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Can dietary changes lead to remission of type 2 diabetes even if a person does not lose weight?

Submission date
13/02/2020

Recruitment status
Suspended

Registration date
26/02/2020

Overall study status
Completed

Last Edited
04/04/2023

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
Significant weight loss (more than 10 kg) can help a large majority of people to come off their medications and achieve remission of their type 2 diabetes. However, for many people, weight loss might not be possible or desired. Promising studies show that low-carbohydrate diets can reduce blood sugar to the level of someone without type 2 diabetes without any weight loss. However, these low-carbohydrate diets also included a lot of high-protein foods. Protein might help the pancreas produce more insulin. Therefore it is not clear whether carbohydrate restriction alone is enough to normalise blood sugar. This study will test the effect of changing the amount of protein in the diet while people are on a low-carbohydrate diet in people with and without type 2 diabetes.

Who can participate?
People aged 45 to 60 with and without type 2 diabetes

What does the study involve?
Participants will come to the University of Westminster (115 New Cavendish Street, London W1W 6UW) for a medical screening. This should take about half an hour. If the participant meets the inclusion criteria at the screening, they will be formally invited to take part. If the participant agrees to take part will arrange the study visits. They will be randomly allocated to receive either the high-protein diet or the low-protein diet first. An individualized meal plan will be created for them. In addition, they will be provided with some study foods to help them meet the carbohydrate and protein targets of the study. They will follow this diet for 2 weeks, and then switch. So, if they were on the high-protein diet for 2 weeks, they will switch to the low-protein diet for 2 weeks and vice versa. On the fifth and final week, they will then switch you back to the diet they had in week 1 and 2. People will not lose weight in this study. The aim of the study is to see whether lowering carbohydrate and/or increasing protein lowers blood glucose without weight loss. Therefore, a really important aspect of this study is that the study is not designed to achieve weight loss. Participants will be given weighing scales so that they can weigh themselves daily. The weighing scales will be Bluetooth enabled so that participants' daily weights are sent to the study team. If a participant starts to lose weight the study team will instruct them to eat more of certain foods. If a person gains weight the study team will instruct them to eat less of certain foods. The study team will use a Dexcom G6 continuous glucose

monitor to measure participants' blood glucose throughout the study (https://www.dexcom.com/en-GB). This device uses a sensor which is inserted just under the skin using an automatic applicator. This should be no more uncomfortable than a simple blood test. A small, reusable transmitter connects to the sensor and records blood glucose every 5 minutes 24 hours a day. The study team will replace the sensor every 8/9 days during the 5-week study and remove it on the final day. Participants will need to attend the University of Westminster approximately once every 8/9 days for a weigh-in, to collect study foods and for replacement of the Dexcom G6 glucose monitor.

What are the possible benefits and risks of participating?
A disadvantage is the time and inconvenience as this study will require daily weighing during the 5 weeks, and to stick to the assigned diet. The Dexcom G6 could cause some discomfort when it is placed, but this should be no more uncomfortable than any normal blood test. The sensor adhesive of the Dexcom G6 can cause an allergic reaction in some people. If this occurs the study team can remove the sensor until any reaction subsides, and then replace the Dexcom G6 with an alternative adhesive.

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

When is the study starting and how long is it expected to run for?
May 2018 to September 2020

Who is funding the study?
Diabetes Research and Wellness Foundation (UK)

Who is the main contact?
Dr Nicola Guess
guessn@westminster.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Nicola Guess

Contact details
Principal Investigator
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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Towards remission of type 2 diabetes without weight loss

Study objectives
That a low-carbohydrate, high-protein diet lowers blood glucose more than a low-carbohydrate, low-protein diet.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/12/2019, University of Westminster Liberal Arts and Sciences Research Ethics Committee (Mandy Walton, College Support Officer, College of Liberal Arts & Sciences, Room 4.102A, 115 New Cavendish Street, London, W1W 6UW, UK; +44 (0)20 3506 4178; M.J. Walton@westminster.ac.uk), ref: ETH1819-2029

Study design
Single-centre randomised crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Home

Study type(s)
Treatment

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

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

Interventions
Participants will follow a low-carbohydrate diet for 5 weeks and be randomized to high>low>high protein or low>high>low protein diets while the carbohydrate intake remains constant. The first two dietary assignments will last for 2 weeks each, and the final dietary assignment will last for one week only. Carbohydrate will be kept at 20% of energy intake. The low-protein diet is defined as 15% of energy intake and the high protein diet is defined as 30% of energy intake. There will be no wash-out period. Continuous glucose monitoring will be used to assess 24-hour glucose concentrations throughout the study.

Intervention Type
Behavioural

Primary outcome measure
24-hour glucose concentrations measured using the Dexcom G6 during the high protein versus the low protein dietary periods

Secondary outcome measures
1. Fasting glucose concentrations measured using the Dexcom G6 during the high protein versus the low protein dietary periods
2. Post-prandial glucose concentrations for 3 hours following a meal (to be identified from the glucose profiles) measured using the Dexcom G6 during the high protein versus the low protein dietary periods
3. Mean amplitude of glucose excursions measured using the Dexcom G6 during the high protein versus the low protein dietary periods
4. High blood glucose index measured using the Dexcom G6 during the high protein versus the low protein dietary periods
5. Change in bodyweight measured using BlueTooth enabled scales from the first day to the last day of each low protein and high protein period
6. Mean steps per day measured by pedometer during the high protein versus the low protein dietary periods

Overall study start date
01/05/2018

Completion date
30/09/2020

Eligibility

Key inclusion criteria
This study will recruit 15 people with type 2 diabetes and 15 people without type 2 diabetes

Inclusion criteria for all participants:
1. Males and post-menopausal females
2. Aged 45 to 60 years
3. BMI of 23 to 35 kg/m²
4. Reporting a stable weight for 3 months prior to study commencement
5. Must be able to give informed consent, and be willing to follow the diets as described in the telephone screening

Specific criteria for group with type 2 diabetes:
1. Must be diagnosed within the last 3 years
2. T2D must be diet-controlled or on metformin only

Specific criteria for group without type 2 diabetes:
1. Must have no family history of diabetes

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Kidney disease
2. Type 1 diabetes
3. Liver disease
4. Hematologic abnormalities
5. Congestive heart failure
6. Untreated thyroid disease

Date of first enrolment
09/01/2020

Date of final enrolment
31/07/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Westminster
101 New Cavendish St, Fitzrovia
London
United Kingdom
W1W 6XH

Sponsor information

Organisation
University of Westminster

Sponsor details
115 New Cavendish Street
London
England
United Kingdom
W1W 6XH
+44 (0)20 7911 5000
Research-Office@wesminster.ac.uk

Sponsor type
University/education

Website
https://www.westminster.ac.uk/about-us/visit-us/cavendish

ROR
https://ror.org/04ycpbx82

Funder(s)

Funder type
Charity

Funder Name
Diabetes Research and Wellness Foundation

Alternative Name(s)
Diabetes Research & Wellness Foundation, Diabetes Research and Wellness Foundation UK, DRWF

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
The researchers will publish in an academic journal which will be made open access immediately. Additional documents will not be available.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Nicola Guess (GuessN@westminster.ac.uk). The data available will be the complete CGM datasets for each individual once the primary findings are published. The data will be completely anonymised - only gender, T2D status, BMI and age will be available. Written consent was obtained for all participants.

IPD sharing plan summary
Available on request