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

Submission date 10/01/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 13/01/2022	**Overall study status** Completed	
Last Edited 18/12/2025	**Condition category** Circulatory System	

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

Integrated Research Application System (IRAS)
302919

Central Portfolio Management System (CPMS)
50451

National Institute for Health and Care Research (NIHR)
201320

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

Primary study design
Interventional

Study design
Interventional non-randomized

Study type(s)
Diagnostic

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

Key secondary outcome(s)
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.

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. >=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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
199 Years

Sex

All

Total final enrolment
491

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
Liverpool
England
L7 8XP

Study participating centre
Whiston Hospital
Warrington Road
Prescot
England
L35 5DR

Study participating centre
Arrowe Park Hospital
Arrowe Park Road
Wirral
England
CH49 5PE

Sponsor information

Organisation
University of Liverpool

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)
Huawei Technologies Co., Ltd., Huawei, , ,

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

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