

A randomised controlled trial of telemonitoring and self management in the control of hypertension: Telemonitoring And Self Management IN Hypertension

Submission date 06/10/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 10/11/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/05/2016	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

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

V2 26/06/2006

Study information

Scientific Title

A randomised controlled trial of telemonitoring and self management in the control of hypertension: Telemonitoring And Self Management IN Hypertension

Acronym

TASMINH2

Study objectives

The primary aim of TASMINH2 is to compare self management with usual care in the control of hypertension. The trial has three main research questions:

1. Does self management with telemonitoring and titration of antihypertensive medication by people with poorly controlled hypertension result in better control of blood pressure?
2. Does self management with telemonitoring and titration of antihypertensive medication by people with poorly controlled hypertension result in changes in reported adverse events or health behaviours and is it cost effective?
3. Is self management with telemonitoring and titration of antihypertensive medication achievable in routine practice and is it acceptable to patients?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Sandwell and West Birmingham Local Research Ethics Committee, 10/10/2005, ref: 05/Q2709 /103

Study design

Primary-care based unblinded randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Uncontrolled treated hypertension

Interventions

TASMINH2 is a primary-care based, unblinded, randomised controlled trial with embedded economic and qualitative analyses in order to evaluate the costs and effects of increasing patient involvement in blood pressure management. Randomisation of patients with uncontrolled hypertension will be to either usual care or self management of their hypertension and will take place centrally using the process of minimisation taking into account practice, sex, diabetic status, baseline blood pressure and age.

Usual care will consist of the participant seeing their GP and/or nurse periodically for blood pressure measurement and/or adjustment of medication at the discretion of the GP.

Self management will consist of self monitoring of blood pressure with electronic transmission of readings, and self titration of medication dependant on the self monitoring readings.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Mean change in systolic blood pressure (mmHg) between baseline and each follow up point (six months and 12 months), measured in the surgery by the research team.

Key secondary outcome(s)

1. Adverse events (side effects, anxiety)
2. Health behaviours
3. Patient satisfaction
4. Costs and reasons for non-participation

Completion date

01/10/2009

Eligibility

Key inclusion criteria

1. Aged between 35 and 75
2. Treated hypertension
3. Blood pressure greater or equal to 140/90 (140/80 mmHg for those with diabetes)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Inability to self monitor
2. More than three antihypertensive medications
3. Terminal disease
4. Blood pressure not managed by their General Practitioner (GP)

Date of first enrolment

01/11/2006

Date of final enrolment

01/10/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of Birmingham

Birmingham

United Kingdom

B15 2TT

Sponsor information

Organisation

University of Birmingham (UK)

ROR

<https://ror.org/03angcq70>

Funder(s)

Funder type

Government

Funder Name

NHS executive, Department of Health (UK)

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	17/07/2010		Yes	No
Results article	results	01/07/2015		Yes	No
Protocol article	protocol	16/02/2009		Yes	No