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

Submission date	Recruitment status	Prospectively registered
25/06/2010	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
21/09/2010	Completed	Results
Last Edited	Condition category	Individual participant data
10/01/2012	Nutritional, Metabolic, Endocrine	<ul><li>Record updated in last year</li></ul>

# 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

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: 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(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 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  $\geq$  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  $\geq$ 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**

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- 6.7. Menopause rating scale

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

## Completion date

05/07/2013

# **Eligibility**

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

# **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sl

Participant information sheet 11/11/2025 11/11/2025 No