# Home Blood Pressure Monitoring and blood pressure (BP) control

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

## Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Dr Marshall Godwin

#### Contact details

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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

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
<u>Protocol article</u>	protocol	22/12/2003		Yes	No