ISRCTN62452621 https://doi.org/10.1186/ISRCTN62452621

Dietary Approaches to the Management Of type 2 Diabetes – feasibility study

Submission date
26/03/2018

Recruitment status
No longer recruiting

Registration date
04/04/2018

Overall study status
Completed

Last Edited
07/04/2022

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

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. However, it is not known whether this will work for everyone with diabetes, and whether this diet can be managed without intensive help from specialists. The aim of this study is to find out whether it is possible for GPs and practice nurses to support people with type 2 diabetes to change their diet: first to reduce their energy intake to around 800 calories per day for 8 weeks (mostly by cutting out carbohydrates, found in foods like cakes and biscuits but also bread, pasta, rice and potatoes), and second to gradually increase their energy intake while still severely restricting the amount of carbohydrate.

Who can participate?
Patients aged 18 and over with type 2 diabetes

What does the study involve?
Participants are randomly allocated to the control group or the intervention group. Participants in the control group receive usual care at their first study visit, including a face-to-face appointment with a healthcare professional during which they receive standard dietary and lifestyle information based on the Diabetes UK "healthy balanced diet" information sheets. If their managing GP or nurse feels that they warrant further diabetic care or input (for example, local diabetes education course, if they have not already completed this), and would ordinarily pursue this as part of their routine care outside of the study, they can pursue this as usual. The intervention group attends a behaviourally informed dietary programme, aiming to support patients to reduce their energy intake (to 800-1000kcal/day), reduce their carbohydrate intake, and eat fresh, healthy foods, over an 8-week period, before relaxing the energy and carbohydrate restriction over a further 4-week period. The intervention is delivered in a face-to-face appointment with a practice nurse and GP, and supported with three further face-to-face

visits to follow participants' progress and provide feedback. All participants are then seen again at 12 weeks to measure how well the advice is delivered and how successful people are in following the programme over a 3-month period.

What are the possible benefits and risks of participating?
The findings will help to refine the programme before a full-scale study to investigate whether this diet can improve blood sugar control more effectively than the standard dietary advice for people with diabetes. Participants may benefit from the dietary advice and behavioural support, and may achieve significant weight loss and improvements in their blood glucose control. There are no known serious risks from the dietary advice that is being given in this study. However, sometimes when people change their diet they can be more at risk of becoming constipated – this will be mitigated by advice to prevent this happening, with the option for laxatives if required. If participants are successful in losing weight and lowering their blood glucose levels, their GP may decide to suggest reducing some of their usual medications (for example, blood pressure or diabetes tablets), based on their blood pressure and blood glucose readings – this is to avoid the risk of their blood pressure or blood glucose becoming too low.

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

When is the study starting and how long is it expected to run for?
November 2016 to May 2022

Who is funding the study?
1. National Institute for Health Research (NIHR) (UK)
2. NIHR Oxford Biomedical Research Centre (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
37351

Study information

Scientific Title
A low-carbohydrate, low-energy dietary intervention for patients with type 2 diabetes in primary care: a feasibility study

Acronym
DIAMOND - feasibility

Study objectives
Current study hypothesis as of 11/03/2021:

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. We know that what we eat affects our blood sugar levels, and that changing our diets 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. However, we don't know whether this will work for everyone with diabetes, and whether this diet can be managed without intensive help from specialists.
We aim to investigate whether it is possible for GPs and practice nurses to support people with type 2 diabetes to change their diet. First to reduce their energy intake to around 800 calories per day for 8 weeks (mostly by cutting out carbohydrates, found in foods like cakes and biscuits but also bread, pasta, rice and potatoes), and second to gradually increase their energy intake while still severely restricting the amount of carbohydrate. We will measure how well the advice is delivered and how successful people are in following the programme over a 3 month period. The findings from this early stage testing will help to refine the programme before we progress to a full-scale study, to investigate whether this diet can improve blood sugar control more effectively than the standard dietary advice for people with diabetes.
For the extended follow-up study of this cohort, we aim to contact the original participants in the DIAMOND trial, to gain permission to gather data from their primary care records about their HbA1c and body weight following completion of the study, as well as collecting other information on their health, weight and diabetes control efforts.

Previous study hypothesis:
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Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 03/04/2018, South Central Oxford B Research Ethics Committee (Whitefriars Level 3, Block B, Lewin's Mead, Bristol, BS1 2NT; +44 (0)207 104 8235, +44 (0)207 104 8270; oxfordb.rec@hra.nhs.uk), ref: 18/SC/0071
2. Approved 24/02/2021, Preston Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ; +44 (0)207 104 8206; preston.rec@hra.nhs.uk), ref: 21/NW/0018

Study design
Randomised; Both; Design type: Treatment, Education or Self-Management, Dietary, Psychological & Behavioural, Complex Intervention, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Specialty: Primary care, Primary sub-specialty: Diabetes; UKCRC code/ Disease: Metabolic and Endocrine/ Diabetes mellitus

Interventions
Participants are randomly allocated in a 2:1 intervention:control ratio, using permuted block design randomisation, and allocation stratified by practice.

Control group:
Participants randomised to the control group will receive usual care at their week 0 study visit, comprising of a face-to-face appointment with a healthcare professional, during which they will receive standard dietary and lifestyle information based on the Diabetes UK "healthy balanced diet" information sheets. If their managing GP or nurse feels that they warrant for further diabetic care or input (for example, local diabetes education course, if they have not already completed this), and would ordinarily pursue this as part of their routine care outside of the trial, they can pursue this as usual.

Intervention group:
The intervention consists of a behaviourally informed dietary programme, aiming to support patients to reduce their energy intake (to 800-1000kcal/day), reduce their carbohydrate intake, and eat fresh, healthy foods, over an 8 week period, before relaxing the energy and carbohydrate restriction over a further 4 week period. The intervention will be delivered in a face-to-face appointment with a practice nurse and GP, and supported with 3 further face-to-face visits to follow participants' progress and provide feedback.

All patients will then be seen again at 12 weeks to collect outcome measures.

Total duration of intervention: 3 months (8 weeks + 4 weeks)
Follow-up: 3 months

Intervention Type
Behavioural

Primary outcome measure
The feasibility of the behavioural and dietary intervention, delivered in primary care, aiming to promote weight loss and improved glycaemic control, and whether to progress to a full-scale RCT. The measures of feasibility are:
1. The proportion of allocated intervention group participants who attempt the dietary intervention after randomisation, assessed through nurse documentation at intervention visit
2. Fidelity of intervention delivery: the proportion of essential elements included in intervention delivery sessions; evaluation of transcribed audio-recordings following intervention delivery visits, assessed against a checklist of essential elements
3. The proportion of enrolled participants who attend the final follow-up session, assessed at 12 weeks

Secondary outcome measures
Current secondary outcome measures as of 11/03/2021:
Process measures:
1. Percentage of eligible patients as a proportion of total practice population of patients with type 2 diabetes, assessed through trial data collected from practices at baseline
2. Proportion of patients who enrol in the study with "poor control" (HbA1c above the NICE

target of ≥7% (53mmol/mol), trial data collected at baseline visit
3. Percentage of people who fulfil the recruitment criteria who accept the invitation to participate, assessed through number of invitations sent and number of contacts to the study team at baseline
4. Participant adherence to the protocol, assessed via self-reported concordance at 2, 4, 8 and 12 weeks, and 24 hour dietary recall questionnaire at 2, 8 and 12 weeks
5. Contamination of control group (who choose to follow the principles of the dietary intervention, despite being allocated to the control group), assessed via 24-hour dietary recall questionnaires at baseline and 12 weeks

Effectiveness measures:
1. Change in HbA1C (including change in number of patients classified as having an HbA1c in the "diabetic", "at risk of diabetes", or "diabetes in remission" range), assessed via HbA1c blood test at baseline, 8 and 12 weeks
2. Change in fasting glucose and fasting insulin, converted into HOMA-B and HOMA-S, via blood test at baseline, 8 and 12 weeks
3. Change in weight, measured using a calibrated electronic scale at baseline and 12 weeks
4. Change in diabetic medication (number and dose of diabetic medications; initiation of new medication during study period; initiation of insulin; initiation of injectable diabetic medication), assessed via nurse reporting at 2, 4, 8 and 12 weeks
5. Change in lipid profile, blood test measured at baseline and 12 weeks
6. Change in LFTs (AST:ALT), blood test measured at baseline and 12 weeks
7. Change in urinary metabolomic profile, via urinary metabolomic analysis from urine sample at baseline, 2, and 12 weeks
8. Change in BP (systolic, diastolic), measured using an electronic BP monitor at baseline and 12 weeks
9. Change in antihypertensive medication, measured via nurse reporting at baseline and 12 weeks
10. Change in medication prescribing costs (total and diabetic) across study group and total practice diabetic population, measured at baseline and 12 weeks
11. Effect on patient's problem areas in diabetes (PAID) score, measured using validated questionnaire at baseline and 12 weeks

Qualitative measures:
Acceptability and experience of the intervention for patients and healthcare professionals, assessed via qualitative focus groups after 3 month study follow up completed

Outcome measures at extended follow up:
1. Weight measured using scales at baseline and follow up
2. HbA1c measured from blood samples taken at baseline and follow up
3. Proportion of participants achieving ≥5% and ≥10% weight loss measured using scales at baseline and follow up
4. Mean systolic and diastolic blood pressure measured using sphygmomanometer at baseline and follow up
5. Lipid profile measured from blood samples taken at baseline and follow up

Exploratory outcomes at extended follow up:
1. 10-year cardiovascular risk measured using the QRISK2 score at baseline and follow up
2. Achievement of diabetes remission at any point after enrolment in the study, from baseline to follow up, and between the end of the intervention and follow up, measured from patient notes between baseline and follow up
3. Weight regain between the end of the intervention and follow up measured using scales at 12

weeks and follow-up
4. Medication usage for treatment of diabetes and other cardiovascular risk reduction, including the treatment of hyperlipidaemia and hypertension measured from patient notes between baseline and follow up
5. Ongoing weight management strategies and self-reported dietary intake (for participants consenting to optional additional contact) measured through participant interview including self-reported current weight loss attempts, and the methods used to do so, and self-reported dietary patterns (including the adoption of low-carbohydrate or low-calorie diet principles, and strategies used to achieve these) at follow up

Previous secondary outcome measures:
Process measures:
1. Percentage of eligible patients as a proportion of total practice population of patients with type 2 diabetes, assessed through trial data collected from practices at baseline
2. Proportion of patients who enrol in the study with "poor control" (HbA1c above the NICE target of ≥7% (53mmol/mol), trial data collected at baseline visit
3. Percentage of people who fulfil the recruitment criteria who accept the invitation to participate, assessed through number of invitations sent and number of contacts to the study team at baseline
4. Participant adherence to the protocol, assessed via self-reported concordance at 2, 4, 8 and 12 weeks, and 24 hour dietary recall questionnaire at 2, 8 and 12 weeks
5. Contamination of control group (who choose to follow the principles of the dietary intervention, despite being allocated to the control group), assessed via 24-hour dietary recall questionnaires at baseline and 12 weeks

Effectiveness measures:
1. Change in HbA1C (including change in number of patients classified as having an HbA1c in the "diabetic", "at risk of diabetes", or "diabetes in remission" range), assessed via HbA1c blood test at baseline, 8 and 12 weeks
2. Change in fasting glucose and fasting insulin, converted into HOMA-B and HOMA-S, via blood test at baseline, 8 and 12 weeks
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9. Change in antihypertensive medication, measured via nurse reporting at baseline and 12 weeks
10. Change in medication prescribing costs (total and diabetic) across study group and total practice diabetic population, measured at baseline and 12 weeks
11. Effect on patient's problem areas in diabetes (PAID) score, measured using validated questionnaire at baseline and 12 weeks

Qualitative measures:
Acceptability and experience of the intervention for patients and healthcare professionals, assessed via qualitative focus groups after 3 month study follow up completed

Overall study start date
01/11/2016

Completion date
30/09/2019

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 years or above
3. BMI of ≥30kg/m2
4. Diagnosed with type 2 diabetes
5. Patients must have undergone diabetic retinopathy screening within the last 12 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 38; UK Sample Size: 38

Total final enrolment
33

Key exclusion criteria
1. History of, or features suspicious of, an eating disorder
2. Pregnant, breastfeeding, currently undergoing fertility treatment, or planning to become pregnant during the course of the study
3. Recent MI or CVA (<3 months)
4. Uncontrolled ischaemic heart disease, critical ischaemia, uncontrolled hypertension, uncontrolled cardiac arrhythmia (eg inadequate rate control in AF, inadequate episode control paroxysmal AF), cardiac conduction abnormality (eg long QT syndrome)
5. Cardiac failure (Grade II New York Heart Association, and more severe)
6. Renal failure (CKD Stage 4 or 5)
7. Active treatment for cancer (other than skin cancer treated with curative intent by local treatment only)
8. Intercurrent serious infection at time of recruitment
9. Diagnosed with a significant psychiatric disorder or substance abuse
10. Serious neurological disorder, including epilepsy
11. Recently undergone significant surgery (<6 months)
12. History of bariatric surgery, including gastric banding

13. Are currently using a “fasting”/low-energy diet
14. Unwilling to consider any dietary changes
15. Unable to understand English
16. Are currently using insulin therapy, or SGLT2 inhibitors (Glifozins – e.g. empaglifozin, dapaglifozin, canaglifozin)
17. Non-proliferative retinopathy level R2 or worse (ie, any level more severe than “background” non-proliferative diabetic retinopathy, R1), proliferative diabetic retinopathy, or maculopathy
18. HbA1c ≥ 93mmol/mol (10.5%)
19. Recruiting physician feels they are inappropriate for recruitment due to any other reason

NB: If the patient is taking warfarin, they are not excluded from participating in the study, but will be advised to inform their local monitoring service about their participation, and they may be advised to have additional blood test monitoring of their INR as part of their care.

Date of first enrolment
27/04/2018

Date of final enrolment
30/01/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Nuffield Department of Primary Care Health Sciences
University of Oxford Radcliffe Primary Care Building
Radcliffe Observatory Quarter
Woodstock Road
Oxford
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OX2 6GG

Sponsor information

Organisation
University of Oxford

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR); Grant Codes: 404

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

Funder Name
NIHR Oxford Biomedical Research Centre

Results and Publications

Publication and dissemination plan

The trialists intend to publish the study protocol in a peer-reviewed journal. The investigators within the central research team will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Publication of the study results in a peer-reviewed journal is intended by September 2020.

Intention to publish date
01/09/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made 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?
Statistical Analysis Plan	version V1.0	08/03/2019	26/03/2019	No	No
Protocol article	protocol	17/01/2019	24/02/2020	Yes	No
Results article	results	01/04/2020	06/10/2020	Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No