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Impact of daily blood pressure patterns on detecting hypertension

Submission date 01/09/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 07/10/2021	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 07/10/2021	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

Blood pressure measured by a cuff (sphygmomanometer) in the clinic is often used to screen for hypertension (high blood pressure), a condition associated with long-term cardiovascular complications. UK guidelines state that potentially hypertensive patients detected using cuff measurements in the clinic should have the diagnosis confirmed by 24-hour ambulatory blood pressure monitoring (ABPM) at home. However, the initial clinical cuff measurement used to screen for hypertension fails to account for the natural variability of blood pressure, including its circadian (daily) variability. Thus, some potentially hypertensive patients may be missed by one-off screening measurements.

The typical circadian profile of blood pressure (BP) involves a nocturnal decrease followed by a morning ‘surge’ in blood pressure and higher levels during the day, known as a "dipping" pattern (due to the night-time dip in BP). However, some people experience nocturnal hypertension, where blood pressure is elevated at night compared to its values during the day (known as a "reverse-dipping" pattern). This reverse-dipping pattern is known to be a powerful marker of adverse cardiovascular prognosis, with a reported prevalence of 3% to 39% depending on age, sex and other illnesses.

Patients with reverse-dipping patterns may have blood pressures indistinguishable from those of normotensive (normal BP) patients during clinic hours when cuff measurements are likely to be taken by doctors or nurses in General Practice. Thus, these patients are at a high risk of being missed by the traditional screening process in primary care.

Researchers are investigating the use of a CE-marked, cuffless, wrist-worn blood pressure monitoring device (Aktiia) to establish individual 24-hour BP profiles. This device uses a photoplethysmogram (PPG) sensor to estimate BP using a pulse wave analysis technique in a non-invasive and non-disruptive manner (using the measurement of visible light reflection at the wrist). If this device can be shown to capture an individual’s BP profile accurately, it will enable nocturnal hypertension to be detected with minimal burden to the patient (compared to, for example, ABPM). This, in turn, would allow for preventative steps such as prescribing anti-hypertensive medication to be taken, potentially at bedtime, with the aim of improving outcomes for these patients (reduction of risk of adverse cardiovascular events such as strokes).

Who can participate?

Healthy adults aged between 21 and 69 years

What does the study involve?
This is an observational study that involves the participant wearing a wrist-worn blood pressure monitoring device (Aktiia) for 1 week while otherwise behaving as normal. Each participant visits the lab for 30 minutes at the beginning of the study to be fitted with the device, have it calibrated, and be given instructions. Each participant then returns to the lab for 10 minutes after 1 week to return the device.
The Aktiia device gathers data using a PPG sensor and provides estimates of blood pressure to an app on the participant's smartphone (or a smartphone provided by the research team). These estimates are then entered either by the participant into a Nexus365 OneDrive for Business spreadsheet provided to them by the research team or by the research team at the Institute of Biomedical Engineering (IBME) at the end of the week's home monitoring, when the Aktiia device is returned.

What are the possible benefits and risks of participating?
There are no foreseeable disadvantages or risks to taking part in the study. Participants are asked to wear a wrist-worn device for a week and avoid immersing it in water (the device is splash-proof), but otherwise to act as normal. Participants will not be identifiable from any data that may be published from the study.
If a participant appears to have hypertension, whether diurnal and/or nocturnal hypertension, as assessed by day-time and/or night-time average blood pressure measurements from the Aktiia device, according to the standard criteria defined by the National Institute for Clinical Excellence (NICE), they will be advised to inform their GP and arrange to be screened using ABPM.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
August 2021 to October 2021

Who is funding the study?
National Institute for Health Research (NIHR) Oxford Biomedical Research Centre (BRC) (UK)

Who is the main contact?
Dr Shaun Davidson
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Contact information

Type(s)
Scientific

Contact name
Dr Shaun Davidson

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Additional identifiers

Protocol serial number
R77097/RE001

Study information

Scientific Title
Reverse dipping in blood pressure and its impact on screening for hypertension in the clinic

Study objectives
The researchers are investigating the use of a CE-marked, cuffless, wrist-worn blood pressure monitoring device (Aktiia) to establish individual 24-hour blood pressure (BP) profiles. This device uses a photoplethysmogram (PPG) sensor to estimate BP using a pulse wave analysis technique in a non-invasive and non-disruptive manner (using the measurement of visible light reflection at the wrist). If this device can be shown to capture an individual's BP profile accurately, it will enable nocturnal hypertension to be detected with minimal burden to the patient (compared to, for example, ambulatory blood pressure monitoring [ABPM]).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/08/2021, Central University Research Ethics Committee (Medical Sciences Interdivisional Research Ethics Committee (Research Services, University of Oxford, Wellington Square, Oxford, OX1 2JD, UK; +44 (0)1865 616577; ethics@medsci.ox.ac.uk), ref: R77097/RE001

Primary study design
Observational

Study design
Observational non-interventional case series

Study type(s)
Screening

Health condition(s) or problem(s) studied
Nocturnal hypertension

Interventions
This is an observational study that involves the participant wearing a wrist-worn blood pressure monitoring device (Aktiia) for 1 week while otherwise behaving as normal. Each participant visits

the lab for 30 minutes at the beginning of the trial to be fitted with the device, have it calibrated, and be given instructions. Each participant then returns to the lab for 10 minutes after 1 week to return the device.

The Aktiia device gathers data using a photoplethysmographic (PPG) sensor and provides estimates of systolic blood pressure (SBP) and diastolic blood pressure (DBP) to an app on the participant's smartphone (or a smartphone provided by the research team). These estimates are then entered either by the participant into a Nexus365 OneDrive for Business spreadsheet provided to them by the research team or by the research team at the Institute of Biomedical Engineering (IBME) at the end of the week's home monitoring when the Aktiia device is returned.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Wrist-worn blood pressure monitoring device (Aktiia)

Primary outcome(s)
Systolic blood pressure estimated continuously using the Aktiia device and averaged 2 hourly. 7 days' data will be collected per participant and the 24-hour pattern will be averaged.

Key secondary outcome(s)
1. Diastolic blood pressure estimated using the Aktiia device and averaged 2 hourly for 7 days
2. Heart rate estimated using the Aktiia device averaged 2 hourly for 7 days

Completion date
31/10/2021

Eligibility

Key inclusion criteria
Adults aged between 21 and 69 years of age

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

1. Individuals outside of the specified age range
2. Individuals suffering from tachycardia or atrial fibrillation
3. Individuals suffering from diabetes or renal dysfunction
4. Individuals who are pregnant

Date of first enrolment
01/09/2021

Date of final enrolment
24/10/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Oxford
Institute of Biomedical Engineering
Old Road Campus Research Building
Roosevelt Drive
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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name

NIHR Oxford Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre, Oxford, OxfordBRC, OxBRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

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 Shaun Davidson (shaun.davidson@eng.ox.ac.uk). Data will include deidentified demographics (age, gender) as well as sets of SBP, DBP, and HR measurements from the Aktiia device, provided as Excel spreadsheets. Data will be available from the completion of the study (31/10/2021) for a period of 3 years (to 31/10/2024). Upon reasonable request, the research team will discuss the merits of the proposed use of data and decide whether or not to grant access.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			06/09/2021	No	Yes
Protocol file	version 1.0	16/07/2021	06/09/2021	No	No