

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	<input type="checkbox"/> Prospectively registered
Registration date 21/09/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/01/2012	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Prevention

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:

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Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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.

Key secondary outcome(s)

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 administered 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: ≥ 88 cm for women

3.2. Triglycerides ≥ 150 mg/dL (1.7mmol/L)

3.3. HDL-cholesterol < 50 mg/dL for women (< 1.29 mmol/L)

3.4. Blood pressure: systolic ≥ 130 mmHg and/or diastolic ≥ 85 mmHg

3.5. Fasting glucose ≥ 100 mg/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

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

45 years

Sex

Female

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration