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Trends and satisfaction in hypertensives using Aktiia optical BP monitoring device (SHINE)

Submission date
15/07/2024

Recruitment status
No longer recruiting

Registration date
16/07/2024

Overall study status
Completed

Last Edited
07/05/2025

Condition category
Circulatory System

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The number of adults with high blood pressure, or hypertension, doubled from 650 million in 1990 to 1.3 billion in 2019. Many people don't know they have high blood pressure or don't have it under control. Traditional methods to measure blood pressure use an arm cuff, which can be uncomfortable and sometimes gives inaccurate readings. Other illnesses related to having high blood pressure put a burden on patients and healthcare systems. Using a small, non-invasive at-home device is a possible way of reducing the number of people with high blood pressure and its associated complications worldwide.
This study will observe how blood pressure changes over time using the Aktiia 24/7 device, a comfortable wrist-worn device that measures blood pressure continuously. We want to see how blood pressure changes over time, and how people feel about using this device over 12 weeks. The Aktiia device will be sent directly to the participant's home, who will wear the bracelet 24/7 for 12 weeks. Participants will be asked to download the Aktiia phone application (app) on their smartphone and perform weekly syncs of the device with a cuff and the app.

Who can participate?
We are inviting individuals to participate in this study who are aged 22 - 85 years, with a blood pressure reading within the last 12 months that was either systolic ≥145 mmHg and/or diastolic ≥90 mmHg. This reading can be one taken by a medical professional (e.g. doctor, nurse, pharmacist) or a reading taken from a reliable CE-marked at-home blood pressure measuring device. A member of the study team will check whether you are suitable for the study based on the study eligibility criteria and the blood pressure reading you provide.

What does the study involve?
The study will last for approximately 12 weeks. Participants will be asked to complete some online forms at the beginning of the study, taking around 5 minutes and two questionnaires in the Aktiia study app, one when they first use the Aktiia device and the other at the end of the 12 weeks. Participants may be asked to upload evidence of their high blood pressure (e.g. via a picture of a blood pressure reading or a blood pressure medication, or a screenshot of their medical record in the NHS app) when they join the study. This will be used to confirm they are suitable for the study. Participants will wear the Aktiia bracelet for 12 weeks and should perform weekly syncs of the bracelet with the cuff and app. The app will send notifications to remind

participants to do this. Once participants have completed the study, they will keep the device and be prompted to download the app available on app stores. They will also receive a £50 payment or voucher if they have completed all study activities (3 questionnaires and 12 weekly syncs with the cuff and app).

What are the possible benefits and risks of participating?
Taking part in this study may not have any direct benefit to participants, but their participation may help to generate knowledge on how the device could be used in the future to improve management of high blood pressure. In addition, the Aktiia 24/7 device offers continuous blood pressure monitoring, providing participants with a more comprehensive understanding of their blood pressure over time.
The Aktiia 24/7 device is not expected to cause any side effects. The device should be kept clean to prevent skin irritation on the wrist. The device is 'CE marked', which means the manufacturer has checked that the device meets certain safety, health and environmental requirements. Using the device may indicate that participants have dangerously high blood pressure. There will be no medical follow-up by the study team if high readings are recorded. If participants are concerned about the blood pressure readings they see on the device, they are asked to seek medical help as soon as possible, via usual care e.g. via their GP or by calling 111.

Where is the study run from?
Lindus Health (UK)

When is the study starting and how long is it expected to run for?
May 2024 to April 2025

Who is funding the study?
Aktiia S.A. (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Public, Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT06356077

Integrated Research Application System (IRAS)
345157

Protocol serial number
LH-AKT-01

Study information

Scientific Title
Blood pressure evolution and user satisfaction in a hypertensive population using the Aktiia 24/7 Optical Blood Pressure Monitoring (OBPM) device: a prospective observational cohort study

Acronym
SHINE

Study objectives
The SHINE study aims to gather data on the evolution of participant's blood pressure and to correlate this with demographic, lifestyle and health factors in a hypertensive population as well as, to gather data on participants' perception of the device under test (Aktiia 24/7).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/07/2024, London – Queen Square REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8284; queensquare.rec@hra.nhs.uk), ref: 24/PR/0776

Primary study design
Observational

Study design

Single-centre observational cohort study

Study type(s)
Other, Prevention

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

Interventions
Each study subject will receive an Aktiia device and will use it continuously for 12 weeks. Study participants will have to complete two different surveys: one at baseline, and one after 23 weeks of Aktiia device use to give their perception on the Aktiia device use as compared to other blood pressure monitors currently on the market.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Aktiia 24/7 Optical Blood Pressure Monitoring (OBPM) device

Primary outcome(s)
Blood pressure measured by Aktiia 24/7 optical blood pressure monitoring device continuously for 12 weeks

Key secondary outcome(s)
1. Number of participants with preferences using Aktiia 24/7 device, as compared to Home Blood Pressure Monitor, or Ambulatory Blood Pressure Monitor to monitor their blood pressure measured using responses to questionnaire at baseline and week 12
2. Sociodemographic, lifestyle and health factors measured using questionnaires regarding their lifestyle, socioeconomic environment and general health at week 12

Completion date
30/04/2025

Eligibility

Key inclusion criteria
1. Adult participants aged 22 to 85 years old
2. A participant whose last self-reported blood pressure reading was within the last 12 months and was either:
2.1. Systolic Blood Pressure (SBP) ≥145 mmHg
2.2. or Diastolic Blood Pressure (DBP) ≥90 mmHg
3. People who use either an iOS or Android smartphone
4. People with two arms
5. Able and willing to provide Informed Consent and adhere to study procedures

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
22 Years

Upper age limit
85 Years

Sex
All

Total final enrolment
1729

Key exclusion criteria
1. Participants whose BP data submitted is >180 mmHg systolic OR >120 mmHg diastolic.
2. Participants with a self-reported known diagnosis of:
2.1. Atrial fibrillation
2.2. Congestive heart failure
2.3. Heart valve disease
2.4. Pheochromocytoma
2.5. Raynaud’s disease
2.6. Arm lymphedema
3. Participants who take insulin
4. Participants who are on hemodialysis
5. Women who are known to be pregnant
6. Participants whose arms shake uncontrollably or are paralyzed (cannot move)
7. Participation in another interventional clinical study or use of investigational drugs in the last 30 days.

Date of first enrolment
29/07/2024

Date of final enrolment
04/11/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Lindus Health
2nd Floor, 90 Union Street
London
United Kingdom
SE1 0NW

Sponsor information

Organisation
Aktiia S.A.

Funder(s)

Funder type
Industry

Funder Name
Aktiia S.A.

Results and Publications

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