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Feasibility of a very low calorie diet in type 2 diabetes and foot ulcers

Submission date
18/10/2020

Recruitment status
No longer recruiting

Registration date
14/04/2021

Overall study status
Completed

Last Edited
14/04/2021

Condition category
Skin and Connective Tissue Diseases

[_] 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. There is high-quality research emerging which demonstrates the safety of using a very low-calorie diet (VLCD) in people who only been diagnosed with Type 2 diabetes shorter duration, with the potential for these patients to put their diabetes into remission. However, there is no research looking specifically at the impact of VLCD in people having podiatry treatment for non-healing foot ulcers. In people with Type 2 diabetes, foot ulcers are present in 80% of amputations, and the cost to the NHS high. Adding a dietary intervention for people with non-healing neuropathic foot ulcers is currently an under-researched area.
The study aims to find out how people with type 2 diabetes, who are also having treatment for foot ulcers, respond to and experience the VLCD over an 8 week period.

Who can participate?
Adult participants from 21 years upwards who have type 2 diabetes

What does the study involve?
The Very Low Calorie Diet involves stopping participants usual diet, and having meal replacements and some additional vegetable or salad foods. The maximum calorie intake on the VLCD is 800 calories per day. Participants receive support to reintroduce a long term diet suitable for the participant when the study period is over. Participants are responsible for buying your own meal replacements and vegetables for the period of the study. There are suitable meal replacements (e.g. drinks or bars) available for all budgets from most supermarkets or online, which the dietitian can provide further information about. Participants podiatry treatment will continue as usual. There may be changes to your medication regimen as a result of this VLCD. Participants medication for diabetes and blood pressure will be reviewed when participants start the diet. This will usually mean a reduction in the dose or number of medications that participants have to take. There are 12 study visits over a 15 week period which include well being measurements, weight, blood glucose and HbA1c and blood pressure and measurements (including photos) of foot ulcer.

What are the possible benefits and risks of participating?
The diet does not affect participants' usual activity or job and they can bring a partner or carer

with them to any of the dietetic appointments if they wish. Benefits include weight loss, lower blood glucose levels, increased energy, and fewer medications. Risks include hunger, feeling cold more often than usual, change in bowel habits, and episodes of low blood glucose.

Where is the study run from?
Wrexham Maelor Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2019 to October 2021

Who is funding the study?
RCBC Wales (UK)

Who is the main contact?
Elaine Jennings
elaine.jennings@wales.nhs.uk

Contact information

Type(s)
Public

Contact name
Mrs Elaine Jennings

Contact details
Wrexham Maelor Hospital
Department of Nutrition and Dietetics
Croesnewydd Road
Wrexham
United Kingdom
LL12 0EQ
+44 (0)1978727159
Elaine.Jennings@wales.nhs.uk

Type(s)
Public

Contact name
Mrs Elaine Jennings

Contact details
Croesnewydd Road
Wrexham
United Kingdom
LL12 0EQ
+44 (0)1978727159
Elaine.Jennings@wales.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
267086

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 267086

Study information

Scientific Title
Exploring the feasibility of a dietetic led very low calorie diet intervention for patients with type 2 diabetes and non-healing neuropathic foot ulcers, targeting blood glucose, weight, effect on wound healing and quality of life

Study objectives
This is a feasibility study, using case study methodology, therefore it is not designed to test a hypothesis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/09/2019, Wales Research Ethics Committee 4, Wrexham (HCRW Support centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)7976 982591; Wales.REC4@wales.nhs.uk), ref: 19/WA/0233

Study design
Single-centre international open-label feasibility study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Healing of neuropathic foot ulcers in adult patients with type 2 diabetes

Interventions
The very low calorie diet (VLCD) is known to be a safe and effective treatment for people with type 2 diabetes, particularly early on in the disease process. However, the impact or feasibility is not known at the point in the Type 2 diabetes care pathway when a person is being treated for neuropathic foot ulcers. Adults, between 18 and 75 years will be eligible to participate in this study. This study intervention will be led by a specialist diabetes dietitian, experienced in delivering the VLCD with patients with Type 2 diabetes. It will be delivered within the podiatry

ulcer service at a general hospital. The study will use case study methodology to investigate up to three subjects. Qualitative and quantitative data will be collected (weight, ulcer size, blood glucose control (HbA1c) and mental wellbeing scores). Eligible patients will receive a dietetic led 8-week VLCD and a suitable diet plan for a longer term diet. The intervention will take up to 15 weeks in total.

Intervention Type
Behavioural

Primary outcome(s)
1. Patient wellbeing measured using the Warwick-Edinburgh Mental Well-being scale at baseline, week 9-12 and week 13
2. Hba1C (blood test) at baseline and week 13; weight and blood glucose at baseline and weekly until week 9, and weight at week 13
3. Weight and blood glucose measured using hospital or home scales (weight) and hospital or home glucose monitors (blood glucose) at baseline and weekly until week 9, and weight at week 13

Key secondary outcome(s))
Wound healing at week 13 measured by reducing in size of the neuropathic foot ulcer

Completion date
07/10/2021

Eligibility

Key inclusion criteria
1. Able to give written informed consent
2. Age 21 - 75 years
3. Type 2 diabetes (any duration and oral hyperglycaemic agents) with non-healing foot neuropathic foot ulcers (longer than 6 weeks duration)
4. Attending podiatry ulcer clinic in Wrexham Maelor Hospital
5. BMI >27 kg/m² and <45 kg/m²

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Significant arterial disease
2. Recent routine HbA1c >108 mmol/mol
3. Unintentional weight loss of > 5 kg in the last 6 months

4. Recent eGFR <30 ml/min/1.73 m²
5. Substance misuse
6. Undergoing active treatment for cancer
7. Myocardial infarction within the previous 6 months
8. Severe heart failure defined as equivalent to the New York Heart Association grade 3 (NYHA)
9. Learning difficulties
10. Current treatment with anti-obesity drugs
11. Diagnosed eating disorder or purging
12. Pregnant/considering pregnancy and/or breastfeeding
13. Patients who have required hospitalisation for depression (in the past 2 years) or are prescribed antipsychotic medication
14. People currently participating in another clinical research trial
15. Frailty (identified by The Canadian Study of Health and Aging Clinical Frailty Scale (CFS)) as defined by a frailty scale greater than 4
16. Prescribed Insulin for Diabetes management

Date of first enrolment
07/10/2020

Date of final enrolment
07/04/2021

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Betsi Cadwaladr University Health Board
Wrexham Maelor Hospital
Dept Nutrition & Dietetics
Croesnewydd Road
Wrexham
United Kingdom
LL12 0EQ

Sponsor information

Organisation
Betsi Cadwaladr University Health Board

Funder(s)

Funder type
Government

Funder Name
RCBC Wales, First into Research Sponsorship (FIRS)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to lack of consent to share.

IPD sharing plan summary
Not expected to be made available

Study outputs

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