

**Patient Information Sheet**

**S**creening for **A**trial **F**ibrillation using **E**conomical and Accurate **T**echnolog**Y (SAFETY) –** a pilot study

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You are being invited to take part in a research study based within general practice surgeries in Hampshire. Before you decide it is important for you to understand what is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. It will take about 10 minutes for you to read this to help decide whether or not you wish to take part. Thank you for reading this.

**What is the purpose of the study?**

At the moment there is no UK screening programme for AF. Several relatively low cost devices with good accuracy now exist which can be used to pick up AF. These measure the electrical heart trace or pulse over short time periods (less than a few minutes) and can also be used in GP surgeries to screen for AF. We wish to test the accuracy of several devices and to find out how people feel about using the devices.

We are testing several devices to screen for Atrial Fibrillation (AF). AF is an irregular heart rhythm that can lead to blood clots forming within the heart which can come loose and cause a stroke. Blood thinning medication can be given to people with AF to help prevent strokes. About **12% of all strokes in the UK could be prevented by screening for AF**. About 5% of people between 65 and 74 will have AF which is often intermittent (can come and go) and can occur without any symptoms.

We aim to test four different devices (a blood pressure meter, a hand-held device, a heart rate monitor belt and a wearable heartbeat recording device) to help detect AF along with a standard ECG which records the electrical activity of the heart. Each test is likely to take just a few minutes and the entire visit around 30-40 minutes. We are inviting both adults aged over 65 (who do not have pacemakers) who are already known to have AF and also those not known to have AF. People who are over 65 and are found to have AF are at a greater risk of having an AF-related stroke. As the testing will include the use of gel electrodes, we do not want to recruit participants who have previously had a moderate or severe skin reaction to electrode gel.

**Why have I been invited?**

You have been asked to take part because you are aged over 65 (and do not have a pacemaker).

**Do I have to take part?**

Participation in the study is entirely voluntary. It is up to you to decide whether to take part. You are able to withdraw at any time without giving any reason. If you decide to withdraw or not to take part this will not affect your future standard of care.

Attached to this document is an independent factsheet on clinical studies published by the AF Association and Arrhythmia Alliance explaining what a clinical study is and what it might involve. If you wish to speak to someone form these organisations they would also be happy to answer any questions you may have about participation.

**What would happen to me if I take part?**

You will be given an appointment to attend your GP surgery. On arrival you will be asked to sign a consent form to participate in the study. A nurse will then perform the screening tests using the devices which should take a couple of minutes per device. The devices are non-invasive (they fit on the skin); one device uses the pulses detected while a blood pressure reading is taken; the second device obtains an electrical trace of the heart by simply holding the device with your fingertips; the third device uses a heart rate monitor belt (used by athletes) that straps comfortably to the chest to obtain electrical pulse signals; and the 4th device also attaches to the chest using two gel electrodes. You will then go on to have a standard ECG test which will be used as the benchmark test for AF. We will ask you to rate the devices in terms of comfort and suitability. You will only have to attend the surgery once and we expect the visit to last around 30-40 minutes.

If you have any questions about your heart rhythm you may wish to make a follow-up appointment with your GP.

We will invite some participants who do not have AF to use one of the wearable devices of their choice over the course of a week to see how they feel about longer-term use of the device and then to meet up once to talk about this with other people who have also tried the devices in a small group. This is because AF can be intermittent and occur without symptoms.

We will store any details such as address, date of birth and questionnaire results in locked storage and only the research team will have access to this. We will store data obtained from the trial which can be used to check our work and for future research and development work. No information that could be used to identify you will be stored in this database.

**What are the possible benefits of taking part?**

If you are found to have AF and did not know about this we will inform you and your GP and send you a patient information leaflet on treatment options which you can then talk about with your GP.

**What are the possible risks and disadvantages of taking part?**

This study will involve no significant risk as the tests are not invasive. The devices used carry a quality assured (CE) mark. Very rarely, patients may have some skin irritation after having an ECG taken (caused by the electrode gel). This type of reaction is usually very minor.

**Am I a suitable candidate to take part?**

We want to recruit a sufficient number of participants aged > 65 both with and without AF who do not have a pacemaker. Patients aged over 65 have a higher risk of having AF and also of having an AF-related stroke.

**What happens after the research study finishes?**

You will not need to do anything else after the research study finishes. We plan to publish the results in medical journals and present them at international medical meetings. We will send you a brief summary of the results at the end of the study, and you may contact Dr. Lown if you have further questions.

**What if there is a problem?**

We do not anticipate there being any problems with this simple study however any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this study, you should ask to speak to the research team who will do their best to answer your questions (023 8064 2538). If you have a complaint and remain unhappy and wish to complain formally, you can do this by telephone or in writing to Head of Research Governance, University of Southampton (023 80595058) or the Patient Advisory Liaison Service (023 8079 8498). In the unlikely event that something does go wrong and you are harmed during the research and this is due to someone‘s negligence then you may have grounds for legal action for compensation against University of Southampton but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

**Will my taking part in the study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. Only the study team will have access to any study forms or questionnaires that you complete, which will be kept in locked storage with Dr Lown as the key-holder. Some parts of the data collected for the study may be looked at by authorised persons from the University of Southampton or regulatory bodies to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will endeavour to meet this duty.

**What if relevant new information becomes available?**

If new information becomes available or the study is stopped for any reason, we will tell you.

**What will happen if I don’t want to carry on with the study?**

You have the right to withdraw from the study at any time and do not have to give a reason for doing so. This will not affect your medical care in any way. If you are willing to, we would ask for your feedback at an exit interview. If you withdraw from the study, we will destroy all identifiable information that may already have been provided.

**Who is organising and funding the research?**

The trial is being sponsored by the University of Southampton, and funding is being provided by the National Institute of Health Research (NIHR). The research team includes Dr Mark Lown, GP & Clinical Lecturer (Primary Care Research), University of Southampton, Prof Paul Little, (Primary Care Research), University of Southampton, Prof Mike Moore, (Primary Care Research), University of Southampton, Dr James Rosengarten (Cardiologist).

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by \_\_\_\_\_\_\_\_\_\_\_\_\_\_Research Ethics Committee.

**Where can I get further information about the study?**

If you have any unanswered questions about the study then please feel free to contact Dr Mark Lown.

**What’s the next step..?**

If you wish to sign up as a participant on the study please return the enclosed form. Thank you for taking the time to read this information.