ISRCTN25796154 https://doi.org/10.1186/ISRCTN25796154

Effects of a lifestyle modification program in overweight and obese women at risk of diabetes in the early menopause stage

Submission date
25/06/2010

Recruitment status
No longer recruiting

Registration date
21/09/2010

Overall study status
Completed

Last Edited
10/01/2012

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
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Éric Doucet

Contact details
200 Lees Ave.
Building E, Room E021
Ottawa
Canada
K1S 5S9
+1 613 562 5800 ext.7364
edoucet@uottawa.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OTG 88590

Study information

Scientific Title
Effects of a 12-month lifestyle modification with or without training program in overweight and obese women at high risk of diabetes in the early menopause stage: A 3-arm, randomised controlled trial

Study objectives
1. A better improvement will be obtained using structured programs compared to lifestyle advice: higher fat mass (total & ectopic fat infiltration) loss and better metabolic profile improvements
2. For a similar caloric deficit the combination of diet and exercise will provide a better improvement than diet restriction alone: higher fat mass (total & ectopic fat infiltration) loss and better metabolic profile improvements

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Ottawa Research Ethics Board approved on the 10th of May 2010 (ref: H02-09-06)
2. Montreal Institute of Clinical Research (Institut de recherches cliniques de Montréal [IRCM]) approved on the 28th of April 2010 (ref: 2009-20)

Study design
Multicentre 3 arm randomised controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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
Obesity, menopause, diabetes

Interventions
All groups will be followed for 12 months.

Control group: Standard care. This group will receive the Canadian Food Guide and the Canadian Physical Activity Guide.

Groups with caloric restriction (group 2) and caloric restriction + exercise training (group 3)
Dietary intervention: Subjects from groups 2 will follow a calorie-restricted (-700 kcal/day) balanced diet in line with major dietary recommendations for prevention of cardiometabolic risk factors. Energy requirements will be fixed using an indirect calorimetry measurement plus an activity factor of 1.4. Group 2 will also receive the Canadian Physical Activity Guide. The calorie-restricted for subjects from group 3 will be a -500 kcal/day since they are also involved in the training intervention.

Training intervention: Subjects from group 3 only will accumulate 200 minutes of physical activity per week. They will undergo 2 weekly 45 minutes supervised sessions comprising of aerobic and resistance training. Classes will be offered at University of Ottawa (BMRU) and Institut de recherches cliniques de Montréal since the study will involve 2 centres. Women will also be encouraged to perform aerobic activity three times a week to reach 200 min/week.

Dietary intervention: Subjects in groups 2 and 3 will meet individually with the research dietician weekly during the first month, monthly for the next 11 months. The first 4 sessions with the dietician will focus on understanding the diet plan (using Canada Food Guide choices), setting goals, and learning how to self-monitor. The remaining sessions with the dietician will address 'problem solving' including personal and environmental barriers, 'talking back to negative thoughts', 'managing stress', and discussing 'ways to stay motivated'. The same approach will be used with the kinesiologist in group 3.

Joint/Secondary sponsor details:
Institut de Recherches Cliniques de Montréal (IRCM)
110 Avenue des Pins Ouest
Montréal (Québec)
Canada H2W 1R7

Joint/Scientific contact details:
Dr Rémi Rabasa-Lhoret
Institut de Recherches Cliniques de Montréal
110 Avenue des Pins Ouest
Montréal (Québec)
Canada H2W 1R7
Remi.Rabasa-Lhoret@ircm.qc.ca

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Total fat mass, measured at baseline, 4 and 12 months
2. Dual-photon x-ray (DXA) will be used to measure the following:
2.1. Body weight
2.2. Height
2.3. Bone density
2.4. Percent fat
2.5. Percent lean body mass
Each subject's scan will be divided into several regions: arms, legs, trunk (pelvis, spine and ribs)

and head using an on-screen image of the subject's skeleton and specific skeletal landmarks to obtain regional body composition.

Secondary outcome measures

Secondary outcomes as of 10/01/2012
1. Epicardial fat measured by echocardiography of the heart (sub-samples)
2. Insulin sensitivity measured by oral glucose tolerance test
A 75g oral glucose tolerance test will be performed in the morning after an overnight (12 hours) fast. Glucose will be administrated in the form of a flavoured drink (300 ml) containing 75 g of glucose.
3. Metabolic syndrome determined by using the following determinants:
3.1. Waist circumference: ≥88cm for women
3.2. Triglycerides ≥ 150mg/dL (1.7mmol/L)
3.3. HDL-cholesterol <50mg/dL for women (<1.29mmol/L)
3.4. Blood pressure: systolic ≥130 mmHg and/or diastolic ≥ 85mmHg
3.5. Fasting glucose ≥100mg/dL (5.6mmol/L)
4. Energy and metabolism:
4.1. Resting metabolic rate will be measured by using a Vmax Encore (SensorMedic) with a plexiglass hood placed over the participants head for 30 minutes through which fresh air will be drawn.
4.2. Accelerometry: we will use the Sensewear Armband (SWA) placed on the right arm for a period of 7 days to record the energy expenditure, activity levels and duration, caloric expenditure linked to activity, number of performed steps, sleep duration and efficacy. The Armband enables continuous physiological data collection such as movement, heat flow, skin temperature, and heart rate.
4.3. Thermic effect of food (sub-samples) will be measure with the same equipment as for the resting metabolic rate after the participant eats a standardized breakfast meal (bread, peanut butter, strawberry jam, cheddar cheese and orange juice).
4.4. Visual analogue scale: they will be used to determine the sensation and desire of eating and hunger by asking 4 questions to the participant on how they feel before and after standardized breakfast.
4.5. Double label water (sub-samples): A resting urine sample is collected before drinking the doubly-labelled water. Next, the subject drinks the doubly-labelled water. This marks day #0. The next morning, at least 14 hours after consumption of the doubly-labelled water, two urine samples are collected within a span of at least 30 minutes and within 4 hours at most. This day then corresponds to day #1. Ten days later (day #10), two more urine samples are collected in the same manner
5. Exercise capacity:
5.1. VO2max performed on a treadmill with Vmax 229d (SensorMedic). The level of exercise will be increased every three minutes by increasing the incline or speed of the treadmill. The test is stopped when the participant reaches exhaustion. This is generally achieved within 10-15 minutes.
5.2. Strength test (1-RM) will be determined by doing 1 maximum repetition (RM) of each major muscle groups (Bench press, pull down, leg press).
6. Psychosocial questionnaires:
6.1. Self Efficacy
6.2. Perceived Benefits
6.3. Body Esteem Scale (Mendelson et al)
6.4. Medical Outcome Survey - Quality of Life Questionnaire
6.5. 3-Factor Eating Questionnaire (Stunkard & Messick)
6.6. Diet History Questions

6.7. Menopause rating scale
6.8. Olfactory performance test
6.9 Force food preference test
6.10 A genetic component to the study

Previous Secondary outcomes
1. Epicardial fat measured by echocardiography of the heart (sub-samples)
2. Insulin sensitivity measured by oral glucose tolerance test
A 75g oral glucose tolerance test will be performed in the morning after an overnight (12 hours) fast. Glucose will be administrated in the form of a flavoured drink (300 ml) containing 75 g of glucose.
3. Metabolic syndrome determined by using the following determinants:
3.1. Waist circumference: ≥88cm for women
3.2. Triglycerides ≥ 150mg/dL (1.7mmol/L)
3.3. HDL-cholesterol <50mg/dL for women (<1.29mmol/L)
3.4. Blood pressure: systolic ≥130 mmHg and/or diastolic ≥ 85mmHg
3.5. Fasting glucose ≥100mg/dL (5.6mmol/L)
4. Energy and metabolism:
4.1. Resting metabolic rate will be measured by using a Vmax Encore (SensorMedic) with a plexiglass hood placed over the participants head for 30 minutes through which fresh air will be drawn.
4.2. Accelerometry: we will use the Sensewear Armband (SWA) placed on the right arm for a period of 7 days to record the energy expenditure, activity levels and duration, caloric expenditure linked to activity, number of performed steps, sleep duration and efficacy. The Armband enables continuous physiological data collection such as movement, heat flow, skin temperature, and heart rate.
4.3. Thermic effect of food (sub-samples) will be measure with the same equipment as for the resting metabolic rate after the participant eats a standardized breakfast meal (bread, peanut butter, strawberry jam, cheddar cheese and orange juice).
4.4. Visual analogue scale: they will be used to determine the sensation and desire of eating and hunger by asking 4 questions to the participant on how they feel before and after standardized breakfast.
4.5. Double label water (sub-samples): A resting urine sample is collected before drinking the doubly-labelled water. Next, the subject drinks the doubly-labelled water. This marks day #0. The next morning, at least 14 hours after consumption of the doubly-labelled water, two urine samples are collected within a span of at least 30 minutes and within 4 hours at most. This day then corresponds to day #1. Ten days later (day #10), two more urine samples are collected in the same manner
5. Exercise capacity:
5.1. VO2max performed on a treadmill with Vmax 229d (SensorMedic). The level of exercise will be increased every three minutes by increasing the incline or speed of the treadmill. The test is stopped when the participant reaches exhaustion. This is generally achieved within 10-15 minutes.
5.2. Strength test (1-RM) will be determined by doing 1 maximum repetition (RM) of each major muscle groups (Bench press, pull down, leg press).
6. Psychosocial questionnaires:
6.1. Self Efficacy
6.2. Perceived Benefits
6.3. Body Esteem Scale (Mendelson et al)
6.4. Medical Outcome Survey - Quality of Life Questionnaire

6.5. 3-Factor Eating Questionnaire (Stunkard & Messick)
6.6. Diet History Questions
6.7. Menopause rating scale

All measurement will be taken at baseline, 4 and 12 months

Overall study start date
05/07/2010

Completion date
05/07/2013

Eligibility

Key inclusion criteria
Current inclusion criteria as of 10/01/2012
Participants - inclusion criteria
1. Women aged 45 years or older.
2. Overweight or obese (BMI higher than 27 kg/m2 and lower than 40 kg/m2)
3. Women with menstrual irregularities or without menses for 48 months or less
4. Non-smokers
5. Low to moderate alcohol consumers (less than 2 drinks/day)
6. Sedentary (less than 30 minutes of exercise per week)
7. Total risk score ≥12 from the type 2 diabetes risk assessment form

Previous inclusion criteria
1. Women aged 45-55 years
2. Overweight or obese (BMI higher than 27 kg/m2 and lower than 40 kg/m2)
3. Women without menses within the last 6 to 18 months
4. Non-smokers
5. Low to moderate alcohol consumers (less than 2 drinks/day)
6. Sedentary (less than 30 minutes of exercise per week)
7. Total risk score ≥12 from the type 2 diabetes risk assessment form

Participant type(s)
Patient

Age group
Adult

Lower age limit
45 Years

Sex
Female

Target number of participants
120 distributed on 2 sites: University of Ottawa-Behavioural and Metabolic Research Unit (BMRU) and Institut de recherches cliniques de Montréal (IRCM) - Diabetes, metabolism and obesity

Key exclusion criteria
1. Pregnant or who plan to become pregnant
2. Women with medical problems and/or are taking medications which may impact on menopause or on study outcome
3. Women who had hysterectomy or bi-lateral ovariectomy
4. Known diabetes
5. Known coronary heart disease

Date of first enrolment
05/07/2010

Date of final enrolment
05/07/2013

Locations

Countries of recruitment
Canada

Study participating centre
200 Lees Ave.
Ottawa
Canada
K1S 5S9

Sponsor information

Organisation
University of Ottawa (Canada)

Sponsor details
Tabaret Hall
550 Cumberland St
Room 246
Ottawa
Canada
K1N 6N5
+1 613 562 5841
recherche@uottawa.ca

Sponsor type
University/education

ROR
https://ror.org/03c4mmv16

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: OTG 88590)

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