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LOGIC (LOw carbohydrate diets for Glucose Control in type 2 diabetes)

Submission date
12/04/2024

Recruitment status
No longer recruiting

Registration date
17/04/2024

Overall study status
Completed

Last Edited
02/05/2024

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] 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 common disease in which a person's blood glucose levels are too high. We know that what we eat affects our blood glucose levels, and that changing our diets and losing weight can both help to control type 2 diabetes. However, it is not clear what the best advice is to help people achieve this goal. We know that it is possible for some people to improve their blood glucose levels by following a low-carbohydrate diet (cutting out starchy and sugary foods), but it is not clear whether the benefits come from eating less carbohydrate itself, or from losing weight at the same time (from eating less overall). We want to help answer this question by comparing two sorts of low-carbohydrate diets – one designed to help people lose weight at the same time, and one where people stay at the same weight but improve their blood glucose levels by changing the food they eat. This will help us give better advice to people living with type 2 diabetes about what is the right diet for them, to help them achieve their health goals.

Who can participate?
We are looking for 30 people who have type 2 diabetes to take part in this study.

What does the study involve?
This study will compare two types of low-carbohydrate eating plans (reducing the amount of starchy and sugary foods) – one will involve eating the same number of calories as usual each day, and one weight loss diet which will involve reducing the number of calories eaten each day to help weight loss (around 2-4kg over the 4 week diet period).
Participants will be randomly allocated (like tossing a coin) to one of these two eating plans. Food won't be provided as part of this study, however, we will provide information and support to follow the eating plans at home. Participants will wear a device on their arm which measures blood glucose levels constantly throughout the day and night. Participants will attend three study visits at their local GP practice, where they will meet with one of the research team. During these visits, participants will be asked to answer some questions about diet and medication, complete questionnaires, and give blood samples. With the GP's approval, we may pause some regular medication at the start of the study to prevent low blood sugar and low blood pressure. Weight and blood pressure will be monitored throughout the study.

What are the possible benefits and risks of participating?
Benefits
- We hope that most people who try the eating plans in this study will see some improvements in their blood glucose levels, which can be beneficial to health and general wellbeing.
- Many people with type 2 diabetes are keen to experience using a continuous glucose monitor (CGM), as these are not usually available on the NHS for this condition but can help with understanding how the diet affects blood glucose levels. Participants will get a 4 week period of CGM if you take part in this study.
- Knowledge gained in this study will help our research and in the future may help us advise people with diabetes about which types of diets might be most helpful for them.

Risks
- There are no known serious risks from the dietary advice that is being given in this study.
- Some people find blood tests temporarily uncomfortable, or that they can develop a small bruise afterwards.
- Some people may experience constipation if they reduce the amount of food they are eating during a weight loss diet, but we will give advice on how to avoid this if allocated to follow the weight loss diet.
- Some people will experience improvements in their blood sugar and/or blood pressure when following these eating plans, which could lead to someone experiencing low blood sugar or low blood pressure levels, but we will monitor blood pressure throughout the study and help manage medication to avoid this.
- If participants take warfarin medication, changes in diet could lead to a changes in INR levels, participants will be advised to inform the team monitoring INR levels that they will be following a new eating plant for 4 weeks and may recommend an additional blood test to monitor for any changes.

Where is the study run from?
This study is being run from GP practices in the Oxfordshire area (UK)

When is the study starting and how long is it expected to run for?
July 2023 to April 2025

Who is funding the study?
This study is funded by the National Institute for Health Research (NIHR) Biomedical Research Centre (BRC) in Oxford, and the Wellcome Trust (UK)

Who is the main contact?
Dr Sam West, LOGIC@phc.ox.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
334413

Central Portfolio Management System (CPMS)
58895

Study information

Scientific Title
Disentangling the contribution of weight loss and diet composition on glycaemia in type 2 diabetes

Acronym
LOGIC

Study objectives
We aim to assess whether a low carbohydrate diet can improve glycaemic control in patients with type 2 diabetes with and without weight loss. We hypothesise that we will observe a greater improvement in glycaemic control in the low carbohydrate diet with weight loss group compared with the low carbohydrate diet without weight loss group.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/03/2024, HRA and Health and Care Research Wales (HCRW) (15 Cowbridge Road, Cardiff, CF11 9AB, United Kingdom; +44 2920 230457; HCRW.approvals@wales.nhs.uk), ref: 24/LO/0070

Primary study design
Interventional

Study design
Observational (pre-post) dietary intervention study with secondary comparison between randomised groups

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Type 2 diabetes

Interventions
Participants will have blood glucose monitored for 2 weeks before randomisation.

Then participants will be randomly allocated to receive:

Diet A: Low carbohydrate, low-energy food-based diet 800-1000kcal/day; (<26%% total energy from carbohydrate, absolute carbohydrate content approx. 60-65g/day).

Diet B: Low carbohydrate “ad libitum” (eucaloric) diet (no energy restriction, aiming for no significant weight change; estimated 2000-2500kcal/day; <26% total energy from carbohydrate – absolute carbohydrate content approx. 125g/day).

The dietary intervention lasts for 4 weeks.

Intervention Type
Behavioural

Primary outcome(s)
Glycaemic control measured using continuous glucose monitoring. Participants will wear the monitor for the entire 6-week duration of the study.

Key secondary outcome(s)
1. Glycaemic control measured using continuous glucose monitoring. Participants will wear the monitor for the entire 6-week duration of the study
2. Cardiometabolic risk - assessed via changes in blood lipids (Total-, HDL-, LDL- cholesterol and triglycerides), liver function (bilirubin, ALT and ALP) and blood pressure at baseline, at the end of the 2-week habitual phase and at the end of the 4-week intervention phase
3. Subjective measures of appetite - assessed using VAS scores for hunger fullness, desire to eat and planned consumption using Ecological Momentary Assessment once per week during the habitual and intervention phase
4. Body composition - assessed as body mass, impedance, waist and hip circumference at baseline, at the end of the 2-week habitual phase and at the end of the 4-week intervention phase

Completion date
28/04/2025

Eligibility

Key inclusion criteria
1. Participants willing and able to give informed consent.
2. Adult male or female, aged 18-70 years old.
3. Diagnosed with current type 2 diabetes (i.e. not in remission).
4. BMI of > = 27kg/m².
5. Has a smartphone with internet access and compatible with continuous glucose monitoring (CGM) technology, and participant is willing and able to use this.
6. Is willing and able to change their diet for the study period.
7. Willing to pause one or more usual medications if required for duration of study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Key exclusion criteria
1. Pregnant, breastfeeding, or planning to become pregnant during the course of the study.
2. Recent weight loss (> 2kg in last 4 weeks; self-reported).
3. People who are already following a specific restricted diet.
4. Are currently taking more than two prescribed medications for diabetes glycaemic control.
5. People with HbA1c > = 87 mmol/mol.
6. Are currently using insulin therapy, SGLT2 inhibitors (Gliflozins – eg empaglifozin, dapagliflozin, canagliflozin), or GLP-1 agonists (e.g. exenatide, lixisenatide, liraglutide, dulaglutide and semaglutide).
7. Previous or current eating disorder (or any other psychological condition) that may affect the participant's ability to adhere to study intervention/experimental diets.
8. Recent myocardial infarction or stroke (< 3 months).
9. Renal failure (chronic kidney disease stage 4 or 5).
10. Current active treatment for cancer (other than skin cancer treated with curative intent by local treatment only).
11. Proliferative diabetic retinopathy, or maculopathy.
12. GP feels inappropriate to take part in study (e.g. unable to attend study visits; end of life care, or would not benefit from weight loss or improved diabetes control).
13. Most recent (non-fasting or fasting) triglyceride level > 5 mmol/l.

Date of first enrolment
15/04/2024

Date of final enrolment
30/12/2024

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

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Oxford Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre, Oxford, OxfordBRC, OxBRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data sets generated during and/or analysed during the current study will be made available upon request from Dr Sam West (sam.west@phc.ox.ac.uk)

IPD sharing plan summary

Available on request, Data sharing statement to be made available at a later date