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A trial of the Home & Online Management & Evaluation of Blood Pressure (HOME BP) digital intervention for self-management of uncontrolled, essential hypertension in primary care

Submission date 14/05/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/05/2015	**Overall study status** Completed	
Last Edited 16/05/2023	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
High blood pressure (BP), or hypertension, occurs when a person's blood pressure is continually higher than recommended. It is often referred to as a "silent killer" as, although it rarely results in symptoms of its own, if left untreated it can increase the likelihood of the affected person having a heart attack or a stroke. Treatment involves lifestyle changes for the patient and possibly prescribed medication. The HOME BP intervention is designed to help people self-manage their raised BP through self-monitoring, medication adherence and lifestyle changes using the HOME BP online system with optional nurse support. We want to compare people using HOME BP intervention to those receiving usual GP care for their hypertension. The trial aims to test whether BP is reduced in patients with existing uncontrolled hypertension (>140 /90) when patients and clinicians use HOME BP online to adopt gold standard procedures for home monitoring and adjusting medication.

Who can participate?
Adults (aged at least 18) with above target blood pressure (>140/90), who are currently taking medication to control their blood pressure.

What does the study involve?
Patients are randomly allocated into one of two groups. Those in group 1 (control) receive their usual standard of care. Those in group 2 (intervention) are given access to HOME BP. All patients (from both groups) are given a blood pressure medication review with a GP at the start of the study. Using HOME BP online, patients in group 2 are trained to monitor their blood pressure, and reminded to take their own readings for one week each month. These readings are entered in to HOME BP online, which lets patients and their GPs know when blood pressure has remained too high for too long. Any changes in medication, such as extra or different medications, are based on the home readings and confirmed by the GP. A nurse is available to

help patients use the online programme, the blood pressure monitor or offer support with making healthy lifestyle changes to reduce blood pressure. Patients monitor and record their own blood pressure for 12 months. It is also measured by a research nurse at 6 months and 12 months after joining the study. The main outcome (that is the main thing the trial will measure) is blood pressure and this is compared between HOME BP and usual care groups after 12 months. Other important trial measurements include blood pressure differences at six months, any changes in blood pressure medication, quality of life and patient beliefs about hypertension self-management. Some patients in the HOME BP group will be invited to discuss their experiences of the study.

What are the possible benefits and risks of participating?
Taking part in the study may have a positive impact upon a participant's health. Previous studies have found improvements in blood pressure for people who self-monitor and self-manage their blood pressure. We think there is very little risk of harm in taking part. Their practice nurse will be in contact with each participant throughout the study, and will be able to advise if any participant experiences any problems.

Where is the study run from?
Southampton Primary Medical Care (University of Southampton) and Radcliffe Infirmary ISAT Headquarters (Oxford)

When is the study starting and how long is it expected to run for?
January 2014 to December 2018

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

Who is the main contact?
Kate Morton (public)
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18553

Study information

Scientific Title
The Home & Online Management & Evaluation of Blood Pressure (HOME BP) digital intervention for self-management of uncontrolled, essential hypertension: a randomised controlled trial

Acronym
HOME-BP

Study objectives
Current hypothesis as of 19/05/2016:
The aim of the HOME BP trial is to evaluate the addition of the HOME BP intervention with nurse support into primary care for the self-management of hypertension in comparison to usual care. The study also aims to address:

1. Does the HOME BP intervention to assist self-monitoring and self-management of uncontrolled hypertension result in greater control of systolic blood pressure after one year?
2. Does the HOME BP intervention result in greater control of systolic and diastolic blood pressure after six months and diastolic blood pressure after one year?
3. Is the HOME BP intervention more cost-effective than usual care in managing poorly controlled hypertension in primary care?
4. Which factors are related to patient engagement and adherence to HOME BP?
5. Which factors are related to patient medication adherence and uptake of recommended medication titrations?
6. Does the inclusion of lifestyle change choices and behavioural support result in engagement with lifestyle change?
7. Is the HOME BP intervention acceptable to patients when integrated into routine practice?
8. What are patient and health care practitioner views and experiences of the HOME BP intervention and its integration addition into primary care for the self-management of poorly controlled hypertension?

Previous hypothesis:
The aim of the study is to evaluate the use of the HOME BP programme to assist self-monitoring and self-management of uncontrolled hypertension compared to usual care. The study also aims to address:

1. Is the HOME-BP programme a cost-effective method for managing poorly controlled hypertension in primary care?
2. Is the HOME BP programme acceptable to patients and what are the factors affecting engagement and adherence to the HOME BP programme?
3. What are patient and health care practitioner views and experiences of the HOME-BP programme and its integration into primary care for the self-management of poorly controlled hypertension?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Hampshire A, 19/03/2015, ref: 15/SC/0082.

Study design
Randomised; Interventional and Observational; Design type: Process of Care, Treatment, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Primary Care, Cardiovascular disease; Subtopic: Cardiovascular (all Subtopics), Primary care; Disease: Cardiovascular, All Diseases

Interventions
Interventions as of 19/05/2016:
574 (updated to 610 22/01/18) participants will be randomised to usual care (UC) and the HOME BP intervention arm (1:1):
1. HOME BP: Patients will have access to HOME BP online. Patients will be asked to monitor their blood pressure for 7 days each month, taking two BP measurements, five minutes apart at the same time each day. Patients will record the second blood pressure reading and enter these into HOME BP online after 7 readings have been recorded. HOME BP online will calculate mean blood pressure, using an algorithm to recommend that adjustment of anti-hypertensive medication is required when blood pressure remains above target. Readings triggering the recommendation for medication adjustment will be sent to the healthcare professional by email, who will then issue a prescription or indicate that this is not required. Very high or low readings will follow an offline procedure where the patient contacts their surgery directly.

2. Usual Care: After a post-randomisation medication review participants will receive usual care for blood pressure management.

Previous interventions:
574 participants will be randomised to usual care (UC) and the HOME BP intervention arm (1:1):
1. HOME BP: Patients will have access to the online HOME BP programme. Patients will be asked to monitor their blood pressure for 7 days each month. Patients will record the second blood pressure reading and enter these into the programme after 7 readings have been recorded. The HOME BP programme will calculate a mean blood pressure, using an algorithm to recommend adjustment of anti-hypertensive medication when blood pressure remains above target. Readings will be sent to the patient and healthcare professionals by email. High or low readings will follow an offline procedure where the patient contacts their surgery directly.
2. Usual Care: After a post-randomisation medication review participants will receive usual care for blood pressure management.

Intervention Type
Behavioural

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 19/05/2016:
1. Systolic and diastolic BP; Timepoint(s) 6 and 12 months
2. Prescribing data and consultations; Timepoint(s) 12 months
3. Patient medication use (number and defined daily doses); Timepoint(s) 6 and 12 months
4. Health-related quality of life; Timepoint(s) 6 and 12 months
5. Questionnaire measures on patient enablement
Costs of equipment and drugs, Health professional and patient time; Timepoint(s) 12 months

Process analysis measures:
1. Questionnaire measure of patient self-efficacy; Timepoint(s) 6 and 12 months
2. Patient medication beliefs, adherence and self-reported side effects; Timepoint(s) 6 and 12 months
3. Patient weight measured within clinic and self-reported lifestyle behaviours; Timepoint 12 months
4. Patient blood pressure (BP) monitoring adherence measured by the HOME BP online system; Timepoint ongoing
5. Utilisation of optional support provision; Timepoint ongoing
6. Digital intervention website usage and engagement, including lifestyle choice, usage and progress; Timepoint ongoing
7. Adherence to recommended medication changes; Timepoint ongoing
8. Prescriber and support provider self-efficacy and outcome expectations; Timepoint baseline
9. Prescriber and support provider confidence in the acceptability of the intervention; Timepoint baseline

Previous secondary outcome measures:
1. Systolic and diastolic BP; Timepoint(s) 6 and 12 months
2. Prescribing data and consultations; Timepoint(s) 12 months
3. Patient medication beliefs, adherence, changes and self-reported side-effects; Timepoint(s) 6 and 12 months

4. Questionnaire measures on patient enablement and self-efficacy; Timepoint(s) 6 and 12 months
5. Health-related quality of life; Timepoint(s) 6 and 12 months
6. Costs of equipment and drugs, Health professional and patient time; Timepoint(s) 12 months

Overall study start date
01/01/2014

Completion date
31/12/2018

Eligibility

Key inclusion criteria
Patients:
1. Adult patients (at least 18) with uncontrolled hypertension (patients with a reading of >140 /90 mmHg at baseline before randomisation), who are currently receiving medication for hypertension control
2. Patients must have access to the internet

Healthcare Practitioners:
1. Employed in primary care setting
2. Involved in treating/managing patients with high blood pressure and enrolled on the HOME BP programme

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 610; UK Sample Size: 610

Total final enrolment
622

Key exclusion criteria
1. Inability to self monitor (including diagnosis of dementia)
2. Mean baseline Bblood pressure >180/110 mmHg
3. Prescribed mMore than three antihypertensive medications
4. Hypertension not managed by family doctor
5. Terminal disease or other condition which in the opinion of the family doctor makes them inappropriate to take part

6. Patients with an acute cardiovascular event in the last 3 months
7. Postural hypotension (>20mmHg systolic drop after 1mn standing)
8. Pregnant or breast feeding
9. Patients with a history of proteinuria
10. Atrial fibrillation (or irregular heartbeat)
11. CKD stage 34-5 diagnosis or CKD stage 3 not managed by GP
12. Household member already enrolled on the study

Date of first enrolment
01/06/2015

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southampton Primary Medical Care
University of Southampton
Aldermoor Health Centre
Aldermoor Close
Southampton
United Kingdom
SO16 5ST

Study participating centre
Radcliffe Infirmary ISAT Headquarters
Oxford
United Kingdom
OX2 6HE

Sponsor information

Organisation
University of Southampton

Sponsor details

University Road
Southampton
England
United Kingdom
SO17 1BJ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/09/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Paul Little (P.Little@soton.ac.uk). Anonymised primary outcome data will be available from the date the main trial outcomes paper is published. Requests for the data will

be assessed by the relevant team to ensure data sharing is appropriate. Participants did not provide explicit consent to the sharing of their data beyond the study team.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/11/2016		Yes	No
Other publications	nested qualitative process study	08/05/2018	17/05/2019	Yes	No
Results article	results	19/01/2021	22/01/2021	Yes	No
Results article	process evaluation results	26/05/2021	28/05/2021	Yes	No
Funder report results	NIHR	31/12/2022	16/05/2023	No	No
HRA research summary			26/07/2023	No	No