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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
[_] 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

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
307150

Central Portfolio Management System (CPMS)
52328

National Institute for Health and Care Research (NIHR)
132317

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

Primary study design
Interventional

Study design
Interventional mixed methods cluster randomized trial

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
Regent Farm Road
Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3HD

Study participating centre
NIHR CRN: North West Coast
Royal Liverpool and Broadgreen University Hospitals NHS Trust
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
NIHR CRN: Yorkshire and Humber
8 Beech Hill Road
Sheffield
United Kingdom
S10 2SB

Study participating centre
NIHR CRN: Greater Manchester
2nd Floor
Citylabs
Nelson Street
Manchester
United Kingdom
M13 9NQ

Study participating centre
NIHR CRN: East Midlands
Knighton Street Outpatients
1st Floor
Leicester Royal Infirmary
Leicester
United Kingdom
LE1 5WW

Study participating centre
NIHR CRN: West Midlands
James House
Newport Road
Albrighton
Wolverhampton
United Kingdom
WV7 3FA

Study participating centre
NIHR CRN: West of England
Whitefriars
Lewins Mead
Bristol
United Kingdom
BS1 2NT

Study participating centre
NIHR CRN: Eastern
Floor 4
Rouen Road
Norwich
United Kingdom
NR1 1QQ

Study participating centre
NIHR CRN: Kent, Surrey and Sussex
Bevendean House
Room BE205
University of Brighton
Falmer
Brighton
United Kingdom
BN1 9PH

Study participating centre
NIHR CRN: Wessex
Unit 7, Berrywood Business Village
Tollbar Way
Hedge End

Southampton
United Kingdom
SO30 2UN

Study participating centre
NIHR CRN: South West Peninsula
F7
Bowmoor House
Royal Devon and Exeter Hospital
(Wonford)
Exeter
United Kingdom
EX2 5DW

Study participating centre
NIHR CRN: North Thames
3rd floor
170 Tottenham Court Road
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United Kingdom
W1T 7HA

Study participating centre
NIHR CRN: North West London
Imperial College Healthcare NHS Trust
3rd Floor Administrative Block South
Hammersmith Hospital Du Cane Road
London
United Kingdom
W12 0HT

Study participating centre
NIHR CRN: South London
16th Floor BRC Faculty
Guy's Tower
Guy's Hospital Great Maze Pond
London
United Kingdom
SE1 9RT

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