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The impact of a multidisciplinary, information technology supported program on blood pressure control in primary care

Submission date 29/06/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/07/2004	**Overall study status** Completed	
Last Edited 01/02/2019	**Condition category** Circulatory System	

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
NCT00374829

Secondary identifying numbers
DCT 67995

Study information

Scientific Title
The impact of a multidisciplinary information technology-supported program on blood pressure control in primary care.

Study objectives
It is hypothesised that blood pressure control will be improved in patients receiving the program by increasing compliance with pharmacotherapy, the use of higher doses of anti-hypertensive agents and the use of more anti-hypertensive agents when appropriate, without adversely impacting quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local ethics committee (Cité de la Santé de Laval Comité d'éthique et de la recherche) in November 2003.

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
Hypertension

Interventions
Intervention:
We have developed an Information Technology (IT)-based system to help empower patients to be responsible for monitoring their Blood Pressure (BP) and compliance and to facilitate communication with healthcare providers. The IT-based system links with actual pharmacy prescription refill and renewal data. Using these data as well as responses to questions on compliance and BP control that patients provide, the system:
a. offers patients counselling and telephone reminders

b. generates prescription refill and renewal reminder calls
c. monitors patient recorded BP

The system generates monthly reports to the treating physician and pharmacist on compliance and blood pressure control, a retroaction that we expect will guide therapy. The system also links patients with a nurse if BP is inadequately controlled and/or if patients are non-compliant. These nurses can then provide appropriate counselling to patients and refer the patients to their physician or pharmacist as appropriate.

Control:
The control group will receive standard care with no access to the IT-based system and multidisciplinary approach.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary objective of this study is to evaluate the impact of a multidisciplinary, information-technology supported hypertension management program on the mean change in 24-hour systolic and diastolic BP levels measured using Ambulatory Blood Pressure Monitoring (ABPM) compared to usual care.

Secondary outcome measures
1. To assess the likely mechanisms that account for the results for the primary objective by measuring refill compliance and the number and dosage of anti-hypertensive agents assessed through pharmacy prescription data records over the 12-month study period as well as the number and nature of interventions by pharmacists, nurses and physicians
2. To assess the effect of the program on mean daytime and nocturnal BP, office BP measured, the proportion of subjects who achieve target office BP
3. To assess the impact of the program on patients perceived health related quality of life
4. To assess the impact of the program on the incidence of adverse cardiovascular events, including hospitalisation for uncontrolled hypertension, new onset angina, myocardial infarction, hospitalisation for unstable angina, hospitalisation for congestive heart failure, hospitalisation for stroke, hospitalisation for other vascular event, and cardiovascular death
5. To evaluate the potential economic benefits of the intervention, from a third-party payers perspective

Overall study start date
01/05/2004

Completion date
01/02/2008

Eligibility

Key inclusion criteria
1. Male and female uncontrolled hypertensive subjects
2. 18 years of age or more

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

Key exclusion criteria
1. Having a life-threatening disease
2. Chronic atrial fibrillation
3. Unable to use an ordinary telephone
4. Pregnant at the initial visit
5. Participating in another clinical trial
6. Living with another subject that is currently participating in the study

Date of first enrolment
01/05/2004

Date of final enrolment
01/02/2008

Locations

Countries of recruitment
Canada

Study participating centre
University of Montreal
Montréal, QC
Canada
H2L 4M1

Sponsor information

Organisation
Canadian Institutes of Health Research (CIHR) (Canada)

Sponsor details
Room 97
160 Elgin Street
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Sponsor type
Research organisation

Website
http://www.cihr-irsc.gc.ca

ROR
https://ror.org/01gavpb45

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: DCT 67995)

Funder Name
Pfizer Canada Inc. (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2009	01/02/2019	Yes	No