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Effects of pulse incorporation into the diet on components of the metabolic syndrome, body fatness and food habits in women

Submission date 17/04/2007	**Recruitment status** No longer recruiting
Registration date 12/06/2007	**Overall study status** Completed
Last Edited 25/10/2021	**Condition category** Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of pulse incorporation into the diet on components of the metabolic syndrome, body fatness and food habits in women

Study objectives
We hypothesise that consumption of pulses, which are low in fat and rich in dietary soluble fibres and plant proteins, will lead to beneficial changes in primary components of the metabolic syndrome (waist circumference, blood pressure, fasting plasma triglyceride, High Density Lipoprotein [HDL]-cholesterol, glucose levels and blood pressure), positively modify fatness composition (decrease in body fatness) and will be associated with positive changes in food habits.

The general objective of the randomised clinical trial will be to investigate the short- and long-term effects of incorporation of whole pulses (beans, peas, lentils and chickpeas) into the diet of women on components of the metabolic syndrome and percentage of body fat, as well as changes in dietary habits.

More specifically, we will investigate:
1. The acute short-term effects (16 weeks) of pulse incorporation into the diet on:
1.1. The primary components of the metabolic syndrome (waist circumference, blood pressure and fasting plasma triglyceride, HDL-cholesterol and glucose levels)
1.2. The secondary components of the metabolic syndrome (insulin sensitivity index and insulinaemia, apolipoprotein A1[apo-A1], apolipoprotein B [apo-B], Lipoprotein a [Lp(a)], Low Density Lipoprotein [LDL] size subfractions, fibrinogen, Plasminogen Activator Inhibitor-1 [PAI-1], C-Reactive Protein [CRP], Interleukin-6 [IL-6], Tumour Necrotising Factor-alpha [TNF-a] and homocysteine), and
1.3. The percentage of body fat evaluated by bioelectrical impedance analysis
2. The long-term effects (eight weeks following the end of the dietary intervention) of participating in a dietary clinical trial and receiving nutritional and health information on:
2.1. Changes in womens dietary habits
2.2. Changes in the foods consumed by their families, and
2.3. Changes in the recommendations they give to their patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the ethical committee of the clinical research of the St-Francois d'Assise Hospital on the 26th October 2006.

Study design
Randomised controlled study design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Metabolic syndrome, nutrition

Interventions
Women will be randomly assigned to either an incorporation of pulse or control meals into their diet, which they will consume for a period of 16 weeks. Women will be seen in the clinical unit for a follow-up check at weeks 8, 16 and 24.

During the dietary intervention, both groups will consume five experimental meals per week. Based on the United States Department of Agriculture (USDA) dietary guidelines, pulse meals will be formulated to provide a total of three cups (approximately 600 g) of pulses per week. On a weekly basis, pulse meals will provide the four groups of pulses (beans, peas, lentils and chickpeas) and possibly more than one type of each group. Control meals will be formulated to conform to dietary recommendations of Canadas Food Guide to Healthy Eating with the exception that pulses will be excluded from these meals. All meals (main dishes) will be formulated as ten rotating meals, repeated eight times.

Experimental and control meals will be formulated to provide the same content of energy on a weekly basis.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Primary outcomes will be evaluated at screening, randomisation and weeks 8, 16 and 24.
1. Lipid profile and glycaemia
2. Waist circumference

Secondary outcome measures
1. Plasma levels of apo A-1, apo B and Lp(a) will be measured at randomisation and at week 16
2. LDL particle size will be measured at randomisation and at week 16
3. Plasma haemostatic balance markers: fibrinogen and PAI-1 will be measured at randomisation and at week 16
4. Plasma inflammation mediators: CRP, IL-6 and TNF-a will be measured at randomisation and at week 16
5. Plasma levels of homocysteine will be measured at randomisation and at week 16
6. Insulin sensitivity (Homeostatic Model Assessment version 2 [HOMA2] and Quantitative Insulin Sensitivity Check Index [QUICKI]) will be measured at randomisation and at week 16
7. Blood pressure will be measured at randomisation and each follow-up visit thereafter
8. Anthropometric variables (weight and height) will be measured at randomisation and each

follow-up visit thereafter
9. Body composition (fat mass, fat-free mass, percentage of body fat, basal metabolic rate will be assessed by impedance analysis) will be measures at randomisation and each follow-up visit thereafter
10. Dietary habit strength (self-report index of habit strength will be measured at randomisation and at week 24)
11. Eating behaviour (51-item Three-Factor Eating Questionnaire (TFEQ) will be evaluated at baseline and at week 24)
12. Changes in the food consumed by their families (questionnaire related to their food-related activities at home evaluated at week 24)

Overall study start date
27/11/2006

Completion date
01/03/2008

Eligibility

Key inclusion criteria
1. Women between 30 and 65 years of age
2. Have a minimum of two of the following four metabolic risk factors:
2.1. Waist circumference equal to or higher than 88 cm
2.2. Fasting plasma triglycerides equal to or higher than 1.7 mmol/l
2.3. Fasting plasma HDL-cholesterol lower than 1.3 mmol/l
2.4. Fasting blood glucose equal or higher to 5.5 mmol/l

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
132

Total final enrolment
134

Key exclusion criteria
1. Personal history of Cardiovascular Disease (CVD) or type two diabetes
2. Uncontrolled hypertension (greater than 140/90 mmHg)
3. Familial hypercholesterolaemia
4. Use of medication that interferes with lipid or glucose metabolism
5. Extreme nutritional habits such vegetarianism

6. Smokers
7. Drink more than two drinks of alcohol per day
8. Have known food allergies

Date of first enrolment
27/11/2006

Date of final enrolment
01/03/2008

Locations

Countries of recruitment
Canada

Study participating centre
45 rue Leclerc
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Sponsor information

Organisation
Pulse Canada (Canada)

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Sponsor type
Industry

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Funder(s)

Funder type

Industry

Funder Name
Pulse Canada (Canada)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		15/04/2010	25/10/2021	Yes	No