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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

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Mean change in LDL-C from baseline to month 12

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

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

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