

PARTICIPANT INFORMATION LEAFLET

Title of Project: Atrial Fibrillation Screening using Single-lead ECG within a South Asian Community

Name of Researcher (s): Mr Vilius Savickas, Dr Sukvinder Bhamra, Dr Adrian Stewart, Dr Emma Veale, Dr Sarah Corlett, Prof Alistair Mathie, MPharm Undergraduates

If you are 18 years or over and interested in taking part in this study, you must understand why the study is being done and what it involves. Please take time to read the following information. Ask if anything is not clear or if you would like more information. Take time to decide if you want to take part or not.

Why is the study being done?

Atrial fibrillation (AF) is a heart condition, which results in an irregular and sometimes very fast heart beat. If you develop AF it means that your heart may not be working properly. However, if AF is detected early, the treatment can prevent serious complications such as heart failure and stroke. This study aims to find out if trained pharmacy students can successfully use mobile and painless electrocardiogram (ECG) devices to accurately detect AF in individuals of South Asian origin. In order to encourage all individuals from the local community to participate, we are carrying out the screening at the Shri Guru Gobind Singh Ji Sikh Temple (gurdwara) and have intentionally selected a research team fluent in Punjabi.

Do I have to take part?

No. It is up to you to decide whether or not to take part. Even if you agree to take part, you can change your mind at any time without giving any reason. If you decide not to take part in the study, your medical care will not be affected in any way.

If I do take part, what would I have to do and what would be done to me?

If you do take part, you will be offered a free heart beat check with a pharmacy student under the supervision of a clinical pharmacist. Before the check, you will be asked to confirm your eligibility and sign a consent form. The test will be carried out at a desk within the temple using a small, painless ECG device. During the check you will be asked to hold two fingers of each hand on two metal pads to record an ECG trace over 30 seconds as shown in the picture below. The student will also ask you a few questions about your lifestyle, past medical history and any medicines you may be taking.



Mobile ECG test

If you are found to have a possible AF or if the test is inconclusive, the student will give you a letter advising to make an appointment at your doctor's surgery to either confirm or reject this provisional diagnosis. You will also be given an optional feedback questionnaire and a form to record any outcomes of your appointment at the surgery, which you may wish to send back to the University using a pre-paid envelope provided.

Are there any risks if I take part?

This study is not associated with any significant risks. In the unlikely event where you feel uncomfortable during the appointment, you can stop at any time. Since we are carrying out the test within the temple, there is a chance that people may see you be tested. However, we can guarantee your personal information and results will be protected as described below.

Are there any benefits if I take part?

You will have your heart beat checked to confirm that it is normal. If you are diagnosed with AF or another heart condition as a result of the test, you and your doctor will be able to decide on how to treat it. Your test results and views will also enable our study to determine how best to deliver and measure future screening programmes for AF amongst the individuals of South Asian origin.

Will anyone know that I've taken part?

We will not tell anyone that you have taken part in the study. Your doctor will not be informed about the result of the test unless you share the letter given to you with the surgery.

What will happen to the results?

All data collected as part of the study will be kept strictly confidential and stored securely at the Medway School of Pharmacy for 5 years in line with the Data Protection Act 2018 and the European Union General Data Protection Regulation. All data except the consent form you sign before the appointment will be anonymised by assigning you a unique number. This data will be used in future reports and publications however it will not be possible to identify you. If you wish receive information about study findings, please email afstudy@kent.ac.uk. More information about the University's use of personal data can be found here: <https://research.kent.ac.uk/researchservices/wp-content/uploads/sites/51/2018/05/GDPR-Privacy-Notice-Research.pdf>.

Who is organising and funding the study?

The study is carried out by researchers at the Medway School of Pharmacy (University of Kent) in conjunction with the AF Association as part of their MPharm and PhD research projects. It is funded by the Medway School of Pharmacy and the University of Kent.

Who should I contact if I want to know more about the study?

The PDAF Study Team by email: afstudy@kent.ac.uk or by phone: 01634 202935 or by post: Medway School of Pharmacy, Anson Building, Central Avenue, Chatham, ME4 4TB.

Who should I contact if I have any concerns about the study or the way it has been conducted?

If you have concerns about this study, please contact Dr Trudy Thomas, Senior Lecturer by email t.thomas@kent.ac.uk or by phone/post as listed above.

For more information about AF, please visit: www.afa.org.uk or www.afa-international.org or contact the AF Association: 01789 867502 or info@afa.org.uk.

Thank you for taking time to consider taking part in this study.

This project has been looked at and approved by the
Medway School of Pharmacy Research Ethics Committee