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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	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/11/2006	**Overall study status** Completed	
Last Edited 05/05/2016	**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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes