DEnTal Examination deTeCtion of Atrial Fibrillation (DETECT-AF)

You are invited to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Take time to decide whether you wish to take part.

What is the purpose of the study?
The aim of the study is to test if dental clinics are a cost effective and suitable place to identify a previously undetected abnormal heart rhythm called atrial fibrillation in adults aged 65 years and older. The study also aims to find out if there is a link between how severe dental disease is and atrial fibrillation, and whether people found to have atrial fibrillation during the study have the right care afterwards.

What is atrial fibrillation?
Atrial fibrillation means the top chambers of your heart (the atria) quiver or twitch. If this happens your heart may beat irregularly, with no set pattern. Treatment and improving lifestyle are important because untreated atrial fibrillation can increase the risk of stroke, heart failure and other heart-related problems. Please visit the British Heart Foundation website for more information: https://www.bhf.org.uk/informationsupport/conditions/atrial-fibrillation. You may be able to tell if you have a regular or irregular heartbeat by checking your pulse. For more information please visit https://www.bhf.org.uk/informationsupport/tests/checking-your-pulse

Why have I been asked to take part?
We are interested in finding previously undiagnosed atrial fibrillation in people attending a dental clinic. You have been asked to take part because you are an adult aged 65 years or older attending an appointment at the Newcastle dental hospital.

Do I have to take part?
No, it is up to you to decide whether to take part. Your decision will not affect your treatment. If you decide to take part, you will be asked to complete a consent form.

What will happen if I take part?
Participating will take about five minutes and you can take part after your dental appointment. The study nurse will briefly ask you questions about your medical history, including asking about symptoms linked to atrial fibrillation like palpitations. We will also ask for your date of birth, sex, ethnicity, address, and postcode, so that we can link your basic periodontal (around tooth) examination results to the study. We will also ask for your telephone number if the nurse finds that you have an unusual heart rhythm so that we can telephone you a month later to see what treatment you have had, and for your general practitioner (GP) details so that we can inform your GP about your results.

You will be asked to place your fingers on a handheld KardiaMobile Electrocardiography (ECG) device for 30 seconds (see picture).

After 30 seconds, the device will interpret and display your heart rhythm trace and the nurse will be able to look at recording on the device screen. You will be given a unique study identification number that will be entered into the device and then the recording be uploaded into a secure KardioPro server. None of your personal details will be entered into the device so you cannot be identified. The record of your heart rhythm can only be looked at by the study team. You will be provided with written information about atrial fibrillation and how to check your pulse.

The study nurse will tell you if the rhythm that the device has recorded looks like it is atrial fibrillation and will write to your doctor to let them know about the result and send them a copy of the heart rhythm recorded by the device. They will advise you about making an appointment to see your GP. The study nurse will call you about one month after you took part in the study to check you have received a follow-up appointment and whether you have been given any medication.

If the device shows that you have an unusual heart rhythm that is not atrial fibrillation, the nurse will ask you to use the KardiaMobile device again. This time you will be asked to place the device on your left knee or ankle for 30 seconds. The nurse will discuss the results with you and advise you about making an appointment to see your GP. The study nurse will call you about one month after you took part in the study to check what happened after your GP appointment.

Your GP will not be contacted if your heart rhythm is normal.

What are the possible benefits of taking part?

You may not get any direct benefit to you as a participant from being involved with this study. It is possible that you may be diagnosed with atrial fibrillation which would enable your GP to offer you appropriate care to reduce your stroke risk. The results will also inform the study researchers if it is possible to identify and treat people aged 65 years and older with undiagnosed atrial fibrillation in a dental clinic setting.

What are the possible disadvantages and risks of taking part?

We do not think that there are any possible disadvantages to taking part, apart from giving up 5 minutes of your time.

Will my taking part in the study be kept confidential?
All information will be kept strictly confidential as per the General Data Protection Regulation (GDPR) 2018. Your name will be removed from the data and replaced with a code number so that you cannot be recognised from it. Only the research team will know which participant has been allocated which unique code.

All data regarding personal information like your name, date of birth, telephone number and postcode will be stored securely on Edinburgh Napier University computers, which are password protected and compliant with data protection protocols.

How will we use information about you?
We will need to use information from you and from your medical records for this research project. This information will include:

- Your name
- Contact details (address, postcode, telephone number)
- Date of birth
- Your basic periodontal examination score from your dental records

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?
You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?
You can find out more about how we use your information
at www.hra.nhs.uk/information-about-patients/
our leaflet available from http://www.hra.nhs.uk/patientdataandresearch
by asking one of the research team
by sending an email to dataprotection@napier.ac.uk, or
by ringing us on **0131 4553392**.

What happens when the study is finished?
At the end of the research the data you have provided will be stored securely by Edinburgh Napier University.

Anonymised data (sex, 5-year age group, race, atrial fibrillation status, periodontal health/disease status) may be shared with other researchers for further analysis once the results of the research have been published. This would only be after an official request, consideration of suitability for sharing, and subject to a data sharing agreement between Edinburgh Napier University and the researcher requesting the data. The data will be stored for at least 10 years.

What will happen to the results of the study?
The results of the study may be written up and published in healthcare journals and presented at conferences. You will not be identifiable in any publication.

Who is organising the research and why?
The principal investigator organising the study is Professor Lis Neubeck, a Professor of Nursing at Edinburgh Napier University. Lis has a special interest in atrial fibrillation.

Who has reviewed the study?
The study proposal has been reviewed and given a favourable opinion by NHS Research Ethics Committee (area and reference to be added).

If you would like to discuss this study with one of the researchers before deciding whether to take part, please contact Alice Pearsons, Research Assistant, a.pearsons@napier.ac.uk Tel: 0131 4553392

If you would like to discuss this study with an independent person or make a complaint, please contact: Dr Janet Hanley, Principal Research Fellow of Edinburgh Napier University in the School of Health and Social Care email J.Hanley@napier.ac.uk