# Ambulatory integrated primary care management program for patients with dyslipidaemia

Submission date	Recruitment status	[X] Prospectively registered
09/08/2005	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
09/08/2005	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
16/04/2010	Nutritional, Metabolic, Endocrine	

### Plain English summary of protocol

Not provided at time of registration

# Contact information

### Type(s)

Scientific

### Contact name

Dr Lyne Lalonde

### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

### Secondary identifying numbers

MCT-75427

# Study information

### Scientific Title

Randomised controlled trial to evaluate an ambulatory integrated primary care management program for patients with dyslipidaemia: TEAM Study

### Acronym

**TEAM** 

### Study objectives

Compared to the usual care (UC) patients, those assigned to the integrated primary care (IPC) intervention will have a larger reduction in low-density lipoprotein cholesterol (LDL-C) and more patients will achieve the recommended target lipid levels.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics and research committee of the Laval Health and Social Service Centre gave approval on the 19th October 2004

### Study design

Randomised controlled trial

## Primary study design

Interventional

### Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

Dyslipidaemia

### **Interventions**

In the integrated primary care (IPC) intervention, family physicians will be responsible for the diagnosis and prescription of the statin treatment. Thereafter, the pharmacists will be responsible for monitoring the effectiveness and safety of the treatment. They will be allowed to request laboratory tests at predetermined time intervals and perform protocol-driven dosage adjustments.

In the usual care (UC) intervention, physicians and pharmacists will receive no instructions regarding the type and frequency of patient visits.

### Intervention Type

Other

### Phase

Not Applicable

### Primary outcome measure

Mean change in LDL-C from baseline to month 12

### Secondary outcome measures

1. Achievement of the recommended target lipid levels, TC, HDL-C, TC/HDL-C, triglyceride, blood pressure, body mass index, fasting blood glucose, adherence and persistence to statin treatment, patient satisfaction, knowledge and decisional conflict, professionals' satisfaction 2. Application of the IPC intervention

### Overall study start date

01/02/2006

### Completion date

01/01/2008

# Eligibility

### Key inclusion criteria

- 1. Aged greater than or equal to 18 years, either sex
- 2. Speak and read French or English
- 3. Are able to give informed consent and understand and follow study procedures
- 4. Agree to participate and sign the informed consent
- 5. According to the results of their last laboratory tests (performed in the previous three months), are candidate for initiating statin monotherapy or are currently on statin monotherapy at a non-optimal dose and are not adequately controlled according to one of the following criteria:
- 5.1. High risk (10-year coronary heart disease [CHD] risk greater than 20%): LDL-C greater than
- 2.5 mmol/l and total cholesterol (TC):high-density lipoprotein (HDL-C) ratio greater than 4
- 5.2. Moderate risk (10-year CHD risk between 11 19%): LDL-C greater than 3.5 mmol/l and TC: HDL-C ratio greater than 5
- 6. Agree to be followed by one of the participating family physicians and one of the pharmacists for the duration of the study (12 months)
- 7. IPC physician agrees to refer the patient to a participating pharmacist for dyslipidaemia-treatment follow-up
- 8. Physician agrees to delay the beginning or change of pharmacotherapy until the initial study visit
- 9. Patients are not patients of a particular pharmacy or report being patients of one of the participating pharmacies

### Participant type(s)

Patient

### Age group

Adult

### Lower age limit

18 Years

### Sex

Both

### Target number of participants

224

### Key exclusion criteria

- 1. Patients already taking lipid-lowering medication and adequately controlled according to the most recent Canadian guidelines for the treatment of dyslipidaemia
- 2. Patients taking more than one lipid-lowering medication
- 3. Patients with acute cardiovascular disease (CVD) event (e.g. myocardial infarction, stroke and revascularisation) in the previous 6 months
- 4. Patients with a life-threatening disease or another health condition (severe mental problems, chronic alcoholism, renal insufficiency [creatinine clearance less than 60 ml/min], hepatic insufficiency [aspartate aminotransferase {AST}, alanine aminotransferase {ALT} greater than 3 x the upper normal limit] etc.) that, according to the referring physician, make them unlikely to complete the study
- 5. Patient with triglyceride greater than 5 mmol/l
- 6. Patient with LDL-C greater than 5 mmol/l
- 7. Patient with contraindication to statin medication (elevated transaminase levels [AST or ALT greater than 3 x the upper normal limit], history of myalgia with creatinine kinase [CK] greater than 10 x the upper normal limit)
- 8. Participating in another clinical trial

### Date of first enrolment

01/02/2006

### Date of final enrolment

01/01/2008

# Locations

### Countries of recruitment

Canada

Study participating centre Équipe de recherche Laval, Quebec

Canada H7M 3L9

# Sponsor information

### Organisation

University of Montreal (Canada)

### Sponsor details

Faculté de Pharmacie Université de Montréal C.P. 6128 Succursale Centre-ville Montreal, Quebec Canada H3C 3J7 +1 514 343 7497 sophie.brisbois@umontreal.ca

### Sponsor type

University/education

### Website

http://www.umontreal.ca/english/

### **ROR**

https://ror.org/0161xgx34

# Funder(s)

### Funder type

Research organisation

### **Funder Name**

Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-75427)

# **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

# Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/03/2010		Yes	No