

# New structured weight management pathway for diabetes remission

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<b>Registration date</b> 07/08/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/07/2025	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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](mailto: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](mailto:newdawn@phc.ox.ac.uk)

## Contact information

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

324924

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

CPMS 57333, IRAS 324924

## 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](mailto:approvals@hra.nhs.uk)), ref: 23/SC/0230

**Study design**

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

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

GP practice, Other

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a participant information sheet

**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 measure**

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

### **Secondary outcome measures**

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

### **Overall study start date**

01/03/2022

### **Completion date**

30/06/2025

## **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/m<sup>2</sup> 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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

70 Years

**Sex**

Both

**Target number of participants**

1788

**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  $\geq 87$  mmol/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**

England

United Kingdom

Wales

**Study participating centre**

**NIHR CRN: Thames Valley and South Midlands**

John Radcliffe Hospital

Headley Way

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**Sponsor information****Organisation**

University of Oxford

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<http://www.ox.ac.uk/>

**ROR**

<https://ror.org/052gg0110>

**Funder(s)**

**Funder type**

Government

**Funder Name**

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

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

30/06/2027

**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