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How accurate are home blood pressure monitors used by patients?

Submission date
17/03/2016

Recruitment status
No longer recruiting

Registration date
17/03/2016

Overall study status
Completed

Last Edited
26/01/2018

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The heart is responsible for pumping blood around the body to deliver oxygen-rich blood. In order to do this a certain amount of pressure is needed in the blood vessels, but if this pressure is too high, then it puts a great strain on the arteries and heart. This is called hypertension (high blood pressure), which is very common and often long-term (chronic). Many people with hypertension are unaware of it, as it rarely causes any noticeable symptoms. If left untreated however, it dramatically increases the risk of heart disease, kidney disease and stroke, earning it the nickname of the “silent killer”. It is therefore very important to monitor these people in order to ensure that they do not develop these complications. There is a wide range of blood pressure monitors available for use at home, although it is not known how accurate the measurements are. The aim of this study is to find out how well home blood pressure monitors work at measuring blood pressure.

Who can participate?
Adults with high blood pressure who own a home blood pressure monitor.

What does the study involve?
Participants are sent a letter by their GP practice asking if they would like to have their home blood pressure monitor tested for accuracy. Those who respond are asked to drop off their blood pressure monitor to their practice on a prearranged day. Monitors are tested and returned to participants, complete with testing results, within 2 weeks. The study team tests the patients’ blood pressure monitors using the OMRON PA350 digital BP tester (a specialised piece of equipment designed to measure how accurately blood pressure monitors can measure pressure). Monitors are inflated following a standard process as recommended by each monitor manufacturer and the British Hypertension Society. Monitors that have a 3mmHg or greater difference from the PA350 reading at any blood pressure level are rated as having failed. The study team also assess whether cuffs are working properly.

What are the possible benefits and risks of participating?
Participants will benefit from learning how accurate their home blood pressure monitor is and so it can be replaced if it is inaccurate. There are no direct risks of taking part, although some participants may find it difficult not having their monitor available while it is being tested.

Where is the study run from?
The testing takes place at the University of Birmingham and participants are recruited from GP practices in the Midlands (UK)

When is the study starting and how long is it expected to run for?
February 2016 to December 2016

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

Who is the main contact?
Dr James Hodgkinson
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20163

Study information

Scientific Title
Accuracy of patient-owned blood pressure monitors compared to Omron PA350 monitor checker

Acronym

ACCU-RATE

Study objectives
Primary aim:
To determine how accurate are home digital upper arm and wrist blood pressure monitors.

Secondary aims:
1. To find out which digital blood pressure monitors are currently used by patients
2. How well they perform;
3. Is there any evidence of decreasing accuracy over time, or with greater usage, or by validation status, or cost (recommended retail price) of device

Ethics approval required
Old ethics approval format

Ethics approval(s)
15/NW/0828

Study design
Non-randomised diagnostic accuracy study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

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
Topic: Primary Care; Subtopic: Primary Care; Disease: All Diseases

Interventions
Eligible patients are sent a letter asking if they are interested in having their monitor tested for accuracy. Those who respond (by telephone or post) will be asked to drop off their monitor to the practice on a prearranged day. Monitors will be tested and returned to participants with results within 2 weeks.

The procedure will be to test patients' blood pressure (BP) monitors using the OMRON PA350 digital BP tester. Monitors will be inflated following a standard process as recommended by each monitor manufacturer and the British Hypertension Society, with a pass rate of +/- 3mmHg or less from the PA350 reading.

Intervention Type
Other

Primary outcome measure
Blood pressure monitor accuracy is determined by recording the proportion of devices with <3mmHg error compared to reference device (PA 350) at all BP ranges.

Secondary outcome measures
1. Mean, standard deviation, median and interquartile range of mean absolute error (MAE) – i.e. the mean difference between the values reported by the test device and reference device over the pressure ranges tested.
2. Association between mean absolute error and:
1. Number of usages of device
2. Length of time in service of device
3. Validation status of device
4. Recommended retail price of device

Overall study start date
11/02/2016

Completion date
31/12/2016

Eligibility

Key inclusion criteria
The inclusion criteria to receive the one page survey are:
Patients on the hypertension register.

The additional inclusion criteria for the monitor testing element:
1. Patients owning blood pressure monitors used at home
2. Participant is willing to take part in the study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 385; UK Sample Size 385

Key exclusion criteria
Exclusion criteria for the monitor testing element:
1. Unable to provide consent

2. Patients who do not use home blood pressure monitors
3. Housebound patients who are unable to arrange for their monitor to be dropped off at the practice

Date of first enrolment
11/02/2016

Date of final enrolment
31/10/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
Department of Primary Care & General Practice
Primary Care Clinical Sciences Building
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B15 2TT

Sponsor information

Organisation
University of Birmingham

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/03angcq70

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 of study findings (at the aggregate level) in a peer reviewed journal, and at an academic conference (most likely SAPC). All participants will receive the full results for their own monitor, and a copy of the overall (aggregate) results if they wish.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The reason for the non-availability of participant level data is simply that our unit of analysis is the blood pressure monitor rather than the human owner of the monitor, so we haven't recorded the characteristics of the owners as they're not relevant to our study.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		20/12/2017	26/01/2018	No	No
HRA research summary			28/06/2023	No	No