loss phase, whereby participants replace all meals with meal replacement products, followed by a gradual food reintroduction phase (weeks 13–18), and a maintenance phase until week-52 focused on healthy eating. The delivery of the programme varies slightly by provider, and therefore not all participants will receive exactly the same number of contacts or receive support in the same way.

3.5. Follow-up call/visits in both arms

3.5.1. 16-week follow up call (pilot only)

This will take place 16 weeks after randomisation and last approximately 5–10 min. Participants in both groups will be contacted by the research team to ask them to report an up-to-date weight measurement (Flowchart 1).

A decision on whether to proceed to the main trial will be based on the a priori progression criteria in Table 3, and with oversight from our Programme Steering Group.

3.5.2. 6 month follow up visit

GP practice staff will record the same measures that were collected at the baseline assessment (excluding height) (Flowchart 1). Additionally, practice staff will record the occurrence of all serious adverse events that have occurred, and the research team will classify these as diabetes related (e.g., macrovascular disease, microvascular disease), and "other".

3.5.3. 9 month follow up visit (conditional)

This assessment is only for participants who stop diabetes medications following the 6 month follow up visit. Practice staff will complete a blood test to measure HbA1c to allow us to classify a person as achieving remission at 12 months if warranted.

3.5.4. 12 month follow up visit

GP practice staff will repeat all measures obtained at 6-month assessment (Flowchart 1).

Table 3
Progression criteria for trial.

Progression criteria	Green	Amber	Red	Sample size*
Proportion of patients offered trial enrolment who enrol	≥50 %	25–49 %	<25 %	40
Fidelity of hub coach to protocol	≥66 %	40–65 %	<40 %	38
Proportion of patients attending follow-up at 16 weeks	≥80 %	65–79 %	<65 %	90
Difference between intervention and control in the proportion of people who agree to start any remission programme at trial entry	≥30 %	10–29 %	<10 %	40
Difference in proportion of people who are still on a weight loss programme at the end of 16-week intervention period compared with control	≥30 %	10–29 %	<10 %	40
Weight difference between arms at 16 weeks intervention period	≥3 kg	1.5–2.9 kg	<1.5 kg	76

* increased by 20 % to account for drop-outs.

3.5.5. 20 year follow up

Long term data linkage will be completed through NHS medical records and data abstracted periodically on diabetes and cardiovascular outcomes, without visits to the practice for specific trial related procedures.

4. Statistical methods

4.1. Sample size

The incidence of T2D in a representative population sample is 45/10,000/year [28], meaning a typical research practice will yield around 45 patients/year newly diagnosed with T2D. Of these 75 % are likely to be eligible for recruitment based on BMI alone, and we aim to recruit >50 % of these patients into the NewDAWN service as people need only commit to hearing about options for achieving remission and follow-up. In the control group offered TDR, we assume remission in 16.6 % based on 30 % uptake and remission rates (46 %) in DiRECT. An improvement in remission by 7 % following the intervention would be considered worthwhile. Assuming 90 % power and 5 % significance, 715/arm are required to detect this difference in remission, adjusted for 20 % loss to follow-up requires 894/arm. This effect size is modest, but this is a public health intervention aiming to recruit people who will not presently consider TDR, and instead offer a credible alternative. We estimate needing 150 to 180 practices.

The required sample size for the internal pilot has been estimated based on the green–red differences using 90 % power and one sided 5 % alpha, following the procedure outlined by Lewis et al. [29]. Based on the required sample size for all progression criteria shown in Table 3, we aim to recruit 150 participants (75 per randomised group).

4.2. Statistical approach and reporting outcomes

In accordance with CONSORT guidelines, we will report participant flow and recruitment, drop-out, and completeness of interventions will be described. Baseline variables will be presented by randomised group using frequencies (with percentages) for binary and categorical variables, and means (and standard deviations) or medians (with lower and upper quartiles) for continuous variables. For the internal pilot study, the proportion meeting each feasibility criterion and mean weight loss will be presented without hypothesis testing.

For the main trial, we will conduct intention to treat analyses including all participants except those who have died. For the primary outcome, a binomial mixed effects generalised linear model (MEGLM) with a logit link function will be fitted to the data with remission as the dependent variable. The model will include the randomised group as a fixed effect and 'GP practice' will be included as a random effect. The adjusted relative risk between the randomised groups and the corresponding 95 % confidence intervals will be obtained from the model and reported alongside the associated *P* value. Participants lost to follow-up will be assumed not to have achieved remission.

All secondary outcomes will be analysed using a linear mixed effects regression model with robust standard errors fitted to the outcomes at 6 and 12 months. The models will include randomised group, assessment time point, baseline value, and an interaction between randomised group and assessment time point as fixed effects; GP practice will be included as a random effect. A random intercept for each participant will be included to account for the repeated measures on the same participant. The adjusted mean difference at 12 months between the randomised groups with 95 % confidence interval and *P* value will be reported. Sensitivity analyses will assess the impact of missingness and calculate patterns of missingness and the as-treated effect will be assessed in sensitivity analyses. Subgroup analyses will be pre-specified in the statistical analysis plan. We will report the proportion of participants experiencing serious adverse events by trial arm without hypotheses tests.

5. Process evaluation

We will carry out a longitudinal process assessment.

We will audio-record the consultations between the hub coaches and participants to examine how the NewDAWN service is delivered and received. Examining the variation in hub coach communication will allow us to identify more helpful communication practices that could optimise engagement of patients in the process of self-experimentation to remit T2D. Data will be analysed using approaches grounded in conversation analysis [24,25].

We will aim to interview hub coaches to assess how the intervention training was received, assess the ongoing adoption and maintenance of the intervention, and how the mission of the organisation is communicated to and received by staff.

We will also invite a maximum variation sample of participants to participate in a semi-structured telephone interview. This will include both those who decline to be part of the trial after the initial discussion with the practice staff (if uptake is <49 %) and participants randomised to and take part in the NewDAWN service. The qualitative interviews will address thoughts about participation in the trial and experiences of the NewDAWN service.

We will interview GP practice staff from participating practices who recruited participants to understand their experiences of and thoughts about recruitment.

The intervention materials (including the Continue or Switch protocol) will be iteratively refined and adapted throughout the pilot trial in collaboration with the PAG groups, other stakeholders, and pilot participants and coaches.

A full process evaluation of the PtR intervention offered as usual care is underway [30], so we are not pursuing this in NewDAWN.

We will observe the NewDAWN service to understand the team behaviours, interactions, and wider principles and values of the organisation. Informal discussions will be conducted to better understand the actions or practices observed from the insights from workers and managers. Where relevant, we will use the service's documents to understand their purpose and values. We will spend time with people at different levels of the organisation and make field-notes to understand patterns of practice over time, what contributes to these, and understand how these fit with (or differ from) the theory we have developed.

1. Brief interviews with key staff

We will invite people at different levels of the hub organisation to a brief interview to assess delivery practices, potential underpinning attitudes of the coaches, and the values and principles that inform the coaches' approach to intervention delivery.

2. Recordings of calls from participants to the hub coaches

We will audio record a sample of calls to each hub and analyse them using conversation analysis. We will focus on areas of the conversation that appear troubled (e.g. indicating confusing or conflicting ideas) and decisions about uptake and persistence. This will highlight communication issues potentially hindering uptake and persistence and identify the accuracy and clarity of the presentation of the intervention. We will also use these recordings to examine how theoretical principles are used in practice, and how patients respond to these.

Should interviews with hub staff indicate that further patient interviews are necessary (for example to clarify patient views on processes discussed with hub staff) we will do this.

All transcripts will be coded and managed using software such as NVIVO.

6. Cost-effectiveness evaluation

Economic evaluation will be used to assess the cost-effectiveness of

the NewDAWN service with NHS 'usual care' (i.e. offered only PtR). The analysis will take an NHS and personal social services (PSS) perspective. The primary cost-effectiveness analysis will develop an existing simulation model to generate discounted lifetime costs and quality-adjusted-life-years (QALYs) for both trial arms and then estimate an incremental cost-effectiveness ratio of the NewDAWN service versus PtR. Probabilistic sensitivity analyses will describe the uncertainty in model outcomes. If necessary, the evaluation will be performed based on the outcomes from the pilot trial with value of information analysis to estimate the benefits of progressing to a full trial [31]. If we progress to a full trial, we will update our analysis of the cost-effectiveness of the NewDAWN service with NHS 'usual care' (i.e. offered only PtR). Pre-specified sub-group analyses will explore the impact by gender, socio-economic status, and ethnic group.

The School for Public Health Research (SPHR) diabetes model will be used to assess the cost-effectiveness of NewDAWN service versus NHS best offer using the metric of incremental cost per quality adjusted life year gained (discounted) and is described in full elsewhere [32]. The model will undergo model testing and quality assurance processes with an independent researcher, experienced in the model programming.

The costs of the NewDAWN service in each of the hubs will be obtained using micro-costing surveys. The surveys include estimates of the administrative costs of setting up and running the hub, costs for training the hub staff, resources used, and administration costs, the cost per patient of time spent in consultation with the hub (using staff surveys and diaries of time spent per patient on supporting and monitoring patients). Standard unit costing methods will be used. We will obtain unit costs for professional NHS staff from nationally representative sources [33]. Delivery costs of the weight loss programmes available to participants will be based on the cost of commissioned services offered by the hubs. The costs of usual care – the NHS best offer - will include the cost of PtR for those patients who pursue this treatment option.

Responses to the health resource use and ModRUM questionnaires will be used to estimate difference in healthcare utilisation between the NewDAWN intervention and NHS usual care. Items from the questionnaire (e.g. hospital stay or A&E attendance) will be costed using the National Schedule of NHS costs to estimate the annual non-intervention healthcare cost for each arm.

Sensitivity analyses will explore model sensitivity to intervention costs, adherence, and assumptions relating to the duration of benefits of the intervention. Cost-effectiveness outcomes will be stratified by socioeconomic groups defined by IMD quintile and ethnic groups (White, South Asian, Other). The sub-group analysis will identify differences in incremental costs and health outcomes between these groups and indicate whether the policy may increase or decrease health inequalities.

7. Conclusion

The PtR programme offers people newly diagnosed with T2D a chance of remission by achieving weight loss. However, only a minority of eligible patients commence the programme. Since weight loss is the primary driver of remission, the NewDAWN trial aims to support people to find the right weight loss service for them through guided self-experimentation, to encourage more people to take up the offer of weight loss to achieve remission, and persist with weight loss attempts. If successful, the NewDAWN service could become the gold-standard not just for T2D remission but also for general weight management.

CRediT authorship contribution statement

Nicola Guess: Writing – review & editing, Writing – original draft, Project administration, Methodology, Conceptualization. **Sarah Wane:** Writing – review & editing, Writing – original draft, Software, Project administration, Methodology, Conceptualization. **Charlotte Albury:** Writing – review & editing, Methodology, Investigation, Funding acquisition. **Penny Breeze:** Writing – review & editing, Methodology. **Alan Brennan:** Writing – review & editing, Methodology, Funding acquisition. **Jack B. Joyce:** Writing – review & editing, Methodology, Investigation. **Ushma Galal:** Writing – review & editing, Methodology, Formal analysis. **Elizabeth Morris:** Writing – review & editing, Methodology, Funding acquisition. **Carolyn Newbert:** Writing – review & editing, Investigation, Funding acquisition. **Caroline Mitchell:** Writing – review & editing, Methodology, Funding acquisition. **Ly-Mee Yu:** Writing – review & editing, Software, Methodology, Funding acquisition, Formal analysis. **Paul Aveyard:** Writing – review & editing, Supervision, Methodology, Funding acquisition, Conceptualization. **Susan A. Jebb:** Writing – review & editing, Supervision, Methodology, Funding acquisition, Conceptualization.

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Declaration of competing interest

PA and SJ are investigators on a publicly funded trial that obtained TDR products from Nestle to support NHS treatment costs. NG has previously received consultancy payment from Oviva who are a provider of digital weight management and education programmes for type 2 diabetes. PA and SAJ are members of the advisory board for the PtR programme. None of the other applicants have conflicts of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cct.2025.108050.

Data availability

No data was used for the research described in the article.

References

[1] E. Morris, S. Jebb, P. Aveyard, Type 2 diabetes: treating not managing, Lancet Diabet. Endocrinol. 7 (5) (2019) 326–327.
[2] M.E. Lean, et al., Primary care-led weight management for remission of type 2 diabetes (DiRECT): an open-label, cluster-randomised trial, Lancet 391 (10120) (2018) 541–551.
[3] N. Sattar, et al., Dietary weight-management for type 2 diabetes remissions in South Asians: the South Asian diabetes remission randomised trial for proof-of-concept and feasibility (STANDby), Lancet Region. Health-Southeast Asia (2023) 9.
[4] J.M. Leavy, P.M. Clifton, J.B. Keogh, The ROLE OF CHOICE IN WEIGHT LOSS STRATEGIES: A SYSTEMATIC REVIEW AND META-ANALYsis, Nutrients 10 (9) (2018).
[5] C.V.A. Albury, et al., Discussing weight loss opportunistically and effectively in family practice: a qualitative study of clinical interactions using conversation analysis in UK family practice, Fam. Pract. 38 (3) (2021) 321–328.
[6] A.L. Ahern, et al., Participants' explanatory model of being overweight and their experiences of 2 weight loss interventions, Ann. Fam. Med. 11 (3) (2013) 251–257.
[7] N.M. Astbury, et al., Participant experiences of a low-energy total diet replacement programme: a descriptive qualitative study, PLoS One 15 (9) (2020) e0238645.
[8] A.G. Dulloo, Explaining the failures of obesity therapy: willpower attenuation, target miscalculation or metabolic compensation? Int. J. Obes. (Lond.) 36 (11) (2012) 1418–1420.
[9] K. Morphett, et al., A qualitative study of smokers' views on brain-based explanations of tobacco dependence, Int. J. Drug Policy 29 (2016) 41–48.
[10] J. Hartmann-Boyce, et al., Experiences of reframing during self-directed weight loss and weight loss maintenance: systematic review of qualitative studies, Appl. Psychol. Health Well Being 10 (2) (2018) 309–329.
[11] project, I.i.o.u.-s.g.i.c.r.G.f.I.

[12] J. Buckell, et al., Identifying preferred features of weight loss programs for adults with or at risk of type 2 diabetes: a discrete choice experiment with 3960 adults in the UK, Diabet. Care (2024).
[13] J. Chan, et al., Addressing health inequalities in diabetes through research: recommendations from Diabetes UK's 2022 health inequalities in diabetes workshop, Diabet. Med. 40 (4) (2023) e15024.
[14] W.H. Polonsky, et al., Assessment of diabetes-related distress, Diabetes Care 18 (6) (1995) 754–760.
[15] E. Stolk, et al., Overview, update, and lessons learned from the international EQ-5D-5L valuation work: version 2 of the EQ-5D-5L valuation protocol, Value Health 22 (1) (2019) 23–30.
[16] S.H.J. Hageman, et al., Estimation of recurrent atherosclerotic cardiovascular event risk in patients with established cardiovascular disease: the updated SMART2 algorithm, Eur. Heart J. 43 (18) (2022) 1715–1727.
[17] K. Garfield, et al., Development of a brief, generic, modular resource-use measure (ModRUM): cognitive interviews with patients, BMC Health Serv. Res. 21 (1) (2021) 371.
[18] N.M. Astbury, et al., Doctor Referral of Overweight People to Low Energy total diet replacement Treatment (DROPLET): pragmatic randomised controlled trial, Bmj 362 (2018) k3760.
[19] E. Morris, et al., A food-based, low-energy, low-carbohydrate diet for people with type 2 diabetes in primary care: a randomised controlled feasibility trial, Diabet. Obes. Metabol. 22 (4) (2020) 512–520.
[20] K. Jolly, et al., Comparison of range of commercial or primary care led weight reduction programmes with minimal intervention control for weight loss in obesity: lighten up randomised controlled trial, Bmj 343 (2011) d6500.
[21] K.J. Dixon, S. Shcherba, R.R. Kipping, Weight loss from three commercial providers of NHS primary care slimming on referral in North Somerset: service evaluation, J. Public Health (Oxf.) 34 (4) (2012) 555–561.
[22] M. Noreik, et al., Testing the short-term effectiveness of primary care referral to online weight loss programmes: a randomised controlled trial, Clin. Obes. 11 (6) (2021) e12482.
[23] T. Thorgeirsson, et al., Randomised trial for weight loss using a digital therapeutic application, J. Diabet. Sci. Technol. 16 (5) (2022) 1150–1158.
[24] C. Albury, et al., Relationship between clinician language and the success of behavioural weight loss interventions: a mixed-methods cohort study, Ann. Intern. Med. 176 (11) (2023) 1437–1447.
[25] C. Albury, et al., What happens when patients say "no" to offers of referral for weight loss? - results and recommendations from a conversation analysis of primary care interactions, Patient Educ. Couns. 105 (3) (2022) 524–533.
[26] NHS England, NHS Improvement, N.L.C.D.P.P.G.f.G.p.a.r, Public Health England, 2025.
[27] https://www.nice.org.uk/guidance/ng28., N.I.f.H.C.E.T.d.i.a.m.N.g.N.J.D.A.f.
[28] S.S. Zghebi, et al., Examining trends in type 2 diabetes incidence, prevalence and mortality in the UK between 2004 and 2014, Diabet. Obes. Metab. 19 (11) (2017) 1537–1545.
[29] M. Lewis, et al., Determining sample size for progression criteria for pragmatic pilot RCTs: the hypothesis test strikes back!, Pilot Feasibil. Stud. 7 (1) (2021) 40.
[30] T.S. Evans, et al., Does the design of the NHS Low-Calorie Diet Programme have fidelity to the programme specification? A documentary review of service parameters and behaviour change content in a type 2 diabetes intervention, Diabet. Med. 40 (4) (2023) e15022.
[31] K. Claxton, E. Fenwick, M.J. Sculpher, Decision-making with uncertainty: the value of information, in: The Elgar Companion to Health Economics, Second Edition., Edward Elgar Publishing, 2012.
[32] P. Breeze, et al., Cost-effectiveness of population-based, community, workplace and individual policies for diabetes prevention in the UK, Diabet. Med. 34 (8) (2017) 1136–1144.
[33] Jones Helen, Birch Sarah, Castelli Adriana, Chalkley Martin, Dargan Alan, E. Forder Julien, Gao Jinbao, Hinde Seb, Markham Sarah, Ogunleye Della, Premji Shainur, Roland Daniel, Unit Costs of Health and Social Care 2022 Manual. Technical Report, Personal Social Services Research Unit (University of Kent) & Centre for Health Economics (University of York), Kent, UK, 2023, https://doi.org/10.22024/UniKent/01.02.100519 (KAR id:100519).