

# 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

Prospectively registered

Protocol

**Registration date**  
12/06/2007

**Overall study status**  
Completed

Statistical analysis plan

Results

**Last Edited**  
25/10/2021

**Condition category**  
Nutritional, Metabolic, Endocrine

Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Sylvie Dodin

### Contact details

45 rue Leclerc  
local D6-721  
Québec  
Canada  
G1L 2G1

## Additional identifiers

## 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

### **Study type(s)**

Quality of life

### **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(s)**

Primary outcomes will be evaluated at screening, randomisation and weeks 8, 16 and 24.

1. Lipid profile and glycaemia
2. Waist circumference

### **Key secondary outcome(s)**

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 measured 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)

### **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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

Québec

Canada

G1L 2G1

# Sponsor information

## Organisation

Pulse Canada (Canada)

## Funder(s)

### Funder type

Industry

### Funder Name

Pulse Canada (Canada)

# Results and Publications

## 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?
<a href="#">Results article</a>		15/04/2010	25/10/2021	Yes	No