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Telemonitoring and/or self-monitoring in hypertension

Submission date 17/07/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/07/2014	**Overall study status** Completed	
Last Edited 13/04/2018	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Self-monitoring of blood pressure in hypertension (high blood pressure) is associated with lower blood pressure (BP). However, the evidence for the use of self-monitoring to adjust blood pressure medication by doctors is variable depending which study one looks at. Furthermore, there is some evidence for the effectiveness of telemonitoring (where blood pressure readings are sent electronically) in the management of hypertension, but it is not clear what this adds over and above self-monitoring. This study aims to evaluate whether GP-led adjustment of blood pressure measurement using self-monitoring results in lower systolic BP compared to usual care (using clinic blood pressure readings), and whether telemonitoring adds anything to self-monitoring alone.

Who can participate?
Patients aged 35 or over with poorly controlled hypertension

What does the study involve?
Participants are randomly allocated to either usual care, self-monitoring alone (measuring your own blood pressure and sharing results with GP using a paper record sheet), or self-monitoring with telemonitoring (measuring your own blood pressure, sending the results electronically to your GP). There are follow-up clinics after 6 and 12 months. We also look at whether self-monitoring affects things like how well people take their medication, smoking, diet and exercise, quality of life, adverse events and costs. We talk to a sample of participants about their experiences of the study.

What are the possible risks and benefits of taking part?
The main benefits are likely to be after the study has finished in terms of doctors knowing whether self-monitoring of blood pressure is worthwhile. It is not anticipated that there will be any particular risks in taking part over and above those associated with normal blood pressure treatment. Those who self-monitor will need to spend extra time doing this and blood pressure cuffs can occasionally be uncomfortable. Everyone taking part will be asked to attend three clinics (start, middle and end) which will take around an hour each.

Where is the study run from?
Nuffield Department of Primary Care Health Sciences (UK)

When is the study starting and how long is it expected to run for?
September 2014 to March 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Prof. Richard McManus
richard.mcmanus@phc.ox.ac.uk

Study website
http://www.phc.ox.ac.uk/research/hypertension/monitoring-and-self-monitoring/tasminh4

Contact information

Type(s)
Scientific

Contact name
Prof Richard McManus

ORCID ID
http://orcid.org/0000-0003-3638-028X

Contact details
Nuffield Department of Primary Care Health Sciences
Radcliffe Observatory Quarter
Woodstock Road
Oxford
United Kingdom
OX2 6GG
-
richard.mcmanus@phc.ox.ac.uk

Type(s)
Public

Contact name
Ms Marloes Franssen

Contact details
Nuffield Department of Primary Care Health Sciences
Radcliffe Observatory Quarter
Woodstock Road
Oxford
United Kingdom

OX2 6GG
-
marloes.franssen@phc.ox.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16745

Study information

Scientific Title
Telemonitoring and/or self-monitoring in hypertension (TASMINH4): a randomised controlled trial

Acronym
TASMINH4

Study objectives
The aim of this study is to evaluate the management of hypertension in primary care using self-monitored blood pressure, with or without telemonitoring compared to standard care. The study also aims to address:
1. Is self-monitoring acceptable to patients and cost-effective?
2. Does self-monitoring affect antihypertensive medication adherence?
3. Does self-monitoring affect lifestyle factors including smoking, alcohol, diet and exercise?
4. Is it possible to use routine GP clinical systems to collect sufficiently robust data for a subsequent trial powered on cardiovascular outcomes?

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 25/06/2014, ref: 14/SC/0218

Study design
Randomised; Interventional; Design type: Prevention, Process of Care, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
Current interventions as of 27/05/2016:
370 patients will be randomised to usual care (UC) and 740 randomised to self-monitoring (370 self-monitoring alone and 370 telemonitoring).

1. Self-monitoring alone: Patients in the self-monitoring alone group will be asked to monitor their blood pressure twice each morning and evening (i.e. four times in all) for the first week of each month. A paper record sheet will be used for communication between patient and health care professionals in the self-monitoring alone group. GPs and nurses will be advised to calculate the mean self-monitored blood pressure and to use this to titrate antihypertensive medication.

2. Telemonitoring: the frequency of self-monitoring will be identical to the self-monitoring alone group but blood pressure readings will be transmitted to a secure centralised database from which the GP/ nurse can review the records. Readings will be transmitted by free SMS text message. A mean blood pressure will be automatically calculated. High or low readings will trigger alerts to patient to contact their surgery for a blood pressure check. GPs and nurses will be advised to use the mean self-monitored blood pressure to titrate antihypertensive medication.

3. Usual Care: Management for the control group will be usual care guided by office BP measured by the GP/practice nurse without further instruction.

Previous interventions:
370 patients are randomised to usual care (UC) and 740 randomised to self-monitoring arm.

1. Telemonitoring: Patients in the self-monitoring arms will be asked to monitor their blood pressure twice each morning and evening (i.e. four times in all). Patients will self-monitor for the first week of each month. Frequency identical to self-monitoring but readings transmitted to a secure centralised database from which GP/ nurse can review the records. Readings will be transmitted by free SMS text message. In the telemonitoring group, a mean blood pressure will be automatically calculated. High or low readings will trigger alerts to patient to contact their surgery for a blood pressure check. A paper record sheet will be used for communication in the self-monitoring alone group. Nurses will follow an algorithm that recommends adjustment of antihypertensive medication on the basis of the number of readings above target: if more than half are above target then the algorithm will reco

2. Usual Care: Management for the control group will be usual care guided by office BP measured by the
GP/practice nurse without further instruction.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Systolic BP (mean of 2nd and 3rd BP readings); Timepoint(s): 12 months

Secondary outcome measures
Current secondary outcome measures as of 01/06/2016:
1. Systolic and diastolic BP; Timepoint(s): 6 months and 12 months
2. Costs, health sector resource use, and acceptability; Timepoint(s): 12 months
3. MARS adherence questionnaires and prescribing data; Timepoint(s): 12 months
4. Questionnaire data on lifestyle factors; Timepoint(s): 12 months
5. Comparison between trial outcome data and that from clinical databases; Timepoint(s): 12 months

Previous secondary outcome measures:
1. Systolic and diastolic BP; Timepoint(s): 6 months and 12 months
2. Costs, health sector resource use, and acceptability; Timepoint(s): 24 months
3. MARS adherence questionnaires and prescribing data; Timepoint(s): 12 months
4. Questionnaire data on lifestyle factors; Timepoint(s): 12 months
5. Comparison between trial outcome data and that from clinical databases; Timepoint(s): 24 months

Overall study start date
01/09/2014

Completion date
28/03/2017

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the trial
2. Male or female, aged 35 years or above
3. On practice hypertension register, not already taking more than 3 anti-hypertensive agents and above clinic target BP (i.e. =140/90 mmHg) at baseline (mean of 2nd/ 3rd readings)
4. Stable dose of current antihypertensive medication for at least four weeks prior to trial entry
5. In the Investigators' opinion, is able and willing to comply with all trial requirements or has a carer able to help sufficiently (e.g. in the case of physical issues with self-monitoring)
6. Willing to allow his or her General Practitioner to be notified of participation in the trial

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 1110; UK Sample Size: 1110

Key exclusion criteria
1. BP below target at baseline (i.e. <140/90 mmHg on clinic measurement at baseline visit)
2. Already taking more than 3 anti-hypertensive agents
3. Orthostatic hypotension: more than 20mmHg systolic drop after standing for 1 minute
4. Diagnosed atrial fibrillation
5. Unwilling to self-monitor
6. BP managed outside of primary care (including secondary hypertension)
7. Unable to provide consent
8. Dementia or score over 10 on the short orientation memory concentration test (and with no carer support)
9. Female participant who is pregnant, lactating or planning pregnancy during the course of the trial.
10. The partner or spouse of an individual already randomised in the trial
11. Chronic Kidney Disease (CKD) Grade 4 or worse; any grade of CKD with proteinuria
12. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participants ability to participate in the trial (e.g. terminal illness, house bound and unable to attend baseline and follow up clinics)
13. Participants who have participated in another research trial involving an antihypertensive medication in the past 4 weeks

Date of first enrolment
13/11/2014

Date of final enrolment
03/02/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nuffield Department of Primary Care Health Sciences
Oxford
United Kingdom
OX2 6GG

Study participating centre

144 practices recruited from the following NIHR Clinical Research Networks:
Thames Valley, West Midlands, East of England, West of England, Kent Surrey and Sussex, North West Coast, North West London
United Kingdom
-

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Department of Primary Care Health Sciences
Radcliffe Observatory Quarter
Woodstock Road
Oxford
England
United Kingdom
OX2 6GG

Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research; Grant Codes: RP-PG-1209-10051

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Two further publications from this trial are planned before the end of 2018, a qualitative paper and a health economics paper. Publications analysing the secondary outcomes are also planned within the next 5 years.

Intention to publish date
13/04/2023

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/02/2017		Yes	No
Results article	results	10/03/2018		Yes	No
HRA research summary			28/06/2023	No	No