

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

Submission date 15/07/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/07/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/05/2025	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

345157

ClinicalTrials.gov number

NCT06356077

Secondary identifying numbers

LH-AKT-01, IRAS 345157

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

Study design

Single-centre observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Internet/virtual

Study type(s)

Other, Prevention

Participant information sheet

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

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

Pharmaceutical study type(s)

Not Applicable

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Aktiia 24/7 Optical Blood Pressure Monitoring (OBPM) device

Primary outcome measure

Blood pressure measured by Aktiia 24/7 optical blood pressure monitoring device continuously for 12 weeks

Secondary outcome measures

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

Overall study start date

06/05/2024

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

Age group

Adult

Lower age limit

22 Years

Upper age limit

85 Years

Sex

Both

Target number of participants

7500

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

England

United Kingdom

Study participating centre

Lindus Health

2nd Floor, 90 Union Street

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Sponsor information

Organisation

Aktiia S.A.

Sponsor details

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Sponsor type

Industry

Funder(s)

Funder type

Industry

Funder Name

Aktiia S.A.

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

31/12/2025

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