

# Can we detect unknown atrial fibrillation by screening people attending dental hospital appointments?

<b>Submission date</b> 17/10/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 26/10/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/02/2024	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and aims:

Atrial fibrillation (AF) is a heart condition that causes an irregular and often abnormally fast heart rate. AF affects over 1.4 million people in the UK, requires frequent hospital admissions and increases the risk of stroke five-fold. AF-related strokes are more likely to be fatal or severely disabling compared to other types of stroke. People aged 65 and over with unknown AF usually benefit from taking oral anti-coagulation medication, which reduces stroke risk in AF by two-thirds. About 5% of those aged 65 and over have AF and this may be higher in people with periodontal (gum) disease. This study will test how many people can be identified with unknown AF by simple screening at a dental hospital.

### Who can participate?

Adults aged 65 years and over who are attending an appointment at Newcastle Dental Hospital. Healthcare professionals who are involved in the care of study participants

### What does the study involve?

Adults aged 65 years and over who are attending an appointment at Newcastle Dental Hospital: If you take part, you will be asked to complete a simple, 30 second screening test for AF where you place your fingers on a device called KardiaMobile that is resting on a table. If the result is unclear, you will be asked to repeat the test, but this time by placing the device on your knee. If the screening detects AF, the research nurse will contact your GP so that they can discuss whether you need any treatment.

### Healthcare professionals:

If you take part in the study, you will be asked to complete a telephone interview with a researcher about your experience of being involved in the care of people in the study.

### What are the possible benefits and risks of participating?

Adults aged 65 years and over who are attending an appointment at Newcastle Dental Hospital: You may be diagnosed with AF as a result of the screening. This may require you to take medication to help reduce the risk of you having a stroke.

Healthcare professionals:

We do not think there are any personal benefits from participating, but your views may influence future screening programmes in dental clinics.

Where is the study run from?

Edinburgh Napier University (UK)

When is the study starting and how long is it expected to run for?

March 2022 to March 2024

Who is funding the study?

Daiichi Sankyo UK Ltd

Who is the main contact?

Professor Lis Neubeck, l.neubeck@napier.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Dr Coral Hanson

### ORCID ID

<https://orcid.org/0000-0003-1602-1968>

### Contact details

Room 4.B.29

Sighthill Campus

Edinburgh Napier University

Edinburgh

United Kingdom

EH11 4BN

+44 131 455 3457

c.hanson@napier.ac.uk

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

311299

### Protocol serial number

IRAS 311299, CPMS 53463

## Study information

**Scientific Title**

Identifying undiagnosed atrial fibrillation in older adults attending dental clinics

**Acronym**

DETECT-AF

**Study objectives**

The study aims to test if dental clinics are a suitable place to identify previously undetected AF.

**Primary objective:**

To identify the proportion of screened participants aged 65 years and older attending a dental clinic with newly identified AF

**Secondary objective**

1. To examine the correlation between periodontal health/disease status; age, sex; ethnicity; Index of Multiple Deprivation; and incidence of AF.
2. To explore the barriers and facilitators to the implementation of atrial fibrillation screening in dental clinics.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 01/03/2022, Yorkshire & The Humber - South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 207 104 8091; southyorks.rec@hra.nhs.uk, ref: 22/YH/0049

**Study design**

Single site cross-sectional study

**Primary study design**

Interventional

**Study type(s)**

Screening

**Health condition(s) or problem(s) studied**

Diagnosis of patients with atrial fibrillation

**Interventions**

Patients: Single time point screening for atrial fibrillation using a KardiaMobile single lead or six lead ECG device.

Healthcare professionals: one semi-structured telephone interview.

**Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

KardiaMobile single lead or six lead ECG device

### **Primary outcome(s)**

The proportion of participants aged 65 years and older attending a dental clinic that take part in single time point atrial fibrillation screening using a KardiaMobile single lead or six lead device that are diagnosed with newly identified atrial fibrillation.

### **Key secondary outcome(s)**

At a single time point:

1. Periodontal health/disease status (most recent basic periodontal score retrieved from patient records)
2. Age, sex; ethnicity; Index of Multiple Deprivation quintile (calculated from postcode)
3. Incidence of atrial fibrillation (as per the primary outcome measure)
4. The barriers and facilitators to implementing atrial fibrillation screening in dental clinics identified via semi-structured interviews with healthcare professionals and student healthcare professionals involved in the screening study.

### **Completion date**

31/03/2024

## **Eligibility**

### **Key inclusion criteria**

Patients:

1. Adults aged 65 years and over
2. Being a patient of the Newcastle dental hospital
3. Able to give informed consent
4. Due to time and financial constraints surrounding the cost translation services and qualitative data transcription, the study will be unable to recruit participants who cannot adequately understand verbal explanations or written information given in English.

Healthcare professionals:

5. Healthcare professionals (and student healthcare professionals) who have been involved in the care of patients who are participating in the study.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Lower age limit**

65 years

### **Sex**

All

## Key exclusion criteria

Patients:

1. Have been diagnosed with severe co-existing conditions (severe dementia or terminal illness)
2. Are unable to give informed consent
3. Due to time and financial constraints surrounding the cost translation services and qualitative data transcription, the study will be unable to recruit participants who cannot adequately understand verbal explanations or written information given in English

Healthcare professionals:

4. Dental hospital staff/students who are not working at the Newcastle Dental Hospital and not involved in the care of study participants
5. GPs who are not involved in the care of study participants

## Date of first enrolment

02/11/2022

## Date of final enrolment

31/03/2024

## Locations

### Countries of recruitment

United Kingdom

England

### Study participating centre

**Newcastle Dental Hospital**

Richardson Road

Newcastle upon Tyne

United Kingdom

NE2 4AZ

## Sponsor information

### Organisation

Edinburgh Napier University

### ROR

<https://ror.org/03zjvnn91>

## Funder(s)

Funder type

Industry

## Funder Name

Daiichi Sankyo UK Ltd.

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. Data generated by the project will be made open after completion of the project once appropriate changes (e.g., all participants assigned a unique identifier and any identifying details have been removed) have been made to honour assurances of confidentiality and anonymity. The Information Commissioner's Office Anonymisation: managing data protection risk code of practice will be adhered to: <https://ico.org.uk/media/fororganisations/documents/1061/anonymisation-code.pdf>. Datasets will be allocated a DOI and stored on the Edinburgh Napier University Open Access Research Repository in accordance with the University research data deposit process.

### IPD sharing plan summary

Stored in publicly available repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Phase 1 version 4	24/08/2022	25/10/2022	No	Yes
<a href="#">Participant information sheet</a>	Phase 2 version 4	24/08/2022	25/10/2022	No	Yes
<a href="#">Protocol file</a>	version 6	20/07/2022	25/10/2022	No	No