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Effects of resistance training and animal protein intake on dietinduced weight loss in obese older women displaying metabolic abnormalities

Submission date
31/08/2011

Recruitment status
No longer recruiting

Registration date
25/01/2012

Overall study status
Completed

Last Edited
25/01/2012

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

Background and study aims
Previous studies show that the percentage of obese female population at a given time is particularly high in women aged 50 to 75 years, in Canada and United States. The higher rate of occurence of obesity in postmenopausal women (PM) may be caused in part by the menopause transition; which is associated with changes in ovarian hormone status, decrease in energy expenditure, increase in fat mass (FM) and cardiovascular diseases risk factors. Part of this risk may be explained by changes in body composition and body fat distribution. PM women tend to gain fat mass mainly in the abdominal region, which is associated with lower insulin sensitivity (a condition where the natural hormone insulin, becomes less effective at lowering blood sugars). These metabolic changes, along with abnormal amount of cholesterol (dyslipidemia) and increased blood pressure (hypertension) are commonly associated with the metabolic syndrome and may predict type 2 diabetes and coronary artery disease in PM women.
Several medical and behavioural approaches have been studied over the past decades in order to prevent or treat obesity. Still, caloric restriction (dietary regimen that restricts calorie intake) and physical activity are the main factors in prevention and treatment of obesity.
The aim of this study is to study the effects of caloric restriction alone or in combination with resistance training on body composition, body fat distribution, metabolic profile and energy expenditure in obese PM women, when taking into account animal protein intakes.

Who can participate?
100 postmenopausal women (60-75 yrs and body mass index between 27 and 40 kg/m²)

What does the study involve?
Subjects will be randomised in one of the 4 groups:
1. Standard hypocaloric diet
2. Standard hypocaloric diet + resistance training
3. Standard hypocaloric diet + animal proteins supplement and
4. Standard hypocaloric diet + animal proteins supplement + resistance training.

What are the possible benefits and risks of participating?
Subjects will receive:
1. Professional supervision regarding nutrition and/or exercise during the study (depending on the treatment group)
2. Professional advises and recommendations regarding nutrition and exercise following the study based on personal results before and after the study
3. Improvements in body composition, body fat distribution and the metabolic profile (blood pressure, lipids and glucose blood levels and
4. Improvements in physical capacity. At the end of the study, each subject will receive a personalized document including data regarding body composition, metabolic, physical capacity and nutrition changes during the study.

The participation to an exercise program involves a risk of injuries which we intend to minimize by creating a progressive protocol. In addition to that, the exercise sessions will be supervised. The exposition to X-rays during DXA (from 0.03 to 0.05 millirem) is comparable to 20 minutes of sun exposition. The principal investigator has several reasons to believe that the advantages to participate in the study overcomes the risks.

Where is the study run from?
Sherbrooke: Centre for Research on Aging, Center for Health and Social Services of the University Institute of Geriatrics of Sherbrooke (CRV - CSSS-IUGS) and Montreal: Clinical Research Institute of Montreal (IRCM)

When is study starting and how long is it expected to run for?
The project is expected to start in January 2012. The anticipated end date is January 2014.

Who is funding the study?
Canadian Institutes of Health Research (CIHR)

Who is the main contact?
Prof Martin Brochu
Martin.Brochu@USherbrooke.ca

Contact information

Type(s)
Scientific

Contact name
Prof Martin Brochu

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OTG 88590

Study information

Scientific Title
Effects of resistance training and animal protein intake on dietinduced weight loss in obese older women displaying metabolic abnormalities: a randomized controlled trial

Study objectives
The combination of caloric restriction + high protein intake + resistance training will be associated with
1. Gain in lean body mass (LBM) and greater decreases in fat mass (FM)
2. Higher total daily energy expenditure (because of better preservation in LBM) and
3. Better improvements in lipids and glucose homeostasis (because of better preservation in LBM and higher daily energy expenditure)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Aging Research Centre for Health and Social Services of the University Institute of Geriatrics of Sherbrooke (Comité déthique de la recherche sur le vieillissement du Centre de santé et de services sociaux de l'Institut universitaire de gériatrie de Sherbrooke), May 19th, 2011 (ref: 2011-04/BROCHU)

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

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, metabolic syndrome, physical capacity.

Interventions
All groups will be followed for 24 weeks (4 weeks of weight stabilisation before and after the intervention + 16 weeks of weight loss program). Women will be randomized to one of the four following groups:
1. Standard hypocaloric diet
2. Standard hypocaloric diet + resistance training
3. Standard hypocaloric diet + animal proteins supplement and
4. Standard hypocaloric diet + animal proteins supplement + resistance training

Standard hypocaloric diet: This diet should induce an average caloric deficit between 500 and 1000 kcal/day (weight loss between 1 and 2 lbs per week). The diet will be based on the Canadian food guide (15% of proteins, 30% of lipids and 50% of carbohydrates). The average daily protein intake should be 0.8 gram per kg of body weight.

Animal proteins supplement: Subjects will be asked to consume a supplement of 25 grams of animal proteins each day. For those in the resistance training group, the supplement will be taken within 2 hours after training on day of training.

Resistance training (RT): Women in RT groups will train three times a week on non-consecutive days, under the supervision of an exercise physiologist. All training sessions will start with a warm-up period consisting of 5 min of low-intensity cycling. Participants then performed the load phase of RT consisting in 3 series of 8 repetitions for nine different exercises.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Dual energy X-ray absorptiometry (DXA) technology to measure total fat mass, bone mass and lean body mass as well as each tissue by region (trunk, legs and arms).
2. Other measures of body composition include weight, height, waist and hip circumferences. They are taken before, during and after the intervention (total of 3 times for DXA outcomes and 8 times for other body composition measurements).

Secondary outcome measures
1. Lipids, glucose homeostasis, inflammation profile, adipokines, energy expenditure, resting arterial blood pressure and heart rate, physical capacity and psychosocial determinants
2. Plasma measures will be taken before, during and after the intervention (total of 3 times): Analyses will be done on the COBAS INTEGRA 400 (Roche Diagnostic, Montréal, Canada) analyzer for total cholesterol, HDL-cholesterol, triglycerides and glucose combined with specific cassettes containing in vitro diagnostic reagent system. LDL-cholesterol concentration will be calculated by Friedewald equation using total cholesterol, HDL-cholesterol and triglycerides.
2.1. Insulin and IGF-I concentrations will be determined with commercially available radioimmunoassay kits (Radioassay System Laboratory, and ICN Biomedicals, Costa Mesa, CA; distributed by Immunocorp, Montreal, PQ, and Diagnostic Systems aboratories-2900, respectively).

2.2. Plasma IGFBP-1,2,3 will be determined by Western blotting.
2.3. Serum adiponectin and leptin (Linco Research, St-Charles, MO, USA) levels will be measured in duplicate with a commercial radioimmunoassay (RIA) procedure using 125I-labeled bioactive human adiponectin and leptin as tracers and a rabbit polyclonal antibody raised against full-length peptides.
2.4. Plasma immunoreactive total and acylated ghrelin levels will be measured in duplicate with a commercial RIA using 125I-labeled bioactive human acylated ghrelin as tracers and rabbit polyclonal antibody raised against full-length total ghrelin and against the Ser3-octanoylated portion of acylated ghrelin, respectively (Linco Research, St. Charles, MO).
2.5. Nonacylated ghrelin values will be calculated as total minus acylated ghrelin. NPY will be measured by RIA kits (Peninsula Lab., Belniont, CA) after plasma extraction on reverse-phase minicolunins. CRP will be measured using an enzyme-linked immunosorbent assay based on purified protein and polyclonal anti-CRP antibodies (sensitivity: 0.08 µg/ml and interassay coefficient of variation: 8.0%) (Calbiochem, San Diego, CA).
2.6. An ELISA will be used to measure IL-6, using commercial kits (detectable limit: 0.10 pg/ml and interassay coefficient of variation: 10.3%) (Quantikine, Minneapolis, MN, USA). Values will be measured in duplicate, and the average will be reported for both assays. Other metabolic variables for screening will be follicle stimulating hormone (FSH), thyroid stimulating hormone (TSH), HBA1c, creatinin, haptoglobin and Sex hormone-binding globulin (SHBG).
3. Glucose homeostasis will be measured before and after the intervention (total of 2 times). A 75g oral glucose tolerance test (OGTT) will be performed in the morning after a 12-hour fast, as recommended. Blood samples will be collected through a venous catheter from an antecubital vein in vacutainer tubes containing Trasylol (Miles, Rexdale, Ontario, Canada) and EDTA, at -15, 0, 15, 30, 45, 60, 90 and 120 minutes. Plasma insulin concentrations will be determined by radioimmunoassay using polyethylene glycol separation and glucose levels will be measured enzymically.
4. Measures of energy expenditure include the resting metabolic rate (RMR) and the metabolic cost of walking at different paces, both measured by indirect calorimetry. Measurement of gas concentrations will be used to determine 24h RMR using the equation of Weir. These measures will be taken before, during and after the intervention (total of 2 times).
5. Resting systolic and diastolic blood pressures and heart rate will be measured in sitting position. First, resting values for each visit will be determined as the average of the last four readings of five (one per min) from a Dinamap (Critikon, Johnson & Johnson, Tampa, FL) automatic machine. Measurements will be performed at different visits before, during and after the intervention (total of 8 times). An appropriate cuff size will be selected for each subject based on arm circumference
6. Physical capacity measures include climbing stairs, standing on one leg, hand grip strength and the 6-min walk test. These measures will be taken before and after the intervention (2 times)
7. Following questionnaires are used to measure psychosocial determinants:
7.1. Self-Efficacy
7.2. Perceived Benefits
7.3. Mendelson et als Body Esteem Scale
7.4. Medical Outcome Survey Quality of Life Questionnaire
7.5. Stunkard & Messicks 3-Factor Eating Questionnaire
7.6. Diet History Questions
7.7. Menopause rating scale

Overall study start date
09/01/2012

Completion date

09/01/2014

Eligibility

Key inclusion criteria
1. Women will be included in the study if they had stopped menstruating for more than 1 yr, and if they have follicle stimulating hormone (FSH) levels > 30 U/L
2. Aged between 60 and 75 years old
3. Body mass index (BMI) between 27 and 40 kg/m2
4. Sedentary (< 2 times a week of exercise)
5. Non-smokers
6. Low to moderate alcohol consumers (< 2 drinks/week)
7. Displaying at least one of the following factor of the metabolic syndrome accordingly to the Adult Treatment Panel III (ATP IIIs) definition [63] [triglycerides > 1.70 mmol/L; high density lipoprotein (HDL)-cholesterol < 1.29 mmol/L; resting blood pressure < 160/95 mmHg (treated or not); fasting plasma glucose > 6.1 mmol/L], 7) stable medication(s) for the metabolic syndrome since 6 weeks and
8. Glycated haemoglobin (HbA1c) < 8%

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
100 post-menopausal women distributed on 2 sites: Sherbrooke and Montréal

Key exclusion criteria
1. More than three medications for high blood pressure
2. Cardiovascular disease and peripheral vascular disease within 3 months
3. Stroke within 3 months and/or causing inability to complete the exercice program
4. Diabetes treated with insulin
5. Cancer within 5 years (excepted skin and thyroid cancer)
6. Severe hypertension (resting blood pressure > 160/95 mmHg under stable treatement)
7. Total cholesterol > 8 mmol/L
8. Triglycerides >10 mmol/L
9. Low density lipoprotein (LDL)-chol > 4 mmol/L
9. Body weight fluctuation > 3 kg in the previous six months
10. Pituitary disease
11. Renal insufficiency (creatine <45 ml/min)
12. Orthopaedic problems causing inability to complete the exercice program
13. Protein intake <0.8 g/kg or >1.2 g/kg body mass per day

Date of first enrolment
09/01/2012

Date of final enrolment

09/01/2014

Locations

Countries of recruitment
Canada

Study participating centre
Centre de recherche sur le vieillissement du CSSS-IUGS
Sherbrooke
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Sponsor information

Organisation
University of Sherbrooke (Canada)

Sponsor details
Université de Sherbrooke - Faculté déducation physique et sportive
2500, Boulevard de l'Université
Sherbrooke
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Sponsor type
University/education

Website
http://www.usherbrooke.ca/feps/accueil/

ROR
https://ror.org/00kybxq39

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) (ref: OTG 88590)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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