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# A low-carbohydrate, low-energy dietary intervention for patients with type 2 diabetes in primary care

**Submission date**
06/04/2022

**Recruitment status**
No longer recruiting

**Registration date**
07/04/2022

**Overall study status**
Completed

**Last Edited**
06/08/2025

**Condition category**
Nutritional, Metabolic, Endocrine

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

## Plain English summary of protocol

Background and study aims
Type 2 diabetes is a lifelong condition in which a person's blood sugar levels are too high. It affects 1 in 16 people in the UK, and causes almost 15% of adult deaths worldwide. If it isn't controlled, it can lead to blindness, kidney failure, and heart disease. It is known that diet affects blood sugar levels, and that changing diet and losing weight can both help to control diabetes. However, it is not clear what the best advice is to help people achieve this goal. Committed clinicians have shown that, in selected patients, low-carbohydrate, low-energy diets can transform the lives of people with type 2 diabetes, reducing the need for medications, improving quality of life and reducing costs for the NHS.
The DiRECT trial (https://www.isrctn.com/ISRCTN03267836) showed that nearly half of people with type 2 diabetes diagnosed in the last six years had remission of diabetes following an intensive weight loss programme in which participants stopped eating their normal food and ate specially formulated 'total diet replacements'. However, total diet replacements do not appeal to all.
We developed the DIAMOND programme using 'real food', with realistic support provided in the NHS. We tested this in a 'feasibility trial' (https://www.isrctn.com/ISRCTN62452621), which showed we could recruit people who followed the programme with nurses delivering the programme as intended. Participants lost 10 kg and two-thirds had blood glucose in the non-diabetic range at three months. We will show whether this can be maintained.

This study aims to show whether a low energy low carbohydrate food-based diet and support from practice nurses can help people with recently diagnosed type 2 diabetes achieve remission, meaning no need for diabetes medicines.

Who can participate?
Adults (aged 18 to 70 years (inclusive)) with type 2 diabetes diagnosed in the past six years, who are socially representative of the UK population.

What does the study involve?
We will ask practices to write to people with diabetes who are overweight and meet the study

criteria. Interested persons will telephone the trial team for more details. If the person appears eligible, s/he will see a nurse at the local practice who will confirm consent and measure height, weight, blood pressure, and a blood test for blood glucose control and cholesterol.
We will decide at random if practices will provide usual care for diabetes or offer the DIAMOND programme. Participants in practices offering the programme will be invited to see the nurse seven times over 6 months. Some will be invited to take part in an interview.
At 1 year, we will repeat the baseline measures. The main outcome is whether people have achieved remission. Thereafter, we will assess whether people have diabetes through the National Diabetes Audit.

What are the possible benefits and risks of participating?
This study involves no identified significant risks to participants. They are primarily consenting to engaging with dietary and behavioural advice which is intended to support them to lose weight and improve their diabetes control and general health. There are known no significant risks of this advice. We do not envision that those in the intervention compared with usual care to be at a greater risk of SAEs. In the DiRECT study, SAEs were less common in the intervention than control group. Similarly, within the DROPLET study, 15 (11%) in the TDR group had adverse events that were classed as moderate or severe, compared with 17 (12%) in the usual care group. Venepuncture for blood samples may cause momentary discomfort. Standard NHS operating procedures as used in routine clinical care will be used for the collection and processing of samples, and all will be carried out by appropriately trained clinicians in the participants' usual GP practice. The participants assessment at baseline and 12 months includes measures that are taken at usual diabetes care visits and so will probably substitute for another visit to the practice for routine care. Thus the main burdens reflect the short questionnaires and the additional visit at 6 months. We have elected to compensate participants for the visits at six and 12 months to reflect the added burden.

Where is the study run from?
University of Oxford (UK)

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

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Jadine Scragg, Jadine.scragg@phc.ox.ac.uk

# Contact information

### Type(s)
Scientific

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## Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
307150

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
CPMS 52328, NIHR132317, IRAS 307150

## Study information

### Scientific Title
Dietary Approaches to the Management Of type 2 Diabetes (DIAMOND) cluster randomised trial

## Acronym
DIAMOND cluster randomised trial

## Study objectives
To show whether a low-energy low-carbohydrate diet and support from practice nurses can help people with recently diagnosed type 2 diabetes achieve remission, meaning no need for diabetes medicines.

This is a cluster randomised trial following on from the DIAMOND feasibility study (https://www.isrctn.com/ISRCTN62452621)

## Ethics approval required
Ethics approval required

## Ethics approval(s)
approved 04/04/2022, East Midlands - Nottingham 2 Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA; +44 2071048016; nottingham2.rec@hra.nhs.uk), ref: 22/EM/0074

## Study design
Interventional mixed methods cluster randomized trial

## Primary study design
Interventional

## Study type(s)
Treatment

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

## Interventions
In this trial, we will recruit practices nationally, aiming to include 508 people from 56 general practices who are socially representative of the UK population. We will ask practices to write to people with diabetes who are overweight and meet the study criteria. Interested persons will contact the trial team for more details. If the person appears eligible, s/he will see a nurse at the local practice who will confirm eligibility and take informed consent and then measure height, weight, blood pressure, and a blood test for blood glucose control (HbA1c) and lipid profile.

We will allocate practices randomly balancing ethnic composition and socioeconomic status to provide usual care for diabetes or offer the DIAMOND programme. Participants in practices offering the programme will be invited to see the nurse seven times over 6 months.

At 6 months, patients will attend the practice for a blood test. At 1 year, we will repeat the baseline measures. The main outcome is whether people have achieved remission ie normal blood glucose at 6 and 12 months and off medication. Thereafter, we will seek permission to get data from NHS records that will tell us whether the programme has led to long-term remission from diabetes and whether people have suffered heart attack or stroke, or have kidney damage or eye problems, which are complications of diabetes.

We aim to assess the impact of the programme on the everyday lives of participants randomised to the DIAMOND programme and how the support was experienced and its impact on their behaviour. Purposive sampling will be used to achieve maximum variation in demographic characteristics including age, gender, ethnicity and socioeconomic status, GP practice, and where data is available, baseline dietary preferences (e.g. vegetarian) and weight loss outcomes. We will ask all participants to consent to interview at baseline, but this will be optional, and will contact to arrange interview only with those who agreed. A researcher will telephone the participant to arrange and then conduct an interview lasting up to 60 minutes covering the impact of the programme, their reactions to the behavioural support programme, and the ways that their behaviour has or has not changed, and their views of the impact of the programme on the participant's diabetes. All telephone interviews will be audio-recorded.

### Intervention Type
Behavioural

### Primary outcome(s)
Remission, defined as HbA1c <48 mmol/mol for 6 months while off diabetes medication between 6 and 12 months assessed by medication use and measurement of HbA1c concentration at both times

### Key secondary outcome(s))
Measured at baseline and 12 months:
1. Glycaemic control measured using concentration of HbA1c (blood test)
2. Lipid profile measured using total cholesterol/HDL ratio
3. Systolic and diastolic blood pressure (sphygmomanometer)
4. Cardiovascular risk measured using QRISK2/SMART score
5. Quality of life measured using problem areas in diabetes (PAID) and WHO-5 scores

### Completion date
07/07/2025

## Eligibility

### Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Adults (18 to 70 years (inclusive)) with type 2 diabetes diagnosed in the past six years
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 and randomised

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
70 years

### Sex
All

### Total final enrolment
626

### Key exclusion criteria
1. Currently diagnosed with type 2 diabetes but who are in remission using the NHS diabetes remission criteria
2. Currently using insulin injections
3. GLP1-agonists or SGLT2 inhibitors started in the 3 months prior to study enrolment
4. Diagnosed with a known eating disorder for whom the programme could be unsafe or require extensive monitoring to ensure safety
5. Participants who are pregnant or planning pregnancy
6. Participants who are breast feeding or planning to breast feed
7. 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
8. Participants with HbA1c >= 87mmol/mol
9. Participants 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
10. People taking part in other research that would compromise either their participation in DIAMOND or the other research study(s) that they are participating in

### Date of first enrolment
01/07/2022

### Date of final enrolment
31/12/2023

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**NIHR CRN: Thames Valley and South Midlands**
John Radcliffe Hospital
Headley Way

Headington
Oxford
United Kingdom
OX3 9DU

**Study participating centre**
**NIHR CRN North East and North Cumbria**
Regent Point
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Newcastle upon Tyne
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**Study participating centre**
**NIHR CRN: North West Coast**
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L7 8XP

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**Study participating centre**
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**Study participating centre**
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**Study participating centre**
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# 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)

**Funder Name**
National Institute for Health Research

**Alternative Name(s)**
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**
The current data sharing plans for this study are unknown and will be available at a later date

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | | 22/04/2023 | 25/04/2023 | Yes | No |
| HRA research summary | | | 20/09/2023 | No | No |
| Participant information sheet | version 1.1 | 31/03/2022 | 07/04/2022 | No | Yes |