ISRCTN11090437 https://doi.org/10.1186/ISRCTN11090437

New structured weight management pathway for diabetes remission

Submission date
15/06/2023

Recruitment status
Stopped

Registration date
07/08/2023

Overall study status
Stopped

Last Edited
09/06/2026

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Existing evidence shows clearly that for people with type 2 diabetes (T2D) who are overweight, the likelihood of remission (normal blood glucose levels without the need for medication) is linearly related to the extent of weight loss. The aim of this study is to increase the uptake of existing NHS and local authority provided weight loss programmes in people with T2D. It does not aim to develop and test new interventions, but to change the way existing interventions are offered by the NHS; increasing the range and the choice of programmes available to patients to achieve remission in a new, patient-centred weight management service. Accordingly, the study focuses on evidence of the effectiveness of weight loss programmes already in use within the NHS or commissioned by local authorities and which might be brought into the new care service.

Who can participate?
Patients diagnosed with T2D in the previous year from about 150 GP practices. The first 150 participants, from about 15 practices, will constitute the internal pilot.

What does the study involve?
Participants will be randomly allocated to either the control group (NHS Pathway to Remission, PtR) or the intervention NewDAWN service.
Participants allocated to the usual care group will be referred by their GP practice to the current NHS Pathway to Remission (previously known as the NHS Low Calorie Diet) pilot pathway. This programme has a 8-12 week intensive weight loss phase, whereby participants receive meal replacement products on prescription by the NHS. In weeks 1-4, they receive weekly contact from the provider, which can be face-to-face, video or telephone calls. During weeks 5-12 these contacts drop to fortnightly. A gradual food reintroduction phase follows this initial weight loss phase whereby participants continue to receive regular contact from the provider, but less frequently. The delivery of the programme varies by provider, and therefore not all participants will receive exactly the same number of contacts or potentially in the same format.
Participants allocated to the intervention group will be referred by the GP practice to the NewDAWN service. They will receive regular calls from a hub coach to support them through their weight loss journey. The hub coaches will discuss the most effective weight loss programme for the participant, and if they agree to this programme, the coach will refer them. They will have a follow-up call after 2 weeks, followed by three further 4-weekly calls from the

coach to ensure the participant is engaging and maintaining progress within the programme. If the participant does not wish to continue with the programme, the hub coach will discuss the next most effective option and refer them to the programme. The participant will be able to try up to four weight loss programmes, including the NHS PtR, and locally commissioned weight loss programmes in their regions.

What are the possible benefits and risks of participating?
This study involves no identified significant risks to participants. They are primarily consenting to engage with dietary and behavioural advice that is intended to support them to lose weight and improve their diabetes control and general health. All the interventions have been previously tested and are in use within the NHS.
One of the advantages of weight loss programmes is the potential for diabetes and blood pressure medications to be withdrawn. However, it is important that this is done safely, as withdrawal of diabetes and blood pressure medications in an individual who does not lose weight, or a certain amount of weight could be at risk of high blood sugar and high blood pressure. Conversely, if diabetes and blood pressure medications are not withdrawn and an individual loses a certain amount of weight, it can put them at risk of hypoglycaemia (very low blood sugar) and low blood pressure. However, the researchers will follow established guidelines used by the NHS Pathway to Remission programme, and NICE standards for blood glucose control to ensure any medication withdrawal is carried out safely.

Where is the study run from?
The study will be managed and run from the University of Oxford's Department of Primary Care Health Sciences (UK). The study assessment visits will be conducted at participating GP practices, with the intervention delivered remotely by an external partner.

When is the study starting and how long is it expected to run for?
March 2022 to June 2025

Who is funding the study?
National Institute for Health and Social Care Research (NIHR) (UK)

Who is the main contact?
Dr Nicola Guess, nicola.guess@phc.ox.ac.uk
In the event of Dr Guess being unavailable, the other members of the study team can be reached at newdawn@phc.ox.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
324924

Central Portfolio Management System (CPMS)
57333

Study information

Scientific Title
New remission care pathway: Diabetes Adaptive Weight management Network

Acronym
NewDAWN

Study objectives
It is hypothesised that by offering a range of alternative treatment approaches that offer a realistic possibility of remission from type 2 diabetes for a proportion of patients we can (i) increase the proportion of patients who are willing to initiate any weight loss attempt and (ii) retain people for whom TDR is unacceptable or unsuitable by offering an alternative programme. If we are successful, this will increase overall remission rates.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/08/2023, Health Research Authority (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8000; approvals@hra.nhs.uk), ref: 23/SC/0230

Primary study design
Interventional

Study design
Two-arm parallel-design open-label randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
The researchers will test in a randomised controlled trial whether a programme that supports people to experiment with a sequence of interventions aimed at type 2 diabetes remission is more successful than the current best care offered in the NHS (a total diet replacement programme). In an internal pilot phase they will test whether the intervention can be delivered as planned, increases uptake to the remission programme, supports more people to remain in the programme and achieve greater weight loss at 16 weeks than the control. If it meets pre-specified progression criteria the researchers will continue the trial with type 2 diabetes remission at 1 year as the primary outcome.

Participants will be randomised by their GP practice using Sortition (a specialised computer programme) to either the control or the NewDAWN service. The control arm will receive the NHS Pathway to Remission programme pilot study; this is a dietary intervention for people with type 2 diabetes aiming to achieve remission (blood glucose levels returning to normal levels without the use of medication) that uses total dietary replacement products followed by a gradual food reintroduction programme. This programme is delivered by coaches and aims to help participants lose weight and achieve remission. The programme will either be delivered in person, face to face, or remotely via video call or telephone and with or without the use of an app (this depends on the area of the country the participant lives).

The NewDAWN service (intervention arm) will provide support for participants to try out different weight loss programmes to help them lose weight and achieve remission. After randomisation, participants in the intervention will be referred to a NewDAWN hub, where they will receive regular calls (video or telephone) with a hub coach who will discuss the most effective programme for them and support them to try it. Participants will be asked to try a programme for 2 weeks and then will have contact with the coach to determine whether they would like to continue on this programme. Participants will be able to try up to four weight loss programmes; these programmes will include the NHS Pathway to Remission, a food-based low-calorie diet, or programmes available within the participant's local NHS trust.

All participants will be followed up for 12 months, with appointments at baseline, 6 months, (9 months for participants who have a change in medication at 6 months) and 12 months. These appointments will include weight and blood pressure readings, blood tests (HbA1c), quality of life scores as well as medication usage.

Intervention Type
Behavioural

Primary outcome(s)
Remission from type 2 diabetes at 12 months; a minimum of 3 months off diabetic medication is required, therefore medication usage and HbA1c levels will be measured at 6 months, 9 months

(for participants who have a change in medication at 6 months) and 12 months after randomisation

Key secondary outcome(s)
1. Weight measured using body weight scales available at the GP practice at baseline, 6 months and 12 months
2. Blood glucose levels will be measured using HbA1c levels in the blood at baseline, 6 months and 12 months
3. Dyslipidaemia measured using a ratio of total cholesterol and high-density lipoprotein (HDL) cholesterol at baseline, 6 months and 12 months
4. Cardiometabolic risk measured via QRISK 2 or SMART score (for those with a history of cardiovascular disease) at baseline and 12 months
5. Blood pressure (diastolic and systolic) measured using a sphygmomanometer three times seated, each at least 1 minute apart, at baseline, 6 months and 12 months
6. Quality of life measured using problem areas in diabetes score (PAID) and EQ-5D-5L at baseline, 6 months and 12 months

Completion date
30/06/2025

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Adults (aged 18 to 70 years) with type 2 diabetes diagnosed in the past 1 year
3. A BMI of at least 27 kg/m² and who may benefit from achieving remission
4. Able to attend baseline visits, adhere to intervention and follow-up appointments
5. Participant is registered at a GP practice that is open for recruitment
6. Participant is willing to be randomised to either treatment option

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
17

Key exclusion criteria
1. Currently diagnosed with type 2 diabetes but who are in remission
2. People currently following the Pathway to Remission programme, or who have previously followed this programme
3. Currently using insulin injections
4. GLP1-agonists or SGLT2 inhibitors started in the 3 months prior to study enrolment
5. Currently taking an SGLT2 inhibitor for an indication other than type 2 diabetes
6. Diagnosed with a known eating disorder for whom the programme could be unsafe or require extensive monitoring to ensure safety
7. People who are pregnant or planning pregnancy
8. People who are breastfeeding
9. Diagnosed with a recent myocardial infarction or stroke in the past three months, uncontrolled cardiac conduction abnormalities e.g. long QT syndrome, maculopathy or proliferative retinopathy
10. People with HbA1c ≥87mmol/mol
11. 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
12. 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

Date of first enrolment
06/11/2023

Date of final enrolment
07/04/2025

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
NIHR CRN: Thames Valley and South Midlands
John Radcliffe Hospital
Headley Way
Headington
Oxford
England
OX3 9DU

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available upon request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		25/08/2025	28/08/2025	Yes	No