

# Determining the use of smart watches to detect irregular heart rhythms for people following a stroke

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<b>Registration date</b> 13/01/2022	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/03/2024	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Atrial fibrillation is a common irregular heart rhythm. Atrial fibrillation increases a person's risk of stroke, but often remains undetected. In previous studies, smart watches have been shown to work well for detecting atrial fibrillation in the general population. The use of smart watches to identify atrial fibrillation in people following a stroke has not yet been explored. Identifying atrial fibrillation for patients following a stroke means appropriate treatment can be started to reduce the person's risk of having another stroke. The aim of the current study is to determine how well Huawei smart watches can identify atrial fibrillation in patient's following a stroke.

### Who can participate?

All adults at participating hospitals who have had an ischaemic stroke (where the stroke is caused by loss of blood flow to the brain) confirmed by a stroke doctor, unless they are unable to provide consent to take part or they are receiving end-of-life care.

### What does the study involve?

At the time of stroke, patients have a lot of information collected about their health, we will copy information from a patient's medical records about their health. We will also ask the patients to complete some additional questionnaires including about their health and well-being. We will ask the patients to wear a smart band for four weeks. The smart band will be linked to a mobile phone application. If the person has a phone which works with the band, we will ask them to download the application to their own phone. If the person does not have a compatible phone, the person will be provided with a phone which will be asked to return at the end of the study period. The smart band will track their heart rhythm and if atrial fibrillation is suspected, the person will be invited to attend a hospital appointment. At the hospital appointment, further tests will be conducted, such as an electrocardiogram (ECG), to determine if the person does have atrial fibrillation. We will ask the patients 6 and 12-months later to repeat the questionnaires.

### What are the possible benefits and risks of participating?

Some of the questionnaires will ask questions about the individual's health. It is possible that

some people might find some of the questions in the assessments upsetting. Participants do not need to answer any questions they would not like to. If the participant has any distress the data collection will be paused to provide time for the individual to consider whether to continue or withdraw from the study. If any medical risk is discovered such as a previously unidentified medical condition, then the information collected may be referred to an appropriate medical practitioner at the hospital for further examination. However, participation in the study is not a substitute for a 'health check'. The smart band has been designed to be worn continuously, but if the participant finds the smart band uncomfortable at any time it can be removed.

Where is the study run from?  
Liverpool University (UK)

When is the study starting and how long is it expected to run for?  
February 2020 to Deember 2025

Who is funding the study?  
National Institute for Health Research (NIHR) (UK).  
Huawei Technologies Co. Ltd. (China)

Who is the main contact?  
Dr Stephanie Harrison,  
Prof Gregory Lip,  
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## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

302919

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

CPMS 50451, NIHR201320, IRAS 302919

## Study information

### Scientific Title

Evaluation of Huawei smartwear for detection of atrial fibrillation in a post-stroke population: the Huawei stroke study

### Study objectives

Is a smart band useful to detect atrial fibrillation in patients following a stroke?  
How is it of relevance and importance to patients and public?

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 23/11/2021, East Midlands - Nottingham 2 Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 203 443 6294; nottingham2.rec@hra.nhs.uk), ref: 21/EM/0214

### Study design

Interventional non-randomized

### Primary study design

Interventional

### Secondary study design

Non randomised study

### Study setting(s)

Home

## **Study type(s)**

Diagnostic

## **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**

Detection of atrial fibrillation in patients who have experienced a stroke

## **Interventions**

We are planning this study for people who have recently had a confirmed ischaemic stroke. We will ask people to take part in the study before they leave hospital following their stroke. We will collect information about people's health following their stroke. At the time of a stroke, a lot of information is already collected about the person who has experienced a stroke, so we plan to collect this information in the study from electronic medical records. There are some questions which are needed for the study which are not already being collected in hospitals for people following a stroke about their wellbeing, quality of life and fatigue. So, we will ask the people involved in the study to answer additional questionnaires about these topics.

We will ask the participants to wear a Huawei smart band for four weeks which will be linked to a smart phone application (app). Prior to participant recruitment, a site initiation visit will be conducted at each site to provide training to the research nurses including training to use the smart band and app, so they can in turn train the recruited patients and/or their family members to use the smart band and app. We have discussed the study design with two people with experience of stroke. Following advice from these individuals, we will provide participants with an easy-to-follow print out of how to use the technology and a phone number to call with an issues using the technology. After the fourweek period, participants who have borrowed a phone will be asked to return it. For participants who are using their own smart phone for the study, they will be able to continue to use the smart band and provide data for the study for up to six months.

A research nurse will determine people who are eligible for the study and ask them if they would like to take part. We are aiming to have 1000 people take part in the study. This has been determined by calculating how many people would be needed to be sufficient for the intended analysis and answer the research question. We will produce an interim report once we have recruited all of the people to the study.

At six and twelve months after the person is admitted to hospital for a stroke and takes part in the study, we will contact them again and ask them to complete the same questionnaires about their health to see how their health has changed one-year post-stroke. We will do this by posting some questionnaires and asking some questions over the telephone or by video call wherever possible. Alternatively, the person can complete these questionnaires at the end of an outpatient appointment. If this is not possible, the person will be invited to attend an appointment at the hospital where they were initially recruited for the study. We will also ask people if we can access their hospital records following their stroke to determine what hospital visits they have had.

We have discussed the study plans with two people with experience of stroke. They gave valuable input to the study plans including advising on training documents for the use of the Huawei smart band.

## **Intervention Type**

Other

## **Primary outcome measure**

Detection of atrial fibrillation by the Huawei smart band measured continuously up to week 4

## **Secondary outcome measures**

Patient outcomes:

1. Performance in activities of daily living measured using the Barthel Index at baseline, 6 months and 12 months.
2. General health measured using the Patient Health Questionnaire (PHQ)-9 at baseline, 6 months and 12 months.
3. Anxiety measured using the General Anxiety Disorder (GAD)-7 at baseline, 6 months and 12 months.
4. Obstructive Sleep Apnea measured using the STOP BANG questionnaire at baseline, 6 months and 12 months.
5. Health related quality of life measured using the EQ-5D-5L at baseline, 6 months and 12 months.
6. Modified European Heart Rhythm Association (mEHRA) symptom score measured at baseline, 6 months and 12 months.
7. Treatment burden questionnaire measured at baseline, 6 months and 12 months.
8. Montreal Cognitive Assessment (MoCA) measured at baseline and 12 months.
9. Participant 'intervention acceptability' survey measured at one-month.
10. Participant interviews, conducted with a sub-sample of patients to explore intervention acceptability at one-month.

Outcomes measured in staff involved in training participants to use the smart bands:

11. Staff interviews to explore challenges in delivery of the training to participants to use the smart bands, time taken (to deliver the intervention and ongoing support with the system provided to the patient), unexpected benefits and/or consequences, and recommendations for improvement at six months.
12. Staff 'intervention acceptability' survey measured at baseline.

## **Overall study start date**

10/02/2020

## **Completion date**

31/12/2025

# **Eligibility**

## **Key inclusion criteria**

1.  $\geq 18$  years old
2. Current in-patient at the time of baseline data collection for recent ischaemic stroke; confirmed by stroke physician and/or imaging (computerized tomography (CT) or magnetic resonance imaging (MRI))

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 1000; UK Sample Size: 1000

**Key exclusion criteria**

1. Inability to provide informed consent
2. Receiving palliative or end-of-life care

**Date of first enrolment**

14/03/2022

**Date of final enrolment**

30/06/2024

**Locations****Countries of recruitment**

United Kingdom

**Study participating centre**

**The Royal Liverpool University Hospital**

Prescot Street

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L7 8XP

**Study participating centre**

**Whiston Hospital**

Warrington Road

Prescot

United Kingdom

L35 5DR

**Study participating centre**  
**Arrowe Park Hospital**  
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## **Sponsor information**

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**Sponsor type**  
University/education

**Website**  
<http://www.liv.ac.uk/>

**ROR**  
<https://ror.org/04xs57h96>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
NIHR Central Commissioning Facility (CCF)

**Funder Name**  
National Institute for Health Research (NIHR) (UK)

**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

**Funder Name**

Huawei Technologies

**Alternative Name(s)****Funding Body Type**

Private sector organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

China

## Results and Publications

**Publication and dissemination plan**

All analyses will be written up and disseminated in appropriate peer-reviewed health and medical journals and submitted for presentation at appropriate conferences. To disseminate the findings to patients and the general public, the findings will be shared with the Stroke Association and an open public lecture will take place at the end of the study. People who have taken part in the study and the general public will be invited to hear the study results. We may also share the results of the study via local media outlets e.g. newspapers and local radio where possible. We will also ask participants if they would like to receive summaries of key findings and copies of journal articles produced from the research.

**Intention to publish date**

30/06/2026

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available due to contracts in place with the study funder.

**IPD sharing plan summary**

Not expected to be made available



**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version 4.0	22/10/2021	13/01/2022	No	No
<a href="#">Protocol article</a>		06/12/2022	12/12/2022	Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No