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A pilot study to look at the efficacy of a dietitian-led intervention using a homemade Very Low Calorie Diet (VLCD) to achieve prevention or remission of type 2 diabetes.

Submission date
27/07/2021

Recruitment status
No longer recruiting

Registration date
07/09/2021

Overall study status
Completed

Last Edited
04/04/2024

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 condition that causes the level of sugar (glucose) in the blood to become too high.
This is a pilot study between the NHS and University of the Highlands and Islands to investigate the efficiency of a dietitian led, homemade, Very Low Calorie Diet (VLCD) on the prevention as well as reversal of type 2 diabetes.
Similar studies have shown the reversal of type 2 diabetes and we aim to see if prevention is possible.

Who can participate?
30 patients with pre-diabetes or early diagnosis (within 4 years) of type 2 diabetes, between the ages of 20 - 70 years, will be able to take part as long as they meet our inclusion criteria.

What does the study involve?
Over a total period of 48 weeks after recruitment, participants will go through 3 different Phases after recruitment.
• Recruitment: Consent, Blood samples and body measurements done.
• Phase 1: 12 weeks of homemade Very Low Calorie Diet. Bloods and body measurements done. Contact with study Dietitian every 2 weeks.
• Phase 2: 12 weeks of food reintroduction. Bloods and body measurements done. Contact with study Dietitian every 2 weeks.
• Phase 3: 12 weeks of Weight maintenance. Bloods and body measurements done.
At each stage, participants will be invited to attend the Diabetes Centre at the Centre for Health Science in Inverness for bloods and measurements to be done. Blood samples are taken by venepuncture by a qualified research nurse, and body measurements may be taken by the research nurse or study dietitian.

What are the possible benefits and risks of participating?
Blood samples are taken by venepuncture by a qualified research nurse, and body measurements may be taken by the research nurse or study dietitian.
Blood sample analysis will in the main be done by Raigmore hospital and the participant will be able to access these results through their GP. Any results which fall outside normal parameters will be reported by researchers to the Chief Investigator, Professor Sandra MacRury, Consultant Diabetologist, who will make the decision for the study dietitians to contact the participant or their GP.

Where is the study run from?
University of the Highlands and Islands (UK)

When is the study starting and how long is it expected to run for?
October 2020 to August 2023

Who is funding the study?
Scottish Government Diabetes Prevention Strategy Group (UK)

Who is the main contact?
Prof Sandra MacRury, sandra.macrury@uhi.ac.uk
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Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
292369

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 292369

Study information

Scientific Title
A pilot study to look at the efficacy of a dietitian-led intervention using a homemade Very Low Calorie Diet (VLCD) in patients with early Type 2 Diabetes or pre-diabetes, to achieve the outcomes of either prevention or remission of Type 2 Diabetes.

Acronym
VLCD T2D

Study objectives
Homemade VLCD intervention and subsequent dietary input can prevent or reverse Type 2 Diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/05/2021, North of Scotland Research Ethics Committee 1 (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224 558458, gram.nosres@nhs.scot), ref: 21/NS/0055

Study design
Pilot single centre open interventional study with no control group

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Prevention or reversal of type 2 diabetes in participants with pre-diabetes or type 2 diabetes diagnosed within the previous 4 years.

Interventions
All participants will be recruited to the Homemade VLCD intervention and they will have baseline blood samples and anthropometric measurements done. In addition they will complete a health questionnaire and an eating habits questionnaire. There are 3 phases to the trial as follows.
1. 12 week VLCD intervention when all diabetes medication will be stopped. They will have contact with a study dietitian every 2 weeks. At week 4 they will complete a diet acceptability questionnaire. Blood samples and anthropometric measurements, they will complete a health questionnaire and an eating habits questionnaire at end of 12 weeks.
2. 12 week food reintroduction with dietetic guidance. They will again have contact with a study dietitian every 2 weeks. Blood samples and anthropometric measurements and they will complete a health questionnaire and an eating habits questionnaire at end of 12 weeks.
3. 12 weeks of weight management support, again contact with a study dietitian every 2 weeks. Bloods and anthropometric measurements at end of 12 weeks, and they will complete a health questionnaire and an eating habits questionnaire.
Final bloods and anthropometric measurements and health questionnaire and eating habits questionnaire at end of 12 weeks (week 48 of study).

Intervention Type
Behavioural

Primary outcome measure
1. HbA1c is measured by Raigmore Hospital Biochemistry department at baseline, and 12, 24, 36, and 48 weeks.
2. Weight (kg) is measured at baseline, 12, 24, 36, and 48 weeks by NHS research nurse team staff using standard Diabetes clinic scales.
3. Waist circumference (cm) is measured at baseline, 12, 24, 36, and 48 weeks by NHS research nurse team staff using standard Diabetes clinic measuring tape.
4. BMI (kg/m^2) is calculated, by research staff using height taken at baseline and weight at baseline 12, 24, 36, and 48 weeks.

Secondary outcome measures
1. Redoxiperoxin and Glutathione is analysed by UHI Division of Biomedical Sciences by way of a novel ALISA technique, Antibody linked Oxi-State Assay and/or HPLC-ECD. All samples will be stored on arrival in the UHI labs and batch analysed at the end of the collection period.
2. Diet Acceptability is measured by way of questionnaire at 4 weeks.
3. Self regulation of eating is measured at baseline, 12, 24, 36, and 48 weeks by way of Self Regulation of Eating Behaviour questionnaire (SREBQ)
4. Quality of life is measured at baseline, 12, 24, 36, and 48 weeks by way of Health Questionnaire EQ-5D-5L

Overall study start date
30/10/2020

Completion date
23/08/2023

Eligibility

Key inclusion criteria
1. Informed written consent
2. Men and women with prediabetes (HbA1c 42 - 47 mmol/mol)
3. Men and women with Type 2 Diabetes, on diet, monotherapy or dual therapy within 4 years of diagnosis and not taking insulin
4. BMI >35kg/m²
5. Age 20 - 70years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30 participants

Total final enrolment
26

Key exclusion criteria
1. BMI < 35 kg/m²
2. HbA1c >100mmol/mol
3. Insulin use
4. Pregnant or planning pregnancy
5. Diagnosed eating disorder
6. Renal function eGFR <30ml/min
7. Myocardial Infarction (MI) withing previous 6 months
8. Severe heart failure

9. Taking part in another research study
10. Cancer
11. Liver disease but not excluding Non Alcoholic Fatty Livr Disease (NAFLD)
12. Severe depression and those on antipsychotic medication
13. History of substance misuse

Date of first enrolment
01/06/2021

Date of final enrolment
01/08/2021

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of the Highlands and Islands
Institute of Health Research and Innovation
Centre for Health Research
Old Perth Road
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Sponsor information

Organisation
University of the Highlands and Islands

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Sponsor type
University/education

Website
http://www.uhi.ac.uk/en

ROR
https://ror.org/02s08xt61

Organisation
NHS Highland

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NHS R&D
Centre for Health Science
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Sponsor type
Hospital/treatment centre

Website
https://www.nhshighland.scot.nhs.uk/

ROR
https://ror.org/010ypq317

Funder(s)

Funder type
Government

Funder Name
Scottish Government Diabetes Prevention Strategy Group

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/06/2024

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