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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
06/10/2006		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
10/11/2006	Completed	[X] Results		
<b>Last Edited</b> 05/05/2016	Condition category Circulatory System	[] Individual participant data		

#### Plain English summary of protocol

Not provided at time of registration

# **Contact information**

# Type(s)

Scientific

#### Contact name

Dr Richard McManus

#### Contact details

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# Additional identifiers

EudraCT/CTIS number

IRAS number

#### ClinicalTrials.gov number

#### Secondary identifying numbers

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

# Secondary study design

Randomised controlled trial

# Study setting(s)

Hospital

# Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

#### 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 measure

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.

#### Secondary outcome measures

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

# Overall study start date

01/11/2006

#### 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

#### Age group

#### Adult

#### Sex

Both

# Target number of participants

478; 239 per group

#### 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

England

**United Kingdom** 

# Study participating centre University of Birmingham

Birmingham United Kingdom B15 2TT

# Sponsor information

#### Organisation

University of Birmingham (UK)

#### Sponsor details

Research and Enterprise Services Edgbaston Birmingham England United Kingdom B15 2TT

#### Sponsor type

University/education

#### Website

http://www.bham.ac.uk

#### ROR

https://ror.org/03angcq70

# Funder(s)

#### Funder type

Government

#### Funder Name

NHS executive, Department of Health (UK)

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