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A remotely delivered behavioural support programme can help people with type 2 diabetes follow a low-carbohydrate, low-energy diet

Submission date
28/02/2024

Recruitment status
No longer recruiting

Registration date
19/03/2024

Overall study status
Completed

Last Edited
06/06/2025

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 (T2D) can be put into remission (achieving normal or near-normal blood glucose levels without medications) if treated with intensive weight loss support. Currently available evidence is that a very low-energy diet (about 800-900kcal per day) delivered using meal replacement products is the most effective way of achieving remission. However, about 75% of people offered a meal replacement programme turn it down, and low-carbohydrate low-energy diets could be an attractive alternative for many. Researchers at the University of Oxford developed a face-to-face low-carbohydrate, low-energy diet (the DIAMOND programme) which achieved on average almost 10kg weight loss and normalisation of blood glucose in a 12-week feasibility study. The patients and healthcare professionals who took part in the DIAMOND study wanted to know whether the same results could be achieved using this dietary approach but provided through digital tools and remote support as an alternative to face-to-face appointments with a practice nurse. This has the potential for more frequent support without increasing the demand on the primary care workforce. Remotely-delivered interventions also offer more flexibility for the patient, without the need to attend a GP practice or physical location at a particular time. Encouraging data from other weight loss programmes shows that a remote version can work just as well as a face-to-face version. Nevertheless, the team want to test whether a remote intervention of DIAMOND can achieve similar weight loss results as seen in the face-to-face version before rolling it out at scale. Therefore, this proof-of-concept study will assess whether a remotely delivered behavioural support programme helps people follow a low-carbohydrate, low-energy diet (eDIAMOND) to achieve clinically significant weight loss compared with no support or dietary advice.

Who can participate?
Adult patients aged between 18 and 65 years old with T2D

What does the study involve?
This study involves recruiting 60 adult patients with T2D and a BMI over 27 kg/m2 (where

individuals are from White ethnic groups) or over 25 kg/m2 (where individuals are from Black, Asian and other ethnic groups). Participants will be individually randomised and randomly assigned to either the intervention group (eDIAMOND programme) or the control group (NHS usual care). The eDIAMOND programme is a low-carbohydrate, low-energy diet intervention delivered remotely with 12 weeks of support for weight loss and 8 weeks of weight maintenance support. Online support from health coaches will be available throughout the programme. All participants from both groups will be enrolled for 5 months from randomisation to final follow-up.

What are the possible benefits and risks of participating?
The benefits of taking part are as follows:
• The research team will offer each participant a £20 gift card at the 20-week follow-up visit. In addition, reasonable travel expenses to any other research-related appointments, should these be necessary, will also be reimbursed, even if the participant drop-outs of the study before it ends
• The knowledge gained in this study will help us know how best to help people with T2D in the future

An initial risk assessment identified the following risks:
• Risk of hypoglycaemia on oral or injectable hypoglycaemic agents. Recommendations will be made available to support GPs with stopping or adjusting oral hypoglycaemic agents on commencement and continuation of hypocaloric dieting (as would be part of routine anticipatory clinical care), such that hypoglycaemia should not occur. Likewise, patients on insulin will be excluded from eligibility for the study as the risk of hypoglycaemia would be greater in this patient group. Participants will receive guidance on how to interpret self-monitoring results from blood glucose monitoring, and when to contact their GP surgery for clinician review should unexpectedly high or low readings occur.
• It is known that sudden normalisation in retinal blood flow, associated with the return of normal glycaemic control, may result in deterioration of retinopathy. Thus, for individuals to be eligible for inclusion in this study, they must have undergone diabetic retinopathy screening within the preceding 12 months. Any patient with proliferative diabetic retinopathy, or maculopathy, will be excluded, due to the potential risks of deterioration in these conditions.
• Risk of hypotension in patients taking antihypertensive medications. Recommendations will be made available to support GPs in their titration of medications according to BP readings (including home BP monitoring) – as forms part of usual clinical care for patients on antihypertensives. Participants will receive guidance on how to interpret their home monitoring BP results, and when to contact their clinician for a review should unexpectedly high or low readings occur.
• Risk of constipation. For anyone undertaking an energy-restricted diet of this nature, there is a risk that they may develop constipation. Recognising this, all participants will be warned about the potential to develop constipation, the importance of increasing their fluid intake, how to recognise early signs of constipation, and when to contact their GP for a laxative. In the health professional's training and manual, advice on how and when to prescribe fybogel to counter constipation will be given.
• Change in INR for patients on warfarin. It is known that changes in dietary patterns can affect patients' INR values (and required warfarin dosing). Patients are routinely advised to inform their warfarin monitoring service (for example, the established RAID system in Oxford) of any significant lifestyle or medication changes, which will guide their clinicians in advising on dosing and frequency of blood tests. Patients will be advised to follow this routine advice if they are taking warfarin, and inform their monitoring service that they will be following a low-carb low-energy diet. They may then be offered an additional INR test at the clinical services' discretion.

Where is the study run from?
Nuffield Department of Primary Care Health Sciences, University of Oxford

When is the study starting and how long is it expected to run for?
January 2024 to June 2025

Who is funding the study?
NIHR Programme Grants for Applied Research

Who is the main contact?
Daisy Harrison (Assistant Trial Manager), e-diamond@phc.ox.ac.uk

Contact information

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Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)

323582

Central Portfolio Management System (CPMS)
56395

Study information

Scientific Title
The effectiveness of a low-carbohydrate, low-energy diet with remote support for patients with type 2 diabetes in primary care on weight loss: a proof of concept (PoC) trial

Acronym
eDIAMOND

Study objectives
It is hypothesised that a remotely delivered behavioural support programme can help people follow a low-carbohydrate, low-energy diet (eDIAMOND) and achieve clinically significant weight loss compared with no support or dietary advice.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/01/2024, East of England - Cambridge East Research Ethics Committee (2 Redman Place, London, EC20 1JQ, United Kingdom; +44 (0)2071048181; CambridgeEast.REC@hra.nhs.uk), ref: 23/EE/0278

Primary study design
Interventional

Study design
Two-arm unblinded randomized controlled trial

Study type(s)
Other, Prevention

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

Interventions
The researchers will test in a randomised controlled trial the effectiveness of a low-carbohydrate, low-energy diet with remote support for patients with type 2 diabetes.

Intervention Type
Behavioural

Primary outcome(s)
Change in weight measured by weighing participants at the 20-week follow-up appointment and comparing this to the measurement taken at baseline

Key secondary outcome(s)
1. Change in HbA1c measured using a blood sample taken at the 20-week timepoint
2. Number of participants with HbA1c <48mmol/L on no medications measured using a blood sample taken at the 20-week timepoint
3. Change in diabetic medication (number of diabetic medications; change in anti-glycaemic medication effect score) measured using medical notes at the 20-week timepoint
4. Change in total cholesterol, LDL-cholesterol, total cholesterol:HDL ratio, triglycerides measured using a blood sample taken at the 20-week timepoint
5. Change in BP (systolic, diastolic) measured using a blood pressure monitor reading at the 20-week timepoint
6. Change in antihypertensive medication (number of medications measured using medical notes at the 20-week timepoint
7. Change in patient's well-being measured using the WHO-5 Well-Being Index (WHO-5) and the Problem Areas in Diabetes (PAID) scale score at the 20-week timepoint
8. Percentage of people who fulfil the recruitment criteria who accept the invitation to participate measured using study records at the baseline timepoint
9. Participant adherence to the protocol assessed by self-reported carbohydrate intake measured using an online food intake questionnaire at the 20-week timepoint
10. To see whether the control group may have also changed their carbohydrate intake (contamination), assessed by self-reported carbohydrate intake measured using an online food intake questionnaire at the 20-week timepoint
11. To explore the experience of the intervention for participants and the impact of the programme on participants' lives and behaviour measured using telephone interviews with participants and an online questionnaire at the 20-week timepoint

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. Male or Female, aged 18 – 65 years old
3. BMI equal to or over 27kg/m² (where individuals are from White ethnic groups) or equal to or over 25kg/m2 (where individuals are from Black, Asian and other ethnic groups)
4. Diagnosed with type 2 diabetes
5. Must have good IT skills (they can use a computer/smartphone)
6. Must complete baseline assessments

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
66

Key exclusion criteria
1. Currently diagnosed with type 2 diabetes but who are in remission using the NHS diabetes remission criteria, or who are recorded as not on diabetes medication and whose HbA1c levels on enrolment are <48mmol/mol at baseline
2. Currently using insulin injections
3. GLP1-agonists or SGLT2 inhibitors started in the six months before study enrolment
4. Diagnosed with a known eating disorder for whom the programme could be unsafe or require extensive monitoring to ensure safety
5. People who are pregnant or planning pregnancy
6. People who are breastfeeding
7. Diagnosed with a myocardial infarction or stroke in the past three months, or uncontrolled cardiac conduction abnormalities e.g. long QT syndrome.
8. Currently diagnosed with maculopathy or proliferative retinopathy
9. People with HbA1c ≥87mmol/mol
10. People with significant life-limiting illnesses that mean that remission is unlikely to improve health (severe cardiac failure, palliatively treated cancer, dementia), or other current severe illness
11. 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 eDIAMOND or the other research study/ies that they are participating in.
13. Taking part in or planning to take part in the NHS Pathway to Remission programme.

Date of first enrolment
01/07/2024

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Thames Valley and South Midlands Clinical Research Network
Unipart House, Nihr Crn: Thames Valley And South Midlands Offices Level 2 West, Garsington Rd, Cowley

Oxford
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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Programme Grants for Applied Research

Alternative Name(s)
NIHR Programme Grants for Applied Research, PGfAR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.2	03/01/2024	06/06/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes