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Post-stroke smartphone screening for atrial fibrillation

Submission date
18/06/2021

Recruitment status
No longer recruiting

Registration date
31/08/2021

Overall study status
Completed

Last Edited
11/10/2022

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Atrial fibrillation (AF) is the most common heart rhythm disturbance. Individuals with atrial fibrillation have an increased risk of developing strokes. Individuals with atrial fibrillation related strokes could still have their atrial fibrillation undiagnosed and be at risk of further strokes. Our smartphone application could help to identify atrial fibrillation early and therefore help them to get treatment early to prevent future strokes.
Aims:
1. To evaluate the use of our smartphone application, Fibricheck in atrial fibrillation screening of post stroke patients.
2. To evaluate the participant experience and satisfaction of using the smartphone application, Fibricheck.

Who can participate?
Participants who have had a stroke in the last 6 months can participate if they do not have a diagnosis of atrial fibrillation. They must have access to a smartphone and cannot have a pacemaker already.

What does the study involve?
The study involves providing the above participants with a smartphone application called Fibricheck and a 3-month monitoring period prescription for the application. The participants will need to take photoplethysmography recordings with their smartphone twice daily for 3 months. The recordings will be reviewed for the detection of atrial fibrillation. They will also receive electronic questionnaires to fill 1 month and 3 months from the start of using the application. This questionnaire will assess application usability.

What are the possible benefits and risks of participating?
The possible benefits of participating are earlier identification of atrial fibrillation and earlier treatment for atrial fibrillation and therefore possible prevention of further AF related strokes or conditions. However, it is also possible there will be no direct benefit to the research participant. There are no foreseeable risks of participating in this study.

Where is the study run from?
West Middlesex University Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2021 to December 2022

Who is funding the study?
Chelsea and Westminster plus charity (UK)

Who is the main contact?
Dr Pavidra Sivanandarajah (Pavidra.sivanandarajah1@nhs.net)

Contact information

Type(s)
Scientific

Contact name
Dr Pavidra Sivanandarajah

Contact details
West Middlesex University Hospital
Twickenham Road
Isleworth
London
United Kingdom
TW7 6AF
+44 (0)2083215336
pavidra.sivanandarajah1@nhs.net

Additional identifiers

Integrated Research Application System (IRAS)
299122

Study information

Scientific Title
Smartphone atrial fibrillation testing post stroke

Acronym
SMARTS project

Study objectives
The smartphone photoplethysmography application Fibricheck can increase atrial fibrillation detection rates in the post stroke population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval 04/08/2021, London-Hampstead REC (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)2071048340; hampstead.rec@hra.nhs.uk), ref: 21/PR/0899

Primary study design
Observational

Study design
Prospective observational cohort study

Study type(s)
Screening

Health condition(s) or problem(s) studied
Atrial fibrillation

Interventions
Participants with a history of previous stroke in the last 6 months will be recruited. They must not already have a diagnosis of atrial fibrillation. They will receive a smartphone application called Fibricheck with a 3-month monitoring period prescription for the App. They will perform photoplethysmography recordings with their smartphone twice daily for 3 months. They will also receive electronic questionnaires to fill 1 month and 3 months from start of using the application. This questionnaire will assess application usability. The total follow up is 3 - 6 months.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Photophlethysmography detection of atrial fibrillation twice daily over 3 months

Key secondary outcome(s)
Assess the application usability using questionnaires

Completion date
30/12/2022

Eligibility

Key inclusion criteria
1. Aged 18 years old or above
2. Had a cryptogenic stroke within the last 6 months
3. Able to provide verbal or signed written informed consent
4. Access to smartphone

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
22

Key exclusion criteria
1. Have already a diagnosis of atrial fibrillation prior to study enrolment
2. Unable to provide verbal or signed written informed consent
3. Below the age of 18 years old
4. Presence of cardiac electronic implantable device

Date of first enrolment
01/09/2021

Date of final enrolment
16/09/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
West Middlesex University Hospital
Chelsea and Westminster NHS Foundation Trust
Twickenham Road
Isleworth
London
United Kingdom
TW7 6AF

Sponsor information

Organisation
Chelsea and Westminster Hospital NHS Foundation Trust

ROR
https://ror.org/02gd18467

Funder(s)

Funder type
Charity

Funder Name
Chelsea and Westminster Health Charity

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

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 confidentiality.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 1	06/04/2021	05/08/2021	No	No