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Comparing the accuracy of a novel wrist-watch blood pressure monitor against standard clinical blood pressure monitors in detecting how high blood pressure affects heart structure

Submission date 09/03/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 26/03/2021	**Overall study status** Completed	
Last Edited 11/03/2022	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims

Accurate blood pressure (BP) measurement is important for managing risk for cardiovascular (heart) disease. Sustained high BP (uncontrolled hypertension) affects the structure of the heart. Specifically, it thickens the heart's muscular wall because it has to pump against a higher load. Heart wall thickening is a good predictor of future risk for heart disease and stroke.

BP is routinely measured at a doctor's surgery, but increasingly patients are measuring their own BP at home or at work. There is evidence that self-measurement, using a systematic protocol, provides a better indication of a patient's true BP. This is because measurements occur whilst people go about their usual daily activities rather than just at formal clinical consultations. Evidence suggests that self-measured BP also shows a stronger relationship with heart muscle thickening. Systematic BP self-measurement is typically done using ambulatory BP monitoring (ABPM). This uses a portable BP monitor worn on a patient's belt or in a special harness. The monitor takes measurements at regular intervals across a 24-hour period, typically every 30 minutes during waking hours and hourly during sleep. However, some people find ambulatory BP monitors uncomfortable to wear, inconvenient, obtrusive or disruptive of sleep. Home BP monitoring is an alternative, where BP is measured using a conventional BP monitor both in the morning and evening across a fixed number of days. However, this may not capture changes in blood pressure associated with work stress or other activities. A new type of monitor which incorporates a BP cuff into the strap of a wrist-watch (Heartguide device) has recently been developed. HeartGuide is comfortable to wear, unobtrusive and allows BP to be measured both at home and across the working day. Measurements are scheduled at regular time intervals or as required. Whilst HeartGuide has been shown to be accurate compared to other BP monitors, it is not known whether its measurements are associated with BP-related heart wall thickening. This study will investigate whether this wrist-watch monitor provides a convenient way for patients to systematically self-measure their BP. It will also investigate whether HeartGuide measurements provide reliable information about the effects of BP on the heart compared to

conventional ABPM. Heart wall thickness will be measured using cardiac magnetic resonance imaging (MRI). The results of this study will show whether HeartGuide provides an accurate and convenient method for BP self-monitoring.

Who can participate?
Men and women aged 35 or older who have elevated BP or currently taking prescription medication to lower their BP.

What does the study involve?
Participants will be asked to attend the research centre for three visits over a 1-month period and to undergo two separate sessions of BP self-measurement. The first study visit will last about 1 hour. The researchers will ask participants questions, including age, gender, ethnicity, education and employment history. They will also ask them about their lifestyle including diet and exercise, smoking or drinking alcohol, medical history and current medications. They will measure their height, weight, blood pressure and heart rate. Participants will undergo an electrocardiogram (ECG) and a cuff-based measurement of arterial stiffness known as cardiac-ankle vascular index (CAVI). At the end of the visit they will be shown how to use the wrist-watch device and asked to monitor their blood pressure with it over at least three consecutive working days. The researchers will also schedule the next two visits. At the second visit, participants will return the HeartGuide device and the researchers will review the BP measurements. Participants' blood pressure will be recorded using a standard clinic BP monitor. They will then be asked to wear an ambulatory BP monitor for a continuous 24-hour period. At the third visit, having returned the ambulatory BP monitor, participants will be asked to undergo an MRI scan. The MRI scanner uses a large magnet and radio waves to generate images. Participants will be asked to lie flat and still in the scanner for about 30 minutes whilst images of their heart are acquired. Occasionally the radiographer may ask them to hold their breath for short periods. If they feel uncomfortable or claustrophobic at any time, participants can ask for the scan to be halted or stopped. Once the scan is finished, they will have completed study participation. No blood, urine or tissue samples will be collected at any visit for this study.

What are the possible benefits and risks of participating?
Study participation will provide an accurate assessment of blood pressure and an MRI scan of the heart which participants may find helpful. There are few risks associated with study participation. Whilst cuff BP measurement is well tolerated, infrequently people experience discomfort or bruising with tight cuff inflation associated with higher blood pressure. If this occurs, the researchers will discuss continued study participation with the participant. Rarely people experience pain or distress such as claustrophobia, back pain or muscle twitches (fasciculation) during MRI scanning. During the scan, participants will be in vocal communication with the MRI operator and will have access to a “panic button” so that the scan can be stopped if necessary. The strong magnet used in MRI scans can cause metal in the body to vibrate. Before the scan participants will complete a detailed questionnaire to ensure that there is no risk of this.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
June 2020 to March 2023

Who is funding the study?
Omron Healthcare Co. Ltd. (UK)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
280191

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Version 1.0, 09 December 2020, 132948, IRAS 280191

Study information

Scientific Title
Relationship between blood pressure profiles measured by a wrist-type blood pressure monitor (HeartGuide) and left ventricular mass index

Acronym
The HeartGuide Study

Study objectives
1. Can the HeartGuide wrist watch blood pressure (BP) device detect the impact of elevated blood pressure on heart wall thickness?
2. Can the HeartGuide wrist watch blood pressure (BP) device detect the impact of elevated blood pressure on heart wall thickness and blood vessels as well as standard clinical ambulatory or clinic BP monitors?
3. To compare relationships between BP measurements acquired using the Heartguide device, ABPM and clinic BP monitors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/01/2021, London-Fulham Research Ethics Committee (Barlow House, 3rd floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 1048103; fulham.rec@hra.nhs.uk), REC ref: 20/PR/0953

Study design
Single-centre cross-sectional observational study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Home

Study type(s)
Diagnostic

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Cardiovascular disease, hypertension (elevated blood pressure)

Interventions
This is an observational study in people with elevated blood pressure (BP). The study will compare relationships between out-of-office blood pressure measurements, i.e. BP measurements made by study participants in their home/work environments, using a new wrist-watch-type BP monitor with measurements made using a conventional arm-cuff ambulatory monitor. The study will also compare relationships between BP, measured using both devices, and MRI-measured heart left-ventricular wall thickness, a robust marker of the effects of elevated blood pressure on heart structure. This will allow a stringent evaluation of the accuracy and usefulness of the new wristwatch device for measuring out-of-office blood pressure against a standard, clinically used device.
In the study, each participant will be asked to attend three outpatient visits across a period of no more than one calendar month. At the first visit, demographic data, clinic BP, and non-invasive measurements of heart electrical activity (ECG) and arterial stiffness (cardiac-ankle vascular index [CAVI]) will be collected. Participants will be also trained in the use of the HeartGuide watch BP monitor which they will then use to monitor their blood pressure intermittently over a minimum of three consecutive working days. At the second visit, BP will be measured using a standard clinic BP monitor and participants will be asked to record their blood pressure over a continuous 24-hour period using a conventional ambulatory BP monitor. At the third and final visit, participants will undergo an MRI scan of their heart. This study involves no therapeutic intervention. All study participants will be asked to monitor their pressure whilst at home/work using both the wrist-watch and ambulatory 24-hour blood pressure monitors. All participants will be asked to undergo an MRI scan of their heart.

Intervention Type

Device

Phase
Not Applicable

Primary outcome measure
1. “Out of office” systolic BP, measured using the HeartGuide watch BP monitor at Baseline – Visit 1
2. Left ventricular mass index (LVMI) measured by cMRI at Baseline – Visit 3

Secondary outcome measures
1. Mean BP indices measured by the HeartGuide watch BP monitor at baseline – Visit 1
2. Mean BP indices measured by 24-hour ambulatory BP monitoring (ABPM) at baseline – Visit 2
3. Mean BP indices measured by seated clinic BP at baseline – Visit 1
4. Heart wall thickness measured as left ventricular mass index (LVMI) or unindexed left ventricular (LV) mass by cardiac MRI (cMRI) at baseline – Visit 3
5. Arterial stiffness measured using the Cardio-Ankle Vascular Index (CAVI) at baseline – Visit 1
6. ECG voltage criteria for LV mass measured at baseline – Visit 1
7. cMRI parameters including LVMI/unindexed LV mass, cardiac volumes and indices of vascular structure/function at baseline – Visit 3

Overall study start date
01/06/2020

Completion date
27/03/2023

Eligibility

Key inclusion criteria
1. Men or women aged 35 years or older
2. Seated clinic systolic BP ≥130 mmHg or previously diagnosed with hypertension and currently taking prescription medication to lower BP
3. Wrist circumference 16-19 cm (i.e. suitable for HeartGuide watch BP monitor)
4. Willing and able to provide informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria

1. People who are unable or unwilling to provide informed consent
2. Women who are pregnant
3. Participants with a wrist circumference >19 cm (unsuitable for the HeartGuide wrist monitor)
4. Participants with an upper arm circumference >42.0 cm (unreliable cuff-based BP measurement)
5. Participants unwilling or unable to undergo a cardiac MRI scan
6. Participants unwilling or unable to undertake a minimum of 3 consecutive weekdays of wrist blood pressure monitoring (using the HeartGuide watch BP monitor)
7. Participants unwilling or unable to undertake a continuous 24-hour period of ambulatory blood pressure monitoring
8. Participants with sustained atrial fibrillation or other significant arrhythmia (makes BP measurement unreliable)
9. People currently enrolled in another on-going clinical trial or study

Date of first enrolment
01/06/2021

Date of final enrolment
01/10/2022

Locations

Countries of recruitment
England

United Kingdom

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Sponsor type
University/education

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ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
Omron Healthcare

Alternative Name(s)
Omron Healthcare Co., Ltd., Omron Healthcare, Inc.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Japan

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/09/2023

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1.0	09/12/2020	26/03/2021	No	Yes
Protocol file	version V1.0	09/12/2020	26/03/2021	No	No
HRA research summary			28/06/2023	No	No