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# Screening for atrial fibrillation with ECG to reduce stroke

**Submission date**
25/01/2019

**Recruitment status**
No longer recruiting

**Registration date**
29/01/2019

**Overall study status**
Completed

**Last Edited**
16/05/2022

**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

Atrial fibrillation (AF) is a heart condition that causes irregular heartbeat. It affects up to 1 in 10 people over the age of 65. Atrial fibrillation greatly increases risk of stroke, but treatment with blood thinning ("anticoagulant") medication can stop this happening. About 10% of strokes happen in people unaware they have atrial fibrillation. Detecting atrial fibrillation can be difficult because it often comes and goes, and may not cause symptoms.

Many clinicians think the NHS should promote atrial fibrillation screening. The UK National Screening Committee has highlighted a lack of evidence that detecting atrial fibrillation in people by screening would benefit them.

We are therefore undertaking a large 8-year programme of work to find out if screening for atrial fibrillation in people aged 65 and over does prevent stroke and other problems like heart attacks, does not cause significant harm, and represents good value-for-money for the NHS. The SAFER Study is a feasibility study to inform the development of what will be the world's largest atrial fibrillation screening trial that will address these questions.

The SAFER Study will take place in 12 GP practices in East England who will invite about 9,600 patients to take part.

Some consented participants will be invited to be screened for atrial fibrillation. Participants will use a handheld single-lead ECG recorder to record ECGs at home over a period of 2-4 weeks. The ECGs will be read by a validated computer algorithm, with diagnoses confirmed by a cardiologist. Participants diagnosed with atrial fibrillation will be invited to a GP appointment to discuss treatment with blood thinning (anticoagulant) medication.

As part of this study we will conduct focus groups and interviews with participants to explore their views and beliefs about screening, atrial fibrillation, and their experience of being screened. We will also conduct interviews with GP practice staff to understand the practice experience of screening for atrial fibrillation.

Background and study aims
Atrial fibrillation (AF) is a heart condition that causes an irregular heartbeat. It affects up to 1 in

10 people over the age of 65, but does not necessarily cause symptoms. Having atrial fibrillation increases the risk of having a stroke 5-fold, but treatment with medication can significantly lower this risk as well as lowering your risk of having a heart attack. The aim of this study is to find out whether screening people over the age of 65 years for atrial fibrillation and treating them with medication:
1. is feasible in GP practices
2. prevents the number of strokes we think it will; and
3. is good value for money for the NHS
The results from this feasibility study will inform the design of a large trial to help the NHS decide whether to start a national screening programme for atrial fibrillation to prevent strokes.

Who can participate?
Men and women aged 65 and over, not on long-term anticoagulation medication, not on the palliative care register and not living in a nursing or care home.

What does the study involve?
Participants consent to give permission for specific information from medical records to be shared with the research team at various points over the next few years. This information is collected from GP practice records and from other health-related records. The kind of information collected included medications, use of healthcare services and stroke and cardiovascular disease related factors (for example weight, age, blood pressure, other medical conditions, and how well their kidneys and liver are working). Participants do not need to do anything to provide this information. Some participants may be invited to be screened for atrial fibrillation at their GP practice. Screening involves simply holding a small, safe, non-invasive recording device for 30 seconds at a time. Not everyone is invited to a screening appointment and, if a participant is, they are under no obligation to attend. On a couple of occasions participants may also receive a questionnaire to complete and return in a Freepost envelope (or complete online). Participants are under no obligation to complete this questionnaire. Some participants may be invited to take part in other studies related to atrial fibrillation and/or screening. Further information about what these would involve is sent. Participants are free to decide at that point whether or not they want to do them.

What are the possible benefits and risks of participating?
There may not be any direct benefit to participants for taking part. However, they may find it rewarding to know that they are contributing to research that aims to prevent stroke and heart attacks in people in the future. Some may receive a diagnosis of AF and therefore be given the opportunity to lower their greater risk of a stroke. Identifiable medical data from practices will be shared with the study team. All data collection, storage and handling processes will comply with the relevant security policies and regulations. Every effort will be made to ensure the security and confidentiality of participants' data.

Where is the study run from?
University of Cambridge (UK)

When is the study starting and how long is it expected to run for?
October 2018 to December 2023

Who is funding the study?
The NIHR School for Primary Care Research and the NIHR Programme Grant for Applied Research (UK)

Who is the main contact?
Andrew Dymond
safer@medschl.cam.ac.uk

# Contact information

### Type(s)
Public

### Contact name
Mr Andrew Dymond

### ORCID ID
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# Additional identifiers

### Protocol serial number
18/LO/2066

# Study information

### Scientific Title
Screening for Atrial Fibrillation with ECG to Reduce stroke (SAFER) - a feasibility study

### Acronym
SAFER

### Study objectives
This is the development and feasibility work to inform the intervention design, measures of psychological outcome and the feasibility of a screening programme for atrial fibrillation (AF) in primary care. These will inform a subsequent large cluster randomised controlled trial. The aim is to:
1. Determine how long and how often people should be screened to see if they have paroxysmal AF
2. Determine the practice experience of AF screening
3. Explore patient attitudes to and experiences of AF screening

4. Determine how best to measure the psychological effects on patients of screening for AF
5. Determine if screening for AF (including paroxysmal AF) is feasible in general practice in people aged 65 and over using a hand-held electrocardiogram (ECG) recorder (supplied by Zenicor)
6. Develop a process of audit, feedback and quality assurance of screening to inform our fidelity assurance in the subsequent trial
7. Finalise target population age range for the cluster randomised trial

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
London - Central Research Ethics Committee, London - Central Research Ethics Committee, 3rd Floor, Barlow House, 4 Minshull Street, Manchester,
M1 3DZ, Tel: +44 (0)207 1048 007, Email: NRESCommittee.London-Central@nhs.net, 20/12 /2018, REC ref: 18/LO/2066

## Primary study design
Interventional

## Study design
Multicentre non-randomised interventional study

## Study type(s)
Screening

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

## Interventions
Patients will be invited to join the SAFER Study with a Participant Information Sheet and Informed Consent Form from their GP surgery. Consent will be given by returning the consent form or by completed the online consent form. This consent confirms that the participant is happy for the research team to access their medical records and to follow them up via electronic health registries. Some participants will, subsequently, be invited to attend a screening appointment at their local GP surgery.

The screening appointment will be led by a nurse/HCA and involve having a single lead ECG using a handheld Zenicor device (provided to the surgery, for the purposes of the study only, by the study team). Participants will be provided with instructions on how to use the device by the nurse/HCA and asked to take the device home and record 2-4 ECGs per day for 2-4 weeks.

On completion of the screening period, and once the device has been returned to the GP surgery by the participant, the ECGs will be reviewed by a study team nurse and cardiologist (if necessary). All results will be fed back to the GP, with the expectation that those participants identified as having atrial fibrillation are invited by the GP surgery for an appointment to discuss medication in order to reduce their increased risk of stroke.

## Intervention Type
Procedure/Surgery

### Primary outcome(s)
As this is a feasibility study with a large qualitative component, there are a number of outcome measures that are considered primary:
1. Incremental increase in new AF detection rate by number of days screened and by number of times screened per day; measured using a handheld single-lead ECG device (Zenicor) at baseline
2. New AF detection rate, measured using a handheld single-lead ECG device (Zenicor) at baseline
3. % of new AF detected that is persistent versus paroxysmal; measured using a handheld single-lead ECG device (Zenicor) at baseline
4. % of patients with an AF code on the GP record who have confirmed AF from the screening process; measuredusing a handheld single-lead ECG device (Zenicor) at baseline
5. % eligible patients who consent – estimated to be around 50%; measured at baseline
6. % people who consent who are screened in six months – estimated to be around 40% over six months; measured at baseline
7. % people screened who have 2-week paroxysmal AF screening; measured using a handheld single-lead ECG device (Zenicor) at baseline
8. % people whose paroxysmal AF screening includes at least 15 ECG traces; measured using a handheld single-lead ECG device (Zenicor) at baseline
9. % people who have AF identified (subdivided by new/previously known; paroxysmal/ permanent); measured using a handheld single-lead ECG device (Zenicor) and compared to previous medical notes at baseline
10. % people who have AF identified who are reviewed by their GP; measured post-screening
11. % people with AF commenced on anticoagulation (sub-divided by new/previously known; CHA2DS2-Vasc score: 1 or ≥1); measured post screening
12. % completeness of baseline data from electronic record; measured post screening
13. All of the above criteria in age sub-groups to refine age entry criteria to the internal pilot, measured after data collection.

### Key secondary outcome(s)
There are no secondary outcome measures

### Completion date
31/12/2023

## Eligibility

### Key inclusion criteria
1. Age ≥ 65 years (patients)
2. Gender: both males and females

### Participant type(s)
Mixed

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. Long-term anticoagulation therapy for stroke prevention.
2. On the palliative care register.
3. Resident in a nursing home.

### Date of first enrolment
01/02/2019

### Date of final enrolment
31/12/2019

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
### University of Cambridge
Department of Public Health and Primary Care: Primary Care Unit
Strangeways Research Laboratory
2 Worts' Causeway
Cambridge
United Kingdom
CB1 8RN

## Sponsor information

### Organisation
University of Cambridge

### ROR
https://ror.org/013meh722

### Organisation
Cambridgeshire and Peterborough NHS Foundation Trust

### ROR
https://ror.org/040ch0e11

# Funder(s)

### Funder type
Government

### Funder Name
National Institute for Health Research

### 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

# Results and Publications

### Individual participant data (IPD) sharing plan
Requests for pseudonymised data should be directed to the study co-ordinator (Andrew Dymond using SAFER@medschl.cam.ac.uk) and will be considered by the investigators, in accordance with participant consent.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |
| Interim results article | Qualitative results | 16/03/2022 | 18/03/2022 | Yes | No |
| Interim results article | How to embed qualitative research in trials: insights from the feasibility study of the SAFER trial programme | 12/05/2022 | 16/05/2022 | Yes | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |