ISRCTN14165221 https://doi.org/10.1186/ISRCTN14165221

Replacing some of the starch in the diet with fibre to manage blood glucose levels in those with type 2 diabetes.

Submission date
18/03/2019

Recruitment status
No longer recruiting

Registration date
03/04/2019

Overall study status
Completed

Last Edited
09/12/2020

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English Summary
Background and study aims
In those with type 2 diabetes (T2D), insulin production is reduced or impaired, leading to higher blood sugar levels. Therefore good control of blood sugar is vital to avoid long term complications, such as damage to the blood vessels. Controlling the amount of carbohydrate (reducing starch and sugar whilst increasing fibre intake) consumed can help manage T2D, by lowering post meal blood glucose levels. It is recommended that the daily diet consist of 50% carbohydrate, however there is little evidence to support recommendations of carbohydrate intake in those with T2D, despite starch making up a substantial part of the daily diet. Additionally, there is misinformation amongst the general public in respect of carbohydrates in terms of what the evidence-base actually shows in terms of the effects on blood glucose. General advice is to replace “white” carbohydrates such as bread and pasta, with “wholegrain” alternatives, however there is resistance in consuming these alternatives, and in reality they contain similar amounts of starch/fibre to “white” carbohydrates, labelling a food “wholegrain” can lead to perception that it is a high fibre product which is confusing. Our comparison of “white bread” versus “wholewheat” bread, demonstrated there was no difference in blood glucose response between the two because there was no difference in digestible starch. Therefore when addressing dietary carbohydrate, the focus must be on the “starch” component of the diet. A health claim was recently approved by the European Food Safety Authority in 2011 due to the weight of evidence, in that replacing only 14% rapidly digestible starch with resistant starch (a type of fibre), can reduce post meal blood glucose levels, however this same effect has not been tested in those with T2D. The aim of this study is to observe the effect of replacing a proportion of starch (not the type of food) with resistant starch in the diet, on blood glucose levels in patients with T2D. Study objectives include: recruiting 20 patients with T2D from local population in Surrey, who meet our inclusion criteria, and primarily recruited through GP surgeries, via local primary care research network. Eligible participants will screened to determine suitability, and if they wish to take part, consent will be obtained. Participants will they undertake a dietary intervention study to examine the effects of 2 x 4 day diets that differ only in their composition of starch, in a randomised order. Non-invasive subcutaneous continuous glucose monitoring will be undertaken during each 4 day period.

Who can participate?
We are inviting people who have been living with T2D for more than 6 months, aged 18-70 to take part, and taking part will involve:

What does the study involve?
Screening: This visit will last approximately 90 minutes, during which time you will complete questionnaires relating to your health and current medication. Height and weight will be recorded, and a fasting blood sample will be collected to assess if you are healthy enough to take part, and allow a baseline HbA1c for you. Your diet will be discussed with a dietician, to determine your normal diet, including likes and dislikes from the food options that are available for the trial.
Study days: You will need to attend the Clinical Investigation Unit (CIU) at the University of Surrey on two separate occasions to be fitted with a glucose monitor to continuously measure your glucose levels over a period of 5 days. The continuous glucose monitors (CGM) are small remote devices, the size of a two pence piece, that sit flush with the skin in a discreet location, once fitted.
The two periods of monitoring consist of the following:
i) A CIU visit, followed by 4 days of dietary intake “diet 1” as per the diet plan provided (control diet), with 50% total energy as digestible starch.
ii) A CIU visit, followed by 4 days of dietary intake “diet 2” as per the diet plan provided (resistant starch diet), with 20% digestible starch replaced with resistant starch.
There will be at least a week between the 2 test diets. Only the 4 day intervention will you be asked to eat only meals on the diet sheet provided to you. You will calibrate the CGM you are wearing, using a lancet device to measure your blood glucose prior to eating and recording this figure. Removal of the CGM will take 5 mins at the CIU on day 6. You are are free to withdraw at any time, including your data prior to the final download on of CGM day 4.

What are the possible benefits and risks of participating?
The benefits of participating include: increased understanding of the role of food in blood glucose management. A report of the CGM data collected during the study can be used form links between dietary habits and blood glucose, which could be considered more efficacious than a single blood sample. Studies like this, can help future dietary guidelines for diabetes management, which may be different from that recommended as part of normal healthy eating. We do not anticipate there to be any risks to taking part as the foods provided come from commercial sources. The CGM are routinely used in clinical practice for the monitoring of free living out-patients. They are deemed safe and non-intrusive. Participants are free to bathe and shower as normal, or go swimming. As the study involves modification to your diet and visits to the University of Surrey campus, participants will be recompensed £200 plus reasonable travel expenses on completion of all study visits.

Where is the study run from?
The study will be run solely from the: University of Surrey, Guildford, FHMS Clinical Investigation Unit (CIU) (UK).

When is the study starting and how long is it expected to run for?
Recruitment is expected to start on 1st July 2019, and will continue for 12 months, during which time the study will continue, ending when data has been collected, and it is anticipated that analysis will begin July 2020.

Who is funding the study?
The project is being funded by Diabetes UK [www.diabetes.org.uk]

Who is the main contact?
Principal Investigator: Dr Denise Robertson, Reader in Nutritional Physiology, Faculty of Health and Medical sciences, Leggett Building, Manor Road Campus, Guildford, GU2 9NR; m.robertson@surrey.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Sineaid Collins

Contact details
Faculty of Health and Medical Sciences
Leggett Building
Manor Park Campus
Guildford
United Kingdom
GU2 7YW
+44(0)1483 686993
s.m.collins@surrey.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
240102

Study information

Scientific Title
Carbohydrate in the diet. A starch exchange model for managing glycaemia in type 2 diabetes.

Study hypothesis
Replacing some of the starch in the diet with resistant starch, will reduce blood glucose levels in those with type 2 diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 24/08/2018, NHS HRA South West - Cornwall & Plymouth Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; 0207 104 8059; nrescommittee.southwest-cornwall-plymouth@nhs.net), ref: REC 18/SW/0204 IRAS number 240102.

Study design
Single centre single blinded randomised controlled crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Home

Study type(s)
Quality of life

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

Condition
Type 2 diabetes

Interventions
Participants will consume either diet 1 or diet 2 for 4 consecutive days. Control diet is “diet 1” and will include 50% carbohydrate comprising standard starch versions of bread, pasta and snack crackers. A one week break will then follow prior to commencement of the alternate treatment period in which the alternate diet is consumed for 4 days consecutively. “Diet 2” will have 20% of the digestible starch being replaced with resistant starch, a type of fibre. This will include high fibre versions (using resistant starch) of pasta, bread and crackers. Both "diet 1" and "diet 2" will be the same in nutrient composition, except for starch/fibre content.
As part of the screening process, the potential participant’s diet will be discussed with a dietitian, and “diet 1” and “diet 2” in order to personalise the diet to ensure it is within daily recommendations of fat, protein and carbohydrate and energy intake, based on height and weight.
Participants will be fitted with a glucose monitor to continuously measure glucose levels.

Intervention Type
Supplement

Primary outcome measure
Postprandial glucose (MAGE) excursion resulting from consumption of both diets. The MAGE calculation will be made by measuring the arithmetic mean of the difference between consecutive peaks and nadirs. Blood glucose will be measured continuously, however time points of interest are: 8.15am-9.00am (post breakfast), 10.30am-11.15am (post snacks), 12pm-12.45pm (post lunch), 6.00pm-6.45pm (post dinner).

Secondary outcome measures

1. Peak postprandial glucose excursion after meals
2. The time to peak postprandial glucose excursion
3. Mean blood glucose
4. The standard deviation of blood glucose
5. 24-hour glucose area under the curve (AUC).
Blood glucose will be measured continuously, however time points of interest are: 8.15am-9.00 am (post breakfast), 10.30am-11.15am (post snacks), 12pm-12.45pm (post lunch), 6.00pm-6.45 pm (post dinner).

Overall study start date
01/05/2019

Overall study end date
06/12/2020

Eligibility

Participant inclusion criteria
1. Patients with a diagnosis of type 2 diabetes > 6 months,
2. Males and females,
3. 18-70yrs,
4. Access to a kitchen,
5. Ability to understand English (to provide informed consent).

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
20

Total final enrolment
20

Participant exclusion criteria
1. Use of insulin and GLP-1 analogues,
2. History of gastroperesis or gastric surgery,
3. Coeliac disease/wheat intolerance,
4. Irritable bowel syndrome,

5. HbA1c >75 mmol/mol,
6. Pregnancy/breast-feeding,
7. Excess alcohol intake,
8. Glucose-lowering drug dosage adjustment within the previous month.

Recruitment start date
01/06/2019

Recruitment end date
06/12/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Investigation Unit (CIU) University of Surrey
University of Surrey
Guildford
United Kingdom
GU2 7XH

Sponsor information

Organisation
University of Surrey

Sponsor details
388 Stag Hill,
Guildford
Guildford
England
United Kingdom
GU2 7XH
+441483 300800
ris@surrey.ac.uk

Sponsor type
University/education

Website
https://www.surrey.ac.uk

ROR
https://ror.org/00ks66431

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK

Alternative Name(s)
DIABETES UK LIMITED, British Diabetic Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A lay summary of the data from the whole study will be provided to participants.
Publication of the data in peer reviewed journals
Presentation of results at conferences and to patient voluntary groups.

Intention to publish date
01/09/2021

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No