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Metabolic education for new diabetics using energy restriction

Submission date
04/04/2016

Recruitment status
No longer recruiting

Registration date
31/05/2016

Overall study status
Completed

Last Edited
23/04/2021

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Diabetes is a condition that causes a person's blood sugar level to become too high. Insulin is the hormone made by beta-cells in the pancreas and controls the amount of glucose in the blood. In type 2 diabetes, the pancreas does not produce enough insulin or the person's cells do not react to insulin. Educating type 2 (T2) diabetics to self-manage their own condition is currently recommend but isn't widely implemented. Existing services focus on recommended population-based guidance and promote the idea that T2 diabetes is a lifelong and progressively worsening condition. In recent times, an improved understanding of the condition has revealed that it can be potentially reversed for many patients. In addition, there is a growing awareness of the need to promote preventive self-management as diabetes and cardiovascular disease have both become created an increasing burden on the health service. This study tests a program (intervention) that involves self-monitoring of blood glucose, energy restriction diets and self-management education to see if it improves the health of T2 diabetes patients .

Who can participate?
Adults aged 18-75 that have been diagnosed with T2 diabetes within the last year and have not been treated with drugs.

What does the study involve?
Participants are recruited to the study by Diabetes specialist nurses, from an existing Diabetes education course. They are asked to attend 6 weekly education sessions of 2-hours each. The course structure includes educational aspects of diabetes management and self-monitoring throughout but the 6-week period will be made up of three phases. In the first two weeks, data is collected from each participant, including information on general health and their health knowledge. In weeks 3-4, participants are asked to go on a 10 day energy restriction diet. The last two weeks focuses on the collection of data after the diet. Data is also collected from each participant every day. This includes
a single fasted fingerstick glucose test, body weight and % body fat from smart-scales that use simple bio-impedance body composition analysis once per day, keeping a hip-worn activity tracker with them all day and a dietary record of everything eaten and drunk each day. In addition, there are two self-administered oral glucose tolerance tests requiring 5 fingerstick results over two hours each time.

What are the possible benefits and risks of participating?
Potential benefits for participants include improved glucose tolerance through reduced visceral fat and enhanced insulin sensitivity, improved health literacy and self-efficacy.Ethical considerations are present around the safety of energy restriction diets. In this case a literature review has been conducted to identify risk areas and found risk to be highly unlikely over such a short time frame. The burden of data recording (daily dietary, blood glucose, body composition and activity data) will be minimized by using a web-based database that stores all information entered in a secure and private online space. Where possible automatic upload of results from measurement kit to database will be used. Specifically, the data from activity tracker, glucometer and body composition scales will automatically synchronise with a paired device (pairing is also automatic and so does not involve the user) to move data into the online record while dietary record will be manually entered into the same device and be transmitted in the same way. This transmission device is likely to be a user's own smartphone or another mobile device (e.g. iPod Touch™) configured and provided by the study team. Fingerstick capillary glucose testing can cause pain, discomfort or the risk of infection. As well as all manufacturer instructions and guidance participants will be provided tuition in best practice for fingerstick based testing. Glucose tolerance tests carry a slight risk of reactive hypoglycemia for certain individuals. This risk is minimised by only conducting the tests when participants are not on low calorie diets and by providing guidance to eat breakfast as soon as the test is finished.

Where is the study run from?
Churchill Hospital, Oxford (UK)

When is the study starting and how long is it expected to run for?
February 2016 to September 2016

Who is funding the study?
Optimum Health Innovations Ltd

Who is the main contact?
Mr James Troke

Contact information

Type(s)
Public

Contact name
Mr James Troke

Contact details
53 Percy Road
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20160209

Study information

Scientific Title
Pilot for interventional diabetes self-management education service

Acronym
MENDERs

Study objectives
Does interventional self-management education based on principles of personal data monitoring, short-term energy restriction and re-balance improve glucose tolerance and health literacy measures amongst newly diagnosed type 2 Diabetics?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single centre Interventional non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

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
Type 2 diabetes mellitus

Interventions

The proposed study intends to bring together diabetes self-management education aligned with current standards, personal data tracking of the components of the energy balance equation (weight, activity, diet) and glycaemic control (capillary blood glucose), online support/resources and a personalised short-duration energy restriction and transition diet to demonstrate the impact of behaviour on metabolism.
The potential participant will be introduced to the research and to the concepts of self-monitoring of blood glucose, energy restriction diets and self-management education. Assuming the patient satisfies inclusion and exclusion criteria, then volunteers for the course and provides consent, they will receive an Introduction Pack to their home address in the post. This pack includes access details to online materials and details of course venue/dates/times and course structure and objectives.

Week 1: 2 hour session focused on introductory topics, includes completion of heiQ (health education impact questionnaire). Over the subsequent week participants begin collection and recording of diet, activity, body composition and blood glucose results including a 2-hour tolerance test from a fasted state on one morning before the next session
Week 2: 2 hour session focused on energy metabolism topics, food types, energy balance and planning energy restriction diet. Over the subsequent week participants maintain collection and recording of diet, activity, body composition and fasting glucose data and prepare to begin energy restriction diet on the day of the next session
Week 3: 2 hour session focused on review of baseline data and diabetes as a chronic condition including complications and recommended and best practice guidance. Over the subsequent week participants adhere to diet and continue collection of daily measures.
Week 4: 2 hour session focused on review of previous week, support with barriers to adherence and planning of transition diet. Over the subsequent week participants maintain data collection and begin increasing dietary amount in the 4 days leading up to the next session
Week 5: 2 hour session focused on review of course and personal learning objectives, goal setting and planning to maintain energy balance. Over the subsequent week participants maintain data collection including a 2-hour tolerance test from a fasted state on one morning before the next session
Week 6: 2 hour session focused on review of post-diet data and collection of feedback/input from participants and educators on the course content and acceptability, includes completion of follow-up heiQ.

Personal data and educational resources (online) will continue to be available to participants for at least 4 weeks after completion of the course at week 6.

Intervention Type
Behavioural

Primary outcome measure
1. Area under 2-hour oral glucose tolerance curve pre and post energy restriction
2. Health Education Impact Questionnaire score pre and post energy restriction

Secondary outcome measures
1. Fasting blood glucose pre and post energy restriction
2. Body composition pre and post energy restriction

Overall study start date
16/02/2016

Completion date
01/09/2016

Eligibility

Key inclusion criteria
1. Aged ≥18-75 years old
2. A confirmed diagnosis of T2DM within the last year treated by metformin and/or lifestyle
3. A body mass index of 22-45 kg/m2
4. Willingness to undertake a structured education programme for 6 weeks
5. Willingness to attend the course venue at specified times on 6 separate occasions
6. Ability to read, write and converse in English without the support of an interpreter
7. Familiar with internet and Smartphone use and with regular access to a connected computer

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
12

Key exclusion criteria
1. Inability to provide informed consent
2. Unwillingness or inability to perform any of the study components required, specifically self-monitoring of blood glucose (finger-stick SMBG) or oral glucose tolerance test (OGTT)
3. Any contra-indication for weight loss
4. Type 1 diabetes mellitus (T1DM) or diagnosed with T2DM > 1 years
5. Currently prescribed insulin, thiazolidenediones or sulfonylurea.
6. Currently prescribed steroids or beta-blockers
7. Serum Creatinine > 150mmol/L
8. Serum ALT greater than 2.5 times the upper limit of the reference range
9. Pregnant or intending to become pregnant
10. HF or any other existing cardiovascular co-morbidity
11. Currently participating in any weight loss or lifestyle modification trial

Date of first enrolment
01/06/2016

Date of final enrolment

01/07/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Churchill Hospital
Oxford Centre for Diabetes, Endocrinology and Metabolism
Oxford
United Kingdom
OX3 7LE

Sponsor information

Organisation
Optimum Health Innovations Ltd

Sponsor details
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Sponsor type
Industry

Website
www.optimumhi.com

Funder(s)

Funder type
Industry

Funder Name
Optimum Health Innovations Ltd

Results and Publications

Publication and dissemination plan
There are no publication plans for this study. As a small scale pilot this research would be considered commercial property and aims to provide evidence of the feasibility of the principles of the service. Thus the main purpose of the research results is to inform further service development.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available