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Low calorie diet in obese type 2 diabetes patients treated with insulin

Submission date
12/03/2012

Recruitment status
No longer recruiting

Registration date
23/10/2012

Overall study status
Completed

Last Edited
16/08/2023

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[X] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Type 2 diabetes is a major risk factor for heart disease, kidney failure and other complications. Insulin therapy is often needed in type 2 diabetes to help control your blood sugars to help reduce these complications. However, insulin therapy can lead to weight gain. Therefore, there is a need to develop interventions to help patients reduce or even come off insulin therapy. Research has shown that using low calorie diets can produce significant weight loss. This research study will test if weight loss through a liquid meal replacement low calorie diet can help you lose weight and reduce or even help you come off your insulin and help reduce the complications associated with your diabetes. This study will aim to recruit 90 patients from North West London to assess the impact of a liquid low calorie diet compared with good clinical care on weight loss and insulin requirements within people with type 2 diabetes requiring insulin.

Who can participate?
Men and women with type 2 diabetes, aged 18-70, who have a Body Mass Index (BMI) over 30 kg /m², are willing and able to give informed consent for participation in the study, and have been on insulin for no more than 10 years.

What does the study involve?
Patients will be randomly allocated to receive either the low calorie diet or routine care for 6 months. This study will use between 800 calories as a benchmark for the low calorie diet. For the first 12 weeks, the patients will be asked to consume a low calorie diet. After this, the patients in the low calorie diet group will gradually have conventional food re-introduced for the next 12 weeks. Patients in the routine care group will be asked to consume a 600 calorie deficit diet throughout the intervention. After 6 months, all patients will be transferred to the same care and follow a 600 calorie deficit diet and will be followed up for 6 months.

What are the possible benefits and risks of participating?
There are no direct benefits from taking part in the study. The study will hopefully help to improve the management of patient within type 2 diabetes on insulin. There is a risk of low blood sugar; the research team will help educate the patient to manage their low blood sugars, adjust their insulin with partnership of the GP and therefore reduce the risk. When having blood taken there is a small chance of fainting, bruising, bleeding, swelling or infection where the

needle was inserted. The risk will be minimised by having qualified and experienced staff members perform this procedure.

Where is the study run from?
Imperial College London (UK).

When is the study starting and how long is it expected to run for?
The study will start in September 2014 and will last for 36 months.

Who is funding the study?
Cambridge Weight Plan Ltd (UK).

Who is the main contact?
Professor Gary Frost
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Contact information

Type(s)
Scientific

Contact name
Prof Gary Frost

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

A randomised controlled trial assessing the impact of a Low Calorie Diet on weight loss in obese patients with type 2 Diabetes Mellitus treated with insulin

Acronym
LCDDM

Study objectives
Current hypothesis as of 11/09/2014:
In obese type 2 diabetes patients treated with insulin, a 12-month dietary intervention with a Low Calorie Diet (LCD) will result in greater weight reduction leading to significant improvement in glycaemic control compared to routine care.

Previous hypothesis:
In insulin-treated type 2 diabetes patients, the Cambridge Diet Based Programme (CDBP), compared to the routine care group, will result in:
1. Greater percentage of patients achieving at least a 5% weight loss
2. Improved body composition
3. Improvement in glycaemic control
4. Reduction of the need for insulin therapy
5. Better quality of life in Type 2 Diabetes (T2D) patients
6. Improvement in cardiovascular risk factors

On 11/09/2014 the following changes were made to the trial record:
1. The public title was changed from 'Cambridge Diet Based Programme in obese type 2 diabetes patients on insulin' to 'Low calorie diet in obese type 2 diabetes patients treated with insulin'.
2. The scientific title was changed from 'A pragmatic randomised controlled trial assessing the impact of a low calorie Cambridge Diet Based Programme (CDBP) on weight loss in obese patients with type 2 diabetes mellitus treated with insulin' to 'A randomised controlled trial assessing the impact of a Low Calorie Diet on weight loss in obese patients with type 2 Diabetes Mellitus treated with insulin'.
3. The acronym was changed from CDBP to LCDDM.
4. The study design was changed from 'Pragmatic randomised controlled trial' to 'Randomised controlled trial'.
5. The overall trial start date was changed from 23/04/2012 to 01/09/2014.
6. The overall trial end date was changed from 27/01/2014 to 01/05/2017.
7. The sources of funding field was changed from 'The Cambridge Manufacturing Company (UK) and NIHR CLAHRC BBC' to 'Cambridge Weight Plan Ltd (UK)'

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - Solihull, substantial amendment and subsequent minor amendment - 30/07/2014 and 6/08/2014, respectively, ref: 12/WM/0199

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

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

Interventions
Current interventions as of 11/09/2014:
Patients will be randomly allocated to receive either the low calorie diet or routine care for 6 months. This study will use between 800 calories as a benchmark for the low calorie diet. For the first 12 weeks, the patients will be asked to consume a low calorie diet. After this, the patients in the intervention group will gradually have conventional food re-introduced for the next 12 weeks. Patients in the routine care group will be asked to consume a 600 calorie deficit diet throughout the intervention. After 6 months, all patients will be transferred to the same care and follow a 600 calorie deficit diet and will be followed up for 6 months. Throughout this time patients will received behaviour change to help with long-term maintenance.

Previous interventions:
Patients will be randomly assigned to receive the Cambridge Diet or routine care for 6 months. The Cambridge Diet group will follow a low calorie diet and routine care will follow a 600 calorie deficit diet. Patients in the intervention group will consume 800 calories for 3 months, thereafter they will follow the 1400 calorie diet for the remaining 3 months. Patients in the routine care will consume 600 calorie deficit diet throughout the intervention. After the intervention all patients will be transferred to routine care.

The previous sponsor for this trial (up to 11/09/2014) was:
University of Birmingham
Edgbaston
Birmingham
B15 2TT
United Kingdom

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Weight loss

Secondary outcome measures
Current secondary outcome measures as of 11/09/2014:
1. Insulin use
2. Diabetes control
3. Beta-cell function
4. Cardiovascular risk factors (including obstructive sleep apnea)
5. Body composition
6. Effects on appetite and hunger
7. Other diabetes medications
8. Quality of life

Previous secondary outcome measures:
1. Changes in body composition
2. Diabetes control, insulin use, and other diabetes medication
3. Cardiovascular risk factors
4. Quality of life

Overall study start date
01/09/2014

Completion date
01/05/2017

Eligibility

Key inclusion criteria
Current inclusion criteria as of 23/07/2015:
1. Have BMI >30 kg/m²
2. Men or women
3. Age 18-70 years
4. Are willing and able to give informed consent for participation in the study
5. Have been on insulin treatment < 10 years or greater than 10 years with a fasting c-peptide of >600

Previous inclusion criteria from 11/09/2014 to 23/07/2015:
1. Have BMI >30 kg/m²
2. Men or women
3. Age 18-70 years
4. Are willing and able to give informed consent for participation in the study
5. Have been on insulin treatment < 10 years

Original inclusion criteria:
1. Have BMI >30 kg/m²
2. Men or women
3. Age 18-70 years
4. Are willing and able to give informed consent for participation in the study
5. Have been on insulin treatment < 4 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
Total of 90. There will be 45 in each group.

Total final enrolment
90

Key exclusion criteria
Current exclusion criteria as of 23/07/2015:
1. Have type 1 diabetes
2. Any significant diabetes microvascular complication
3. Are unable to provide written informed consent
4. Have experienced a cardiovascular disease (CVD) event in the previous 6 months
5. Are at stage 4 chronic kidney disease or greater (eGFR <30 mL/min/1.73 m^2)
6. Have a mental incapacity, unwillingness and/or inability to understand, and be able to complete the mental health questionnaires in the provided language
7. Currently pregnant, lactating, or planning pregnancy within the study period
8. Have binge eating behaviour (will be assessed by Dutch Eating Behaviour Questionnaire)
9. Patient has condition precipitating fluid overload such as heart failure (New York Heart Association grade III-IV) and liver cirrhosis
10. Are using medication clinically deemed to affect metabolic rate and weight (e.g. beta blockers, corticosteroids, diuretics, etc)
11. Have significant psychiatric disorder (e.g. schizophrenia, anxiety, panic disorder, ADHD/ADD, post-traumatic stress disorder, obsessive-compulsive disorder)
12. Uncontrolled depression
13. Have participated in a weight management drug trial in the previous 3 months
14. Difficult to control International Normalising Ratio (INR) within the therapeutic range
15. Have uncontrolled epilepsy
16. Are known or suspected of substance use
17. Are lactose intolerant
18. Severe musculoskeletal conditions preventing walking
19. Gout
20. Have active gallstone disease or known asymptomatic gallstones
21. Clinically assessed hypoglycaemia unawareness
22. On ECG evidence of left bundle branch block

Previous exclusion criteria from 11/09/2014 to 23/07/2015:
1. Have type 1 diabetes
2. Any significant diabetes microvascular complication
3. Are unable to provide written informed consent

4. Have experienced a cardiovascular disease (CVD) event in the previous 6 months
5. Are at stage 4 chronic kidney disease or greater (eGFR <30 mL/min/1.73 m²)
6. Have a mental incapacity, unwillingness and/or inability to understand, and be able to complete the mental health questionnaires in the provided language
7. Currently pregnant, lactating, or planning pregnancy within the study period
8. Have binge eating behaviour (will be assessed by Dutch Eating Behaviour Questionnaire)
9. Patient has condition precipitating fluid overload such as heart failure (New York Heart Association grade III-IV) and liver cirrhosis
10. Are using medication clinically deemed to affect metabolic rate and weight (e.g. beta blockers, corticosteroids, diuretics, etc)
11. Have significant psychiatric disorder (e.g. schizophrenia, anxiety, panic disorder, ADHD/ADD, post-traumatic stress disorder, obsessive-compulsive disorder)
12. Uncontrolled depression
13. Have participated in a weight management drug trial in the previous 3 months
14. Are on anticoagulant medication - excluding aspirin or clopidogrel
15. Have uncontrolled epilepsy
16. Are known or suspected of substance use
17. Are lactose intolerant
18. Severe musculoskeletal conditions preventing walking
19. Gout
20. Have active gallstone disease or known asymptomatic gallstones
21. Clinically assessed hypoglycaemia unawareness
22. On ECG evidence of left bundle branch block

Original exclusion criteria:
1. Have type 1 diabetes
2. Have any significant diabetes microvascular complication
3. Are unable to provide written informed consent
4. Have experienced a cardiovascular disease (CVD) event in the previous 6 months
5. Are at stage 3b chronic kidney disease (eGFR <30 mL/min/1.73 m²)
6. Have a mental incapacity, unwillingness and/or inability to understand and be able to complete the mental health questionnaires in the provided language
7. Currently pregnant, lactating, or planning pregnancy within the study period
8. Have binge eating behaviour (will be assessed by Dutch Eating Behaviour Questionnaire)
9. Patient has condition precipitating fluid overload such as heart failure and liver cirrhosis
10. Are using medication clinically deemed to affect metabolic rate and weight (e.g. beta blockers, corticosteroids, diuretics, etc)
11. Have significant psychiatric disorder (e.g. schizophrenia, anxiety, panic disorder, ADHD/ADD, post-traumatic stress disorder, obsessive-compulsive disorder)
12. Uncontrolled depression
13. Have participated in a weight management drug trial in previous 3 months
14. Are on anticoagulant medication - excluding aspirin or clopidogrel
15. Have uncontrolled epilepsy
16. Are known or suspected of substance use
17. Are lactose intolerant
18. Have severe arthritis preventing walking
19. Have gout
20. Have active gallstone disease or known asymptomatic gallstones

Date of first enrolment
01/09/2014

Date of final enrolment
01/05/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College London
London
United Kingdom
W12 0NN

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
Imperial College London and Imperial College Healthcare NHS Trust
510C Fifth Floor
Lab Block
Charing Cross Hospital
London
England
United Kingdom
W6 8RF
+44 (0)20 3311 0204
becky.ward@imperial.ac.uk

Sponsor type
University/education

Website
http://www3.imperial.ac.uk

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Industry

Funder Name
Cambridge Weight Plan Ltd (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2020	03/06/2020	Yes	No
Protocol file	version 1.10		16/08/2023	No	No
Statistical Analysis Plan			16/08/2023	No	No