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Home Blood Pressure Monitoring and blood pressure (BP) control

Submission date 14/08/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/09/2003	**Overall study status** Completed	
Last Edited 18/03/2010	**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

ClinicalTrials.gov (NCT)
NCT00202137

Protocol serial number
NA 4882

Study information

Scientific Title

Acronym
HBPM

Study objectives
Hypertension is a common problem in Canada with a prevalence of about 15%. The goal of hypertension therapy should be to maximize blood pressure control. Home Blood Pressure Monitoring (HBPM) devices are available and many patients are using them. The role that self-monitoring of blood pressure can play in optimizing blood pressure control is unclear. We hope to clarify the role of home blood pressure monitoring in the treatment of hypertension and explore how it may affect patient and physician behaviours related to blood pressure management. This study will compare a group of hypertensive patients who use HBPM with those who do not use these devices.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

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

Interventions
Patients in the intervention group are provided with a home blood pressure monitor that they are to use at least once a week and report the BP measurements to their physician at each follow up visit.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. The mean daytime blood pressures on Ambulatory Blood Pressure Monitoring (ABPM)
2. The mean night-time blood pressures on ABPM
3. Achieving Blood Pressure (BP) target at end of study
4. Achieving 10% drop in the mean nighttime blood pressures

Key secondary outcome(s))
1. Patient lifestyle changes
2. The number of visits for hypertension
3. Compliance with hypertensive medication use
4. Compliance with the intervention
5. Intensity of treatment
6. Frequency of lifestyle counselling by physician
7. Quality of Life as measured by 36-item Short Form health survey (SF-36)

Completion date
01/11/2006

Eligibility

Key inclusion criteria
1. Adults (age 18 and older) who are patients of family physicians
2. Must be diagnosed with essential hypertension but not have yet achieved target levels

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. A diagnosis of secondary hypertension
2. Pregnancy
3. Hypertension management primarily by a consultant
4. A disability that precludes use of a home blood pressure monitor
5. Enrolled in another hypertension trial
6. White coat hypertension

Date of first enrolment
01/07/2002

Date of final enrolment
01/11/2006

Locations

Countries of recruitment

Canada

Study participating centre
Centre for Studies in Primary Care
Kingston, Ontario
Canada
K7L 5E9

Sponsor information

Organisation
Heart and Stroke Foundation of Ontario (Canada)

ROR
https://ror.org/00qbpyp73

Funder(s)

Funder type
Charity

Funder Name
Heart and Stroke Foundation of Ontario (Canada)

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	28/06/2005		Yes	No
Protocol article	protocol	22/12/2003		Yes	No