Project Title: Identifying undiagnosed Atrial Fibrillation in older adults attending dental clinics

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1 INTRODUCTION

1.1 BACKGROUND

Atrial fibrillation (AF) is a major public health issue, with a high risk of frequent hospital admissions, stroke and premature death.[1] AF affects at least 2 million people in the UK.[1] Data from a large registry with over 4000 people with AF has shown that 11% will have an ischaemic stroke within 5 years, a five to seven-fold increase compared to stroke incidence in the general population.[2] Furthermore, these strokes are likely to be more severe, or fatal.[2] Consequently, almost 70% of people with an AF-related stroke will die, or be left with a permanent disability, compared to 55% of people with non-AF strokes.[1]

An effective, evidence-based treatment to prevent AF related strokes exists. A systematic review including over 75,000 participants, showed effective treatment with oral anticoagulant medications (OACs), such as warfarin, or non-vitamin K OACs (NOACs), reduced the stroke risk in people with AF by two-thirds.[3] The number needed to treat with warfarin to prevent a stroke is 25. Indeed, it is estimated that in England alone, appropriate management of AF can prevent around 7000 strokes and save 2100 lives per year.[4]

Despite this, 10% of all ischaemic strokes are in individuals with undiagnosed AF, which has led to a focus on AF detection in a range of settings, including general practice, community pharmacy, and out-patient clinics.[5] A meta-analysis of patient-level data from 19 screening studies with 141,220 patients concluded that screening patients >65 years old, the detection rate of new AF cases is 1.44% (95% CI, 1.13%–1.82%), and 84% of new AF cases have a Class-1 recommendation for OAC prophylaxis.[5] During the COVID-19 pandemic, opportunistic detection of AF has declined dramatically due to reduced interactions with healthcare providers such as general practitioners and pharmacists. One service that has continued to provide in-person care is the Newcastle Dental Hospital. However, no studies have investigated the potential to undertake a simple screening programme for AF in patients undergoing dental treatment.

Periodontal disease (PD) is strongly associated with cardiovascular disease. A recent study highlighted the high prevalence of AF in a population who have PD.[6] In the dental Atherosclerosis Risk in Communities Study (ARIC) cohort, 5,958 were assessed without prior AF, 754 (13%) were found to have AF.[6] Severe PD was associated with AF on both univariable (crude HR, 1.54; 95% CI, 1.26-1.87) and multivariable (adjusted HR, 1.31, 95% CI, 1.06-1.62) analyses. Mediation analysis suggested AF mediates the association between PD and stroke. In the main ARIC cohort, 9,666 participants without prior AF were assessed for dental care use, 1558 were found to have AF (16%).[6]

1.2 AF SCREENING IN DENTAL CLINICS

Dental clinics provide an ideal location, and an appropriate health professional/community interface, to screen people for AF. Approximately 90% of the UK population visits a dentist every two years making it one of the most accessible healthcare services in the community.[7] Approximately 50% of the adult population have PD, with 30% of the population having treatment for active tooth decay.[7] Those requiring specialist treatment of periodontal disease attend dental hospitals, thus those at highest risk of cardiovascular disease due to periodontal disease are likely to be found in these clinics. The NHS Newcastle Dental Hospital and School is the pre-eminent centre for specialist oral health care, education and research in North England. The Dental Hospital is one of the largest integrated teaching and hospital complexes in the UK, which includes 3 community outreach clinics. The Dental Hospital and School provides a range of dental services and a recent audit showed that in one month over 2500 patients over the age of 65 years attended for treatment. We aim to test if dental clinics are a suitable place to identify previously undetected AF during and beyond the COVID-19 pandemic. The study will aim to 1) determine if there is any correlation between severity of dental disease and AF incidence; 2) test a pathway to ensure that patients are appropriately managed following detection of AF; and 3) to determine cost-effectiveness of identification of AF in dental settings.

1.3 RATIONALE FOR STUDY

AF is prevalent, affecting approximately 5% of those aged 65 years and older. Unrecognised AF is generally not associated with symptoms and raised resting heart rate. Those with unrecognised AF usually have stroke risk scores (i.e., CHA2DS2 VASc scores) high enough to warrant anticoagulation. Furthermore, registry data suggests that incidence of AF may be much higher in a population who have periodontal disease, which generates the hypothesis that there are appreciable numbers who would benefit from early recognition of AF through simple detection programmes, followed by thromboprophylaxis to prevent future stroke.

This study aims to determine the appropriateness and impact of dentistry-based screening, using innovative technology (a single/six lead ECG device, KardiaMobile) that has been used in numerous AF screening studies, focused on identifying people with undiagnosed AF, with onward referral to their GP for appropriate medical management of AF. The study also aims to explore the role of dentists in ongoing management of AF, as well their role in raising AF awareness in the public.

The findings of this study will have broad implications for the general population aged 65 years and older with undiagnosed AF. We anticipate that the study will demonstrate that it is possible to identify and treat people in the community, not identified due to COVID-19 restrictions, who were not previously known to have AF, thus greatly reducing the risk of stroke. Findings from this study will inform the design and refinement of a future intervention for large-scale research and implementation.

2 STUDY AIM and OBJECTIVES

2.1 Aim

The study aims to test if dental clinics are a suitable place to identify previously undetected AF during and beyond the COVID-19 pandemic. It will determine if there is any correlation between severity of dental disease and AF incidence; test a pathway to ensure that patients are appropriately managed following detection of AF; and determine cost-effectiveness of identification of AF in dental settings.

Primary Objective:

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

Secondary Objectives:

- To examine the correlation between periodontal health/disease status; age, sex; ethnicity; Index of Multiple Deprivation; and incidence of AF.
- To assess the suitability and cost-effectiveness of AF screening in a dental setting.

2.2 Primary Endpoint/Outcome Measure

The primary outcome measure will be the proportion of screened subjects with newly identified AF attending a dental clinic aged 65 years and older.

STUDY DESIGN

(Phase 1) A cross-sectional study of screening in dental clinics to identify undiagnosed AF in adults aged 65 years and over. (Phase 2) A qualitative study of healthcare professionals involved in the care of phase 1 study participants to explore factors that might influence sustainability of screening processes beyond the study setting.

STUDY POPULATION

2.3 NUMBER OF PARTICIPANTS

All patients attending the Dental Hospital will be eligible to participate if they are aged 65 years or older (n=1000). Additionally, a sub-sample of dental hospital staff/students and general practitioners involved in the care of the participants will be asked to take part in a qualitative telephone interview (n-20).

2.4 INCLUSION CRITERIA

The following people will be eligible to take part in the study:

Phase 1: patient screening:

- Adults aged 65 years and over

- Being a patient of the Newcastle dental hospital
- Able to give informed consent
- 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.

Phase 2: healthcare professionals' interview:

- Dental hospital staff/students working at the Newcastle Dental Hospital involved in the care of study participants
- GPs involved in the care of study participants.

2.5 EXCLUSION CRITERIA

The following people will not be eligible to take part in the study:

Phase 1: patient screening:

- Have been diagnosed with severe co-existing conditions (severe dementia or terminal illness)
- Are unable to give informed consent
- 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

Phase 2: healthcare professionals' interview:

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

3 PARTICIPANT SELECTION AND ENROLMENT

3.1 RECRUITMENT OF PARTICIPANTS

Phase 1: patient screening

Patient participants (n=1000) will be recruited via two mechanisms: 1) Posters advertising the screening study will be located at the entrance to and within the Dental Hospital inviting patients to directly contact research staff who will be available around the building to help recruitment [Appendix 1]. 2) Dental hospital staff and dental students will ask patients attending for appointments whether they are interested in participating and provide written information about the study (participant invitation [Appendix 2], participant information sheet [Appendix 3], privacy notice [Appendix 4] and consent form [Appendix 5]). The participant information sheet will include an explanation of the screening process, and that information will be shared with their GP if abnormal rhythms are detected. This will include the electrocardiograms (ECGs) collected during the screening process. Participants will also be informed that they may be required to have follow up with the GP if abnormal findings are detected.

The intervention flow chart is displayed in Figure 1.

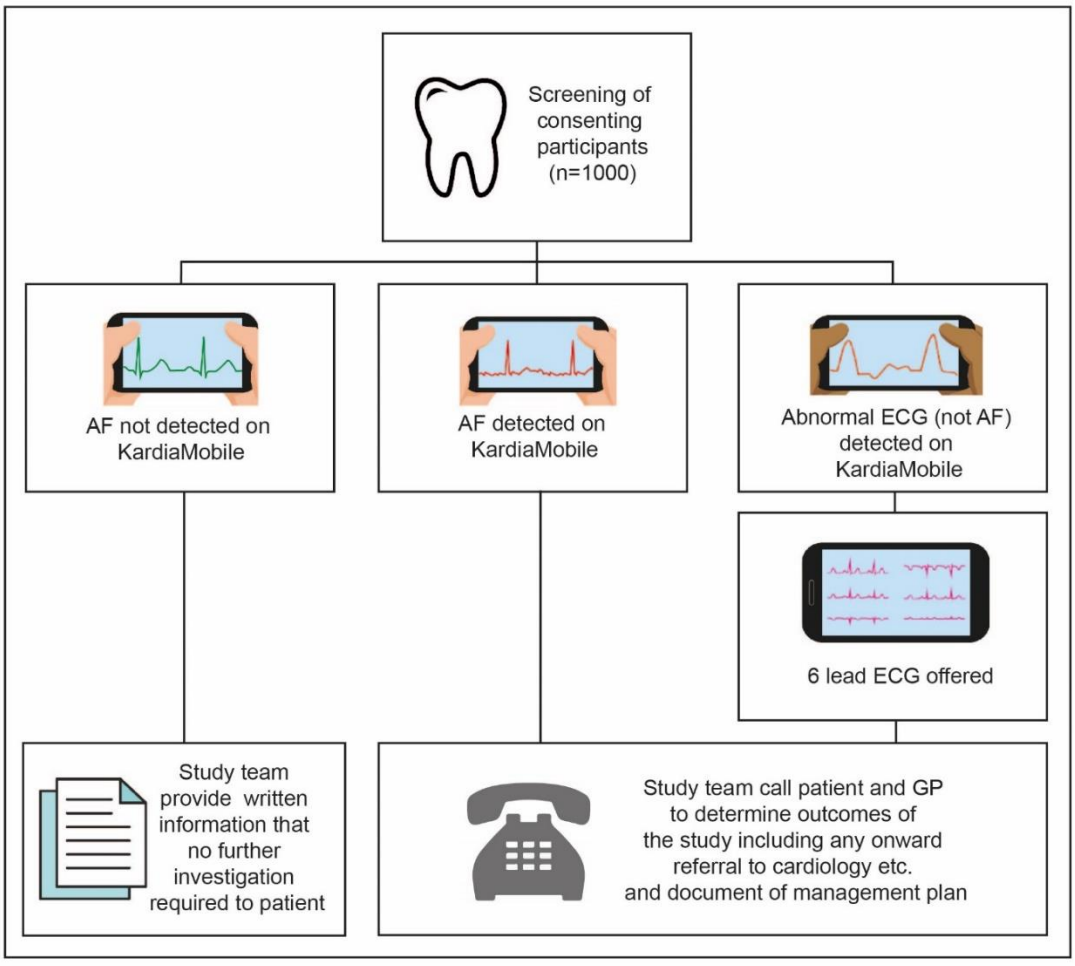


Figure 1 Patient Screening flow chart

Phase 2: healthcare professionals' interviews:

Prior to the start of the study, dental staff and students at the Newcastle Dental Hospital and GPs in the area surrounding the Newcastle Dental Hospital will be sent study information via email (using agreed NHS gatekeepers). This will include an invitation to take part in the healthcare professional element of the study [Appendix 6], a study information sheet [Appendix 7], a privacy notice [Appendix 8] and a link to an online consent form [Appendix 9]. Interested healthcare professionals will complete an online consent form via Novi Survey to register for the study.

Optional education about AF will be offered to any participating interested health care professionals. The training will include information about the causes of AF, symptoms and evidence- based management, the health risks associated with AF, self-care management and cardiovascular risk reduction. Interested team members will also be trained to operate the KardiaMobile device (handheld single-lead/six-lead ECG) and interpret the single-lead ECG trace recording. Training of the team will be undertaken using a structured training module, using a combination of online (https://www.escardio.org/Education/E-Learning/Webinars/detection-and-diagnosis-of-atrial-fibrillation), centralised and onsite training, designed and delivered by a senior cardiologist, specialist nurse, and periodontal surgeon. Participating members of the training module will be eligible to claim Continuing Professional Development points on completion.

Towards the end of patient data collection, NHS gatekeepers will again circulate information via email about the qualitative interview element of the study to healthcare professionals who have been involved in the care of patients who are participating in the study. This will be the same information sent at the beginning of the study.

3.2 CONSENTING PARTICIPANTS

Phase 1: patient screening:

Recruitment will take place at the Newcastle Dental Hospital. Patients eligible and interested in participating in the study will be given study information [Appendix 2, 3

and 4] and a consent form [Appendix 5] by the staff at Newcastle Dental Hospital when they attend for their routine appointment. If patients wish to participate, they will talk to an appropriately trained member of the research team and decide whether they want to take part. An appropriately trained member of the research team will gain written informed consent from all participants prior to conducting the screening assessment. The consent forms will be signed by the participant and a suitable member of the research team who is on the delegation log for this task and GCP trained. Two copies will be taken, one for the participant, one for the dental records. The original will be put in the Investigator Site File which will be stored securely in the Dental Clinic Research Facility. Participation will be voluntary and choosing not to take part will not affect their usual dental care.

The participant will be given every opportunity to clarify any points they do not understand and, if necessary, ask for more information from the dental staff and the study nurse. If participants want to talk to an independent person about the study, details will be included in the Participant Information Sheet [Appendix 3] to facilitate this. The participant will have sufficient time to consider the information provided.

Phase 2: healthcare professionals' interview:

Prior to the start of the study, dental hospital staff and students at the Newcastle Dental Hospital, and GPs in the area surrounding the Newcastle Dental Hospital will be sent study information via email (using agreed NHS gatekeepers). This will include a study invitation to take part in the healthcare professional element of the study [Appendix 6], information sheet [Appendix 7], a privacy notice [Appendix 8] and an online consent form [Appendix 9]. Interested healthcare professionals will return the consent form to the principal investigator to register for the study. Towards the end of patient data collection, NHS gatekeepers will again circulate information via email about the qualitative interview element of the study to healthcare professionals who have been involved in the care of patients who are participating in the study. This will be the same information sent at the beginning of the study.

If participants want to talk to an independent person about the study, details will be included in the Participant Information Sheet to facilitate this. The participant will have sufficient time to consider the information provided.

3.2.1 Withdrawal of Study Participants

Study information will emphasise that the participant may withdraw their consent to participate at any time by contacting a member of the research team. Study data can be withdrawn up until the point that data analysis is completed. This will be made clear in the supporting documentation pre-study. At the end of the study, participants will be provided with a participant debrief summary [Appendix 10], which will reiterate this.

4 STUDY PROCEDURE

4.1 STUDY ASSESSMENTS

Phase 1: patient screening:

The study nurse will complete the following screening protocol:

- The screening will be approximately 5min duration.
- Screening will consist of an initial brief medical history, including pharmacotherapy and screen of AF symptoms. We will also ask for date of birth, sex, ethnicity, postcode so that we can link Basic Periodontal Examination to participants. We will also ask for telephone number and registered GP/GP surgery address only in the case of abnormal rhythm or inconclusive rhythm so that we are able to inform the GP of results and follow up participants [Appendix 11].
- The study team will assess cardiac rhythm using the single-lead recording function on the handheld KardiaMobilie ECG device for 30s. The KardiaMobile ECG device will be the property of ENU and will be in the possession of the study nurse during assessments. The device will not be on participants personal mobile telephones.
- The ECG record with a unique identification number will be transmitted by wireless connection on a secure server to an iCloud by the KardiaMobile software. The ECG record is only accessible by the study team.
- The study team will advise the participant of the suspected diagnosis and ensure they understand the next steps in the pathway
- For every person with an abnormal ECG (not AF), the study team will offer a 6-lead ECG using the KardiaMobile 6-lead functionality. KardiaMobile

records Leads I,II,II, AVL, AVR, and AVF by additional electrode placement on left knee or ankle.

- At the end of the screening, participants will be given a participant debrief sheet [Appendix 10] and those with a normal rhythm will be given a letter stating that no further action is required [Appendix 16].

Protocol if AF is not suspected from the screening

- GP will not be informed of the participant screening.

Protocol if a diagnosis of AF is suspected from the screening

- The study nurse will counsel the participant and advise that their GP will be contacted to arrange follow up.
- Edinburgh Napier University researchers will send a typed letter to the GP explaining the potential diagnosis, which will include a copy of the ECG recording. If required, the letter will include an invitation to refer their patient for a full assessment at any cardiology service of their choosing. A copy will be inserted in the patient notes at Newcastle Dental Hospital.
- The study team will call the participant approximately 1 month after the date of screening, to ensure they have not been lost to follow-up.
- The study team will call the GP surgery to determine if any treatment or further follow up was required.

Protocol if a diagnosis of AF is not suspected from the screening but an abnormal rhythm is detected

- Those participants with an abnormal rhythm detected on single lead ECG, not previously identified, will be offered a 6-lead ECG on the KardiaMobile. This involves placing an additional electrode on either the left knee or left ankle and takes 30 seconds as for a single-lead recording.
- They will be counselled by the study nurse regarding the diagnosis and advised to return to their GP to discuss the next phase of their management.

- Edinburgh Napier University researchers will send a letter to the GP explaining the potential diagnosis, which will include a copy of the 6-lead ECG recording, and an invitation to refer their patient for a full assessment at any cardiology service of their choosing. A copy will be inserted in the patient notes at Newcastle Dental Hospital.
- If the GP refers the participant to the cardiology clinic, the full assessment will be performed by a Cardiologist, according to standard cardiology practice, and will include a 12-lead ECG. If appropriate, the patient may be commenced on appropriate thromboprophylaxis, according to evidence-based guidelines [7]
- The study team will call the participant approximately 1 month after the date of screening, to ensure they have not been lost to follow-up [Appendix 12].

Protocol if a history of AF is known prior to the screening

- Edinburgh Napier University researchers will send a letter to the participant's GP informing them that their patient was screened for AF, stating if they were in sinus rhythm or AF on the day of the screening.

Linking to periodontal health/disease

- The consent form will include consent for dental hospital staff to provide the Basic Periodontal Examination (BPE) result for each routinely conducted at their appointment (Table 1).

Table 1 Basic Periodontal Examination	
0	This indicates that there are **no pockets >3.5mm** (i.e. the black band is completely visible), **no bleeding** and **no calculus or plaque traps** (e.g. overhanging restorations)
1	This indicates that there are **no pockets >3.5mm** (i.e. the black band is completely visible), **no calculus or plaque traps** (e.g. overhanging restorations) but **there is bleeding after probing**
2	This indicates that there are **no pockets >3.5mm** (i.e. the black band is completely visible) but **there is calculus or plaque traps present**

3	This indicates that **probing depths between 3.5mm and 5.5mm** have been found (i.e. black band is partially visible)
4	This indicates **a probing depth of >5.5mm** (i.e. black band is completely hidden in pocket)
*	Indicates **furcation** involvement

- The study team will provide a list of all participants in an encrypted excel spreadsheet (name, date of birth and address) to allow for identification to the dental hospital staff. The dental hospital will provide the result of the basic periodontal examination for each participant on an encrypted excel spreadsheet. Patients will give written consent for this data to be shared with the study team, and an appropriate data-sharing agreement will be in place between Edinburgh Napier University and Newcastle Dental Hospital.

Phase 2: healthcare professionals' interview:

Upon completion of phase one, healthcare participants will be asked to take part in an individual qualitative telephone interview with an Edinburgh Napier University researcher. A semi-structured interview schedule [Appendix 13] will be referred to in the telephone interview. We will explore the barriers and enablers to the screening processes in the AF detection programme and the effects it has had on the reported practice of the healthcare professionals involved with the participant. At the end of the interview, participants will be emailed a participant debrief sheet [Appendix 10].

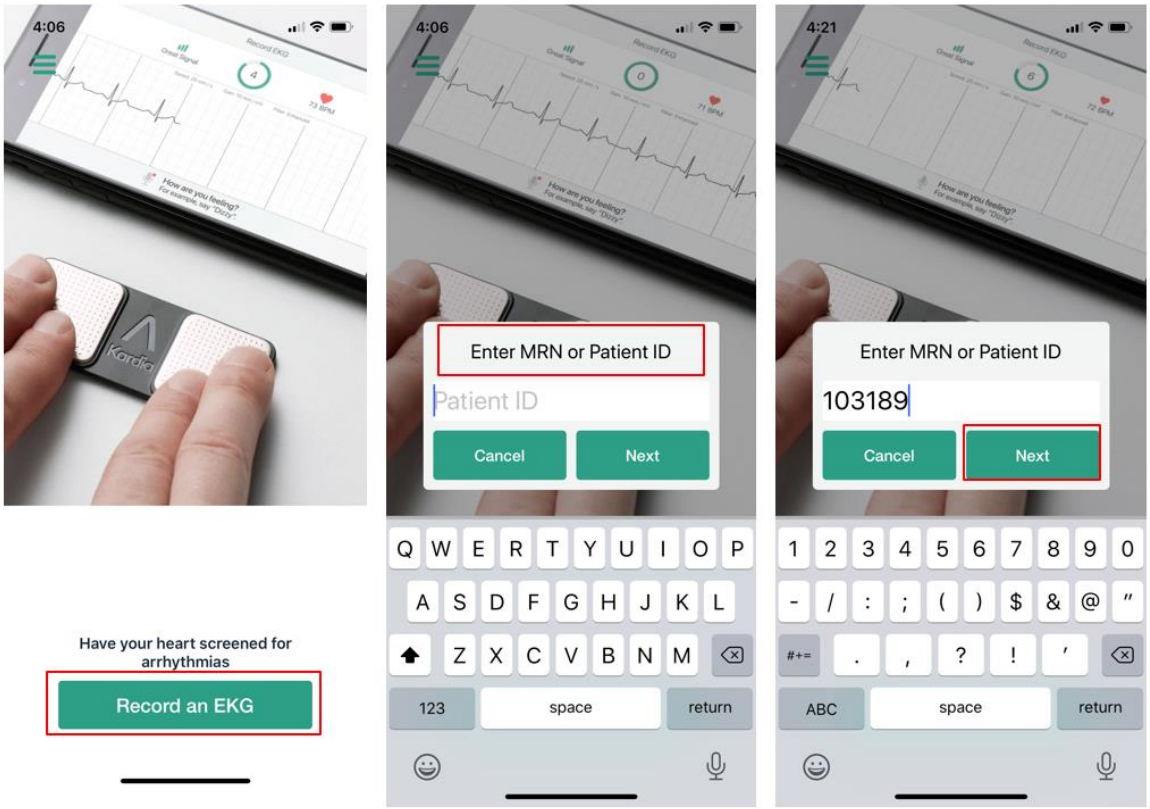
5 DATA COLLECTION AND ANALYSIS

5.1.1 Data Collection

Phase 1: patient screening:

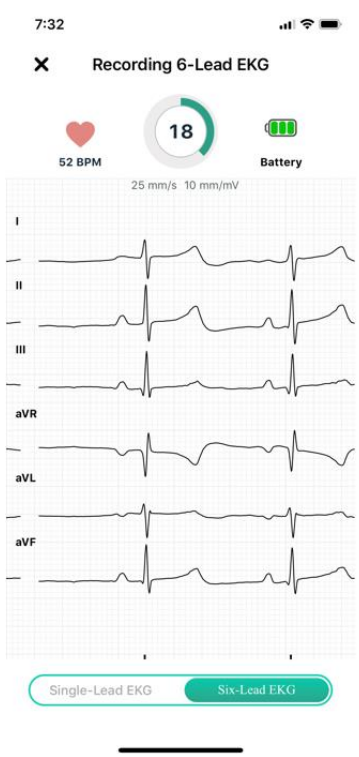
- Data about initial brief medical history, including pharmacotherapy, screen of AF symptoms, date of birth, sex, ethnicity, address, postcode, telephone number and registered GP/GP surgery address will be recorded directly onto the Edinburgh Napier University secure research drive during participant screening via a specialist university managed laptop. Postcodes will be used to identify Index of Multiple Deprivation (IMD) quintile. There will be no paper records of participant data. Participants will be allocated a unique participant ID at this point. This PID will be the only identifier entered onto the KardiaMobile system, meaning that data stored by KardiaMobile will be anonymous.

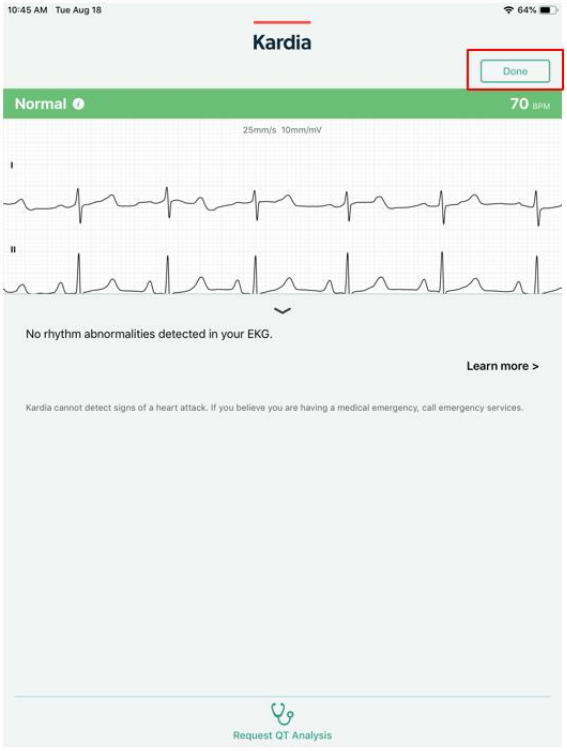
- The study nurse will enter the PID into the KardiaMobile station (single lead ECG) (AliveCor Inc) and ask the participant to place their fingers on the KardiaMobile device for 30 seconds



- Once the ECG has successfully recorded, the device indicates this, and the study nurse is able to view the ECG on the screen. The ECG is

uploaded to the central KardioPro account (AliveCor Inc) linked to the study by pressing the done button on the screen. AliveCor complies with the EU-U.S. Privacy Shield Framework and the Swiss-U.S. Privacy Shield Framework as set forth by the U.S. Department of Commerce regarding the collection, use, and retention of personal information transferred from the European Union and Switzerland to the United States pursuant to the Privacy Shield. AliveCor has certified to the Department of Commerce that it adheres to the Privacy Shield Principles. Their privacy notice can be viewed at https://www.alivecor.co.uk/privacy/en/





- In the case of suspected AF or other abnormal rhythm, the study nurse and other study team members are able to view the ECG by logging into the KardioPro account that has been assigned to the project. This allows for the team cardiologist to view any ECGs as required
- Those participants who have abnormal rhythm (AF or otherwise) will be contacted by telephone by the study team one month after they have participated to ensure that they have not been lost to follow-up. We will ask participants whether they have been prescribed of oral anticoagulants, and whether they have been referred to (and attended) a

full ECG evaluation and cardiology review [Appendix 12]. If participants have not yet received any follow up, the study nurse will write to the participant's GP informing them of this finding.

Phase 2: healthcare professionals' interview:

Data will be gathered from dental staff and students and GPs involved in the care of patients in the study via individual semi-structured qualitative telephone interviews [Appendix 13] using a University provided encrypted audio device and researchers will make field notes during and after interviews. Interviews topics will include the barriers and enablers to the screening processes in the AF detection programme, and the effects it has had on the reported practice of the healthcare professionals involved with the participant. After the telephone interview, the audio file will be securely shared with a company called 1st Class Secretarial Services https://www.1stclass.uk.com to create a typed document (transcript) of what is said.

5.1.2 Data analysis

Phase 1: patient screening:

Primary analyses will be conducted using SPSS (V26). New episodes of AF will be expressed as true positives divided by total number screened with accompanying 95% CIs. A sample size of 1000 will provide a CI of 60.8% assuming an incidence of 1.6%. χ^2 tests will be used to compare new cases by sex and to identify associations between AF incidence and age group or AF risk factors. A Pearson's or Spearman's correlation test, depending on normality of data, will be used to assess the strength and the direction of relationships between parameters. A two-sided p value of < 0.05 will be considered significant.

Cost-effectiveness

A previously tested decision-analytic Markov model[8] will be used to simulate the risk of stroke and bleeding events with standard case finding of newly identified AF (i.e. no screening/usual care) and to then assess the impact that screening with single lead ECG would have on the downstream costs and health outcomes over a 30 year time

horizon. Costs incorporated in the model will include those associated with screening, drugs to offset the risk of stroke (i.e., warfarin or NOACs), adverse events (e.g., systemic embolism, stroke) and the potential complications of warfarin and NOAC treatment (e.g., intracranial haemorrhage, clinically relevant bleed). Health-state utilities associated with pre and post treatment will be incorporated in the model to calculate QALYs. A ceiling ratio of £30,000 per QALY to delineate the cost-effectiveness of opportunistic screening will be applied.[8] Costs and benefits (QALYs) will be discounted at the NICE recommended rate of 3.5% per annum in line with the NICE reference case. Model inputs will be based on several available evidence sources including previous work in AF screening in Scotland. Extensive deterministic sensitivity analysis along with probabilistic sensitivity analysis will be undertaken to investigate model assumption and parameter uncertainty on robustness of the results.

Phase 2: healthcare professionals' interview:

All transcripts and notes from telephone interviews will be thematically analysed using the framework approach[9] following a five step process to code and categorise the data into key concepts and overarching themes. Two researchers will familiarise themselves with transcripts through reading and re-reading, and by listening to audio-recordings to check accuracy. Using NVivo 20 to organise data, they will openly record preliminary concepts and patterns for four telephone interview transcripts. After discussion between the researchers, an initial analytical framework will be established using agreed codes. Another four transcripts will be analysed before refinement and finalising of the framework to allow comparison within and across cases. A matrix will be created within NVivo 20 to map and explore connections within and between participants and categories. During interpretation, analysis will go beyond descriptions of individual cases to develop themes relevant to explore factors that might influence sustainability of screening processes beyond the study setting.

6 ADVERSE EVENTS

The study is considered to carry a low risk of potential adverse events (https://livenapierac.sharepoint.com/sites/rio/research-policy-guidelines/Research%20%20Innovation/Research%20Integirty/Adverse%20Events

%20Reporting%20SOP.pdf), but a risk assessment has been completed [Appendix 14].

There is a possibility that the participant may experience negative emotions when being told the news of suspected AF. In this instance the study nurse will arrange for the participant to be followed up by a GP/cardiology consultant.

7 OVERSIGHT ARRANGEMENTS

7.1 INSPECTION OF RECORDS (where appropriate)

Investigators will permit study monitoring and audits by Edinburgh Napier University where relevant. In the event of audit or monitoring, the principal investigator agrees to allow representatives of the University audit team direct access to all study records and source documentation.

8 ETHICAL CONSIDERATIONS and GOOD CLINICAL PRACTICE

8.1 ETHICAL CONDUCT

The study will be conducted in accordance with the principles of the International Conference on Harmonisation Tripartite Guideline for **Good Clinical Practice** (ICH GCP). Before the study can commence, all required approvals will be obtained and any conditions of approvals will be met.

8.2 INVESTIGATOR RESPONSIBILITIES

The principal investigator will be responsible for the overall conduct of the study and compliance with the protocol and any protocol amendments.

8.2.1 Informed Consent

Phase 1: patient screening and Phase 2: healthcare professionals' interview:

The principal investigator is responsible for ensuring informed consent is obtained before any protocol specific procedures are carried out. The decision of a participant to participate in research is voluntary and should be based on a clear understanding of what is involved.

The participant will be given every opportunity to clarify any points they do not understand and, if necessary, ask for more information. Details of the principal

investigator will be included in the Participant Information Sheet to facilitate this. The participant will have sufficient time to consider the information provided. Study information will emphasise that the participant may withdraw from the study at any point.

8.2.2 Confidentiality

Phase 1: patient screening:

Three copies of the consent form will be made. One will be given to the patient, one will be put in the patient's dental file, and the original will be put in the Investigator Site File, which will be stored securely in the Dental Clinical Research Facility. Participant identifiable data will be entered directly into a Microsoft excel document containing personal contact and GP details, linked to unique participant ID (PID), stored on the Edinburgh Napier University X drive by the research nurse onsite at the Dental Hospital using a secure managed University laptop. All other study data will be entered directly into an anonymised Microsoft Excel document identifiable only via the PID on the Edinburgh Napier University X drive in a folder allocated to this study. There will be no stored paper records of participant data collection forms by Edinburgh Napier University and the PID will be the only identifier entered onto the KardiaMobile system.

Access to electronic data will be limited to study research group membership, which will be set up with information services support on the University X drive. The principal investigator will decide whether users require read-only or read write access. Off-campus access will be via the Virtual Desktop System. Data will not be stored on individual computers or laptops. Any portable electronic devices (including audio recording devices) will be encrypted in line with the University data protection policy. Transfer of patient BPE rating will be by a secure data transfer protocol as outlined in a data sharing agreement that will be in place prior to the start of the study.

Phase 2: healthcare professionals' interview:

All data will be anonymized during transcription and participants will be given a study ID to ensure that they cannot be recognised. Field notes will be typed up and paper copies destroyed. All transcribed and field note documents will be stored records won the Edinburgh Napier University secure research drive (University X drive). All consent

forms will be stored electronically on the x-drive in a password protected folder that is separate to data.

Access to electronic data will be limited to study research group membership, which will be set up with information services support on the University X drive. The principal investigator will decide whether users require read-only or read write access. Off-campus access will be via the Virtual Desktop System. Data will not be stored on individual computers or laptops. Any portable electronic devices (including audio recording devices) will be encrypted in line with the University data protection policy. If any sensitive data needs to be transmitted electronically, this will be done via encrypted email.

There will be no identifiable data, therefore participants will not need to provide written permission for the release of, or access to, any confidential information. The principal investigator and study team will not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed for the purpose of the study. Participants must provide written permission for the release of, or access to, any confidential information. The principal investigator and study team will not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed for the purpose of the study.

8.2.3 Data Protection

The study protocol includes a data management plan [Appendix 15] which details the collection, transfer, storage, processing, and disclosure of personal information related to the study. The study will collect identifiable data; therefore a privacy impact assessment has been completed and approved by Edinburgh Napier University governance team, and privacy notices will be provided to participants in both elements of the study.

All investigators involved with this study will comply with the requirements of the UK-General Data Protection Regulation and Data Protection Act 2018 and will uphold the legislation's core principles. Access to collated participant data will be restricted to individuals from the research team and representatives of regulatory authorities.

Computers used to collate data will have encryption or limited access measures via usernames and passwords.

Published results will not contain any personal data that could allow identification of individual participants.

9 STUDY CONDUCT RESPONSIBILITIES

9.1 PROTOCOL AMENDMENTS

Any changes in research activity, which involve a change in the study protocol (except those required to manage an urgent safety issue), must be reviewed and approved by the principal investigator. All study amendments will be submitted to a School of Health and Social Care representative for review and authorisation before being submitted in writing to NHS REC, and NHS local R&D for approval prior to participants being enrolled into an amended protocol.

9.2 SERIOUS BREACH OF PROTOCOL REQUIREMENTS

A serious breach is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental wellbeing of the participants in the study; or

(b) the scientific value of the study.

If a potential serious breach is identified by the principal investigator or delegates, Edinburgh Napier University School of Health and Social Care must be notified within 24 hours as per Edinburgh Napier University Adverse Events Standard Operating Procedures. It is the responsibility of the School of Health and Social Care to assess the impact of the breach on the scientific value of the study, to determine whether the incident constitutes a serious breach and report to the relevant research ethics committee/s as necessary.

9.3 STUDY RECORD RETENTION

All study documentation will be kept for a minimum of 10 years from the protocol defined end of study point. Data will then be destroyed in line with Edinburgh Napier University guidance. The study co-coordinator will diarize the data destruction date.

9.4 END OF STUDY

The end of study is defined as all data collection and analysis being completed.

The investigators have the right at any time to terminate the study for administrative reasons.

9.5 INSURANCE AND INDEMNITY

Edinburgh Napier University is responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the Chief Investigator and staff.

The following arrangements are in place to fulfil the Universities responsibilities:

- The Protocol has been designed by the principal investigator and researchers employed by the University and collaborators. The University has insurance in place (which includes no-fault compensation) for negligent harm caused by poor protocol design by the principal investigator and researchers employed by the University.

10 REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

10.1 AUTHORSHIP POLICY

Ownership of the data arising from this study resides with the study team.

11 REFERENCES

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12 APPENDICES

12.1 Appendix 1: Recruitment Poster (Version 2: 20/07/2022)

FREE heart rhythm check

Does dental health affect your heart rhythm?

JOIN OUR STUDY TO HELP US FIND OUT

For more information contact
Dental Clinical Research Facility Team on level 4
nuth.newcastledcrf@nhs.net
0191 282 1170

Edinburgh Napier UNIVERSITY

NHS The Newcastle upon Tyne Hospitals NHS Foundation Trust

Newcastle University

Version 2 - IRAS ID: 311299
DETECT AF Poster Date 20/07/2022

12.2 Appendix 2: Participant invitation Phase 1 (version 3: 05/07/2022)

Dear Participant,

We are currently conducting a research study to identify undiagnosed Atrial Fibrillation in older adults attending dental clinics; **"DEnTal Examination deteCTion of Atrial Fibrillation (DETECT-AF)".**

We would like to invite you to take part because you have either responded to posters and flyers advertising the study within the dental hospital and/or you have been introduced to the study by dental hospital staff or students. Additionally, you are 65 years of age, or over, and attending an appointment at the Newcastle Dental Hospital. The study involves:

- asking you questions about your medical history
- asking your permission to access the results of your last basic periodontal (around tooth) examination completed by your dentist.
- an assessment of your heart rhythm using a handheld device for 30 seconds

Professor Lis Neubeck from Edinburgh Napier University is running the study. Taking part in the study will not take up much of your time (an additional 5 minutes to your routine appointment) and your contribution will help us to determine if there is an association between dental disease and atrial fibrillation. Before you decide to take part, it is important that you understand what the study is about, and what you will be asked to do. **Please read the participant information sheet and privacy notice**. **Participation is voluntary and if you decide not to take part, this will not affect your dental treatment.**

If you decide to take part, please complete the consent form given to you by dental hospital staff or students. The completed and signed consent form should be given to a study nurse prior to the screening assessment.

If you would like some further information before you decide whether you want to take part, please feel free to contact Professor Lis Neubeck using the details below.

Thank you for taking the time to consider our study.

Professor Lis Neubeck
Centre for Cardiovascular Health
School of Health and Social Care
EDINBURGH NAPIER UNIVERSITY
Room 4.B.28 | Sighthill Campus | Sighthill Court | Sighthill | Edinburgh | EH11 4BN
Email: l.neubeck@napier.ac.uk

12.3 Appendix 3: Participant information sheet Phase 1 version 4 (24/08/2022)

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 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 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 unique code 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 and telephone number 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 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, Edinburgh Napier University in the School of Health and Social Care email J.Hanley@napier.ac.uk

12.4 Appendix 4: Privacy Notice Phase 1 (version 2: 30/5/2022)

Name of Research Project: DEnTal Examination deteCTion of Atrial Fibrillation (DETECT-AF)

Description of Project: To explore if dental clinics offer a suitable pathway and cost-effective setting to identify previously undetected AF in adults 65 years of age and older and determine the association between the severity of dental disease and AF incidence.

Data Controller	Edinburgh Napier University
Purposes for collection/ processing	To identify the proportion of screened participants with newly identified AF in attending a dental clinic aged 65 years and older.
Legal basis	Under Article 6(1) (e), of the General Data Protection Regulation (as the legal basis for processing data), performance of a task in the public interest/exercise of official duty vested in the Controller by Statutory Instrument No. 557 (S76) of 1993 as amended, e.g., for education and research purposes. Where special category (sensitive) personal data is being processed the additional bases from Article 9 is: Art 9(2)(j) for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. We are asking questions about sex and ethnicity so that we can examine whether there are links between sex, ethnicity, periodontal health/disease status and atrial fibrillation. We are asking questions about health so that we can assess whether this type of screening is cost-effective. We will collect GP details **only** if we need to contact them to tell them about an unusual heart rhythm. All participants will be given an anonymous identification number and research data will be stored only using this number. You have been advised of your right to withdraw consent at any time and how to do this.
Whose information is being collected	Adults aged 65 year of age and over attending an appointment at the Newcastle Dental Hospital.

What type/classes/fields of information are collected	Name, date of birth, sex, ethnicity, address, postcode, telephone number, registered GP/GP surgery address, brief medical history, including medication and atrial fibrillation symptoms, basic periodontal examination score and ECG cardiac rhythm result.
Who is the information being collected from	From the data subject and NHS patient dental records.
How is the information being collected	The information is being collected verbally and in person from data subject, via a KardiaMobile handheld ECG device and from NHS patient dental records.
Is personal data shared externally	Personal data will be shared with Newcastle Dental Hospital to link study data to periodontal examination results. A data sharing agreement is in place between Newcastle Dental Hospital and Edinburgh Napier University. An anonymised version of your ECG recording will be uploaded to KardiaPro (AliveCor). Their privacy notice can be view at https://www.alivecor.co.uk/privacy/en/ If your results show an unusual heart rhythm, we will write to your GP and share a PDF of the rhythm trace with them.
How secure is the information	Personal data and KardiaMobile ECG data output result will be stored immediately upon collection with a unique identifier code on the University's secure research drive. University-managed data storage is protected against corruption. Paper-based copies of consent forms scanned, then stored on Edinburgh Napier University secure drive. Paper copies will be destroyed in confidential waste as per Edinburgh Napier University guidelines. No personal data are stored on the KardiaPro service, so your ECG cannot be identified. For services provided locally by Information Services, information is stored on servers located in secure University datacentres. These datacentres are resilient and feature access controls, environmental monitoring, backup power supplies and redundant hardware. Information on these servers is backed up regularly. The University has various data protection and information security policies and procedures to ensure that appropriate organisational and technical measures are in place to protect the privacy or your personal data. The University makes use of a number of third party, including "cloud", services for information storage and processing. Through procurement and contract management procedures the University ensures that these services have appropriate organisational and technical measures to comply with data protection legislation.

Who keeps the information updated	The researcher.
How long is the information kept for	At the end of the research data will be kept securely for ten years and then will be destroyed as per Edinburgh Napier University guidance on the safe disposal of confidential waste. All electronic files containing data will be deleted from the secure university server where the data is held. Any paper documents will be shredded as confidential waste.
Will the data be used for any automated decision making	No
Is information transferred to a third country? Outside the EEA and not included in the adequate countries list.	No
This information is provided to supplement the University's main Privacy Notices and it is recommended that appropriate notices are reviewed to provide full information about how the University processes personal data. You can access all the University's privacy notices using the following link: https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/statement.aspx You have a number of rights available to you with regards to what personal data of yours is held by the University and how it is processed – to find out more about your rights, how to make a request and who to contact if you have any further queries about Data Protection please see the information online using the following URL: https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/default.aspx	

12.5 Appendix 5: Consent form Phase 1 (Version 4: 18/08/2022)

DEnTal Examination deteCTion of Atrial Fibrillation (DETECT-AF)

To consent, mark each box with your initials and return this completed form to the study nurse.

I confirm I have read and understood the information sheet version 3 dated 05/07/2022 for the above study	
I have had the opportunity to consider the information, ask questions and had them answered satisfactorily.	
I understand that I am under no obligation to take part in this study.	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.	
I understand that once the ECG data analysis is complete, the study team will be unable to delete these data.	
I understand that personal data collected for the study will be stored y Edinburgh Napier University and anonymised data (sex, 5-year age group, race, atrial fibrillation status, periodontal health/disease status) may be shared with other researchers. Data sharing will only be conducted as per the UK Data Protection Act 2018 and UK-GDPR (General Data Protection Regulation).	
I agree to participate in this study.	
I consent to the Newcastle Dental Hospital sharing my Basic Periodontal (around tooth) Examination result with the study team.	

Once you sign the consent form a suitable member of the research team who is on the delegation log for this task and GCP trained will make two copies, one for you and one for your dental records. The original will be put in the Investigator Site File which will be stored securely in the Dental Clinic Research Facility.

Name of participant:	
Signature of participant:	
Telephone Number:	
Address	
Postcode:	
Signature of researcher:	
Date:	

Contact details of the researcher: Professor Lis Neubeck
Centre for Cardiovascular Health, School of Health and Social Care
EDINBURGH NAPIER UNIVERSITY Room 4.B.28 | Sighthill Campus | Sighthill Court | Sighthill | Edinburgh | EH11 4BN Email: l.neubeck@napier.ac.uk

12.6 Appendix 6 Participant invitation phase 2 (Version 2: 05/07/2022)

Dear Participant,

We are currently conducting a research study to identify undiagnosed Atrial Fibrillation in older adults attending dental clinics; **"DEnTal Examination deteCTion of Atrial Fibrillation (DETECT-AF)".**

We would like to invite you to take part in the study because you are a member of the Newcastle Dental Hospital staff, or a general practitioner, involved in the care of participants of the DETECT-AF study. This study involves taking part in a telephone interview with a researcher.

Professor Lis Neubeck is running the study from Edinburgh Napier University. Taking part in the study will not take up much of your time (30-40 minutes) and your contribution will help us to explore the barriers and enablers to the screening processes in the AF detection programme.

Before you decide to take part, it is important that you understand what the study is about, and what you will be asked to do. **Participation in the study is voluntary and if you decide to take part simply read the participant information sheet and privacy notice.** If you are happy to take part, complete the online consent form using this link (insert link).

If you would like some further information before you decide whether you want to take part, please feel free to contact Professor Lis Neubeck. If you decide not to take part, this will not affect your role as a dental hospital staff member or as a general practitioner.

Thank you for taking the time to consider our study.

Lis Neubeck

Professor Lis Neubeck
Centre for Cardiovascular Health
School of Health and Social Care
EDINBURGH NAPIER UNIVERSITY
Room 4.B.28 | Sighthill Campus | Sighthill Court | Sighthill | Edinburgh | EH11 4BN
Email: l.neubeck@napier.ac.uk

12.7 Appendix 7: Participant information sheet Phase 2 (Version 4: 24/08/2022)

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 setting to identify previously undetected abnormal atrial fibrillation (AF) in adults aged 65 years and older. Additionally, this study aims to determine if there is a correlation between the severity of dental disease and AF incidence and whether dental clinics offer a pathway to ensure that patients are appropriately managed following detection of AF.

Why have I been asked to take part?

We are interested in exploring factors that might influence sustainability of AF screening processes beyond the Newcastle Dental Hospital study setting. You have been asked to take part because you are a staff member of the Newcastle Dental Hospital, or a general practitioner involved in the care of participants of the DETECT-AF study conducted 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 role as a dental hospital staff member or as a general practitioner. If you decide to take part, you will be asked to complete an online consent form (insert link).

What will happen if I take part?

If you agree to participate, you will be asked to take part in a telephone interview. The telephone interview will be arranged at a convenient time for you. During the telephone interview you will be asked to share your views about the barriers and enablers to the screening processes in the AF detection programme and the effects it has had on the reported practice of the healthcare professionals involved with the participant. The telephone interview will be led by a researcher from Edinburgh Napier University and all discussions will be audio recorded on an Edinburgh Napier University encrypted audio device. The researcher will also make notes during the telephone interview. The discussion will take approximately 30-40 minutes. After the telephone interview, the audio file will be transcribed by a company called 1st Class Secretarial Services https://www.1stclass.uk.com to create a typed document (transcript) of what is said. Once the transcript has been checked for accuracy, the audio will be destroyed.

What are the possible benefits of taking part?

You may not get direct benefit from taking part in the study. However, the results will 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. Additionally, the findings will inform the design and refinement of a future intervention for large-scale research and AF screening implementation.

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 30-40 minutes of your time to take part in a telephone interview.

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 unique code so that you cannot be recognised from it. Only the research team will know which participant has been allocated which unique code.

All personal information like your name and telephone number will be stored separately to interview data securely on Edinburgh Napier University computers, which are password protected and compliant with data protection protocols. The recorded interview and transcription will be pseudonymised to further protect your privacy.

The recorded interview will be securely shared with a third party, private company called 1st Class Secretarial Services who specialise in interview transcription and are compliant with all data protection laws. This company will not have access to any of your personal data, will not know who you are, and will not be able to contact you.

The data may also be shared with other researchers who want to explore the subject area, but this will be anonymised, and you will not be identifiable from it.

How will we use information about you?

We will need to use information from you for this research project. This information will include your name and contact details (telephone number). 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. These anonymised data may be made available to 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?

Quotes from the data you have provided may be used in publications. 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 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

12.8 Appendix 8: Privacy Notice Phase 2 (Version 2: 05/07/2022)

Name of Research Project: DEnTal Examination deteCTion of Atrial Fibrillation (DETECT-AF)

Description of Project: To explore if dental clinics offer a suitable pathway and cost-effective setting to identify previously undetected AF in adults 65 years of age and older and determine the association between the severity of dental disease and AF incidence.

Data Controller	Edinburgh Napier University
Purposes for collection/ processing	To identify the views of healthcare professionals about atrial fibrillation screening in dental hospitals and the requirements for follow up pathways.
Legal basis	Under Article 6(1) (e), of the General Data Protection Regulation (as the legal basis for processing data), performance of a task in the public interest/exercise of official duty vested in the Controller by Statutory Instrument No. 557 (S76) of 1993 as amended, e.g., for education and research purposes. Where special category (sensitive) personal data is being processed the additional bases from Article 9 is: Art 9(2)(j) for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. You have been advised of your right to withdraw consent at any time and how to do this.
Whose information is being collected	Healthcare Professionals including dental staff/students working at the Newcastle Dental Hospital and involved in the care of study participants, and General Practitioners involved in the care of study participants.
What type/classes/fields of information are collected	Name and telephone number of healthcare professionals/students. Qualitative information will collect the views of healthcare professionals/students about atrial fibrillation screening in dental hospitals and follow up pathways.
Who is the information being collected from	From the data subject (directly)
How is the information being collected	The information is being collected via telephone and audio-recording of qualitative telephone interviews.

Is personal data shared with externally	An external company called 1st Class Secretarial Services will transcribe the audio-recordings. The University has a data-sharing agreement in place with this organisation to ensure that all data is kept secure. You can view their Privacy Statement here https://www.1stclass.uk.com/privacy_statement_01052018.pdf
How secure is the information	Audio data will be recorded on a University provided encrypted audio device. Transcribed data with a unique identifier code will be stored on the University's secure research drive. University-managed data storage is protected against corruption. Paper-based copies of consent forms will be destroyed in confidential waste after being scanned, then stored on Edinburgh Napier University secure drive. For services provided locally by Information Services, information is stored on servers located in secure University datacentres. These datacentres are resilient and feature access controls, environmental monitoring, backup power supplies and redundant hardware. Information on these servers is backed up regularly. The University has various data protection and information security policies and procedures to ensure that appropriate organisational and technical measures are in place to protect the privacy or your personal data. The University makes use of a number of third party, including "cloud", services for information storage and processing. Through procurement and contract management procedures the University ensures that these services have appropriate organisational and technical measures to comply with data protection legislation.
Who keeps the information updated	The researcher.
How long is the information kept for	At the end of the research data will be kept securely for ten years and then will be destroyed as per Edinburgh Napier University guidance on the safe disposal of confidential waste. All electronic files containing data will be deleted from the secure university server where the data is held. Any paper documents will be shredded as confidential waste.
Will the data be used for any automated decision making	No
Is information transferred to a third country? Outside the EEA and not included in the adequate countries list.	No

This information is provided to supplement the University's main Privacy Notices and it is recommended that appropriate notices are reviewed to provide full information about how the University processes personal data.
You can access all the University's privacy notices using the following link:
https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/statement.aspx
You have a number of rights available to you with regards to what personal data of yours is held by the University and how it is processed – to find out more about your rights, how to make a request and who to contact if you have any further queries about Data Protection please see the information online using the following URL:
https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/default.aspx

12.9 Appendix 9: Consent Form Phase 2 (Version 4: 18/08/2022)

DEnTal Examination deTeCtion of Atrial Fibrillation (DETECT-AF)

To consent, mark each box with your initials and return this completed form to the study nurse.

I confirm I have read and understood the information sheet version 3 dated 05/07/2022 for the above study.	
I have had the opportunity to consider the information, ask questions and had them answered satisfactorily.	
I understand that I am under no obligation to take part in this study.	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.	
I understand that once the data analysis is complete, the study team will be unable to delete these data.	
I understand that data collected for the study may be shared with other researchers (on an anonymous basis). Data sharing will only be conducted as per the UK Data Protection Act 2018 and UK-GDPR (General Data Protection Regulation).	
I agree to participate in this study.	
I consent to taking part in the recorded telephone interview.	

Once you sign and return the consent form, a suitable member of the research team who is on the delegation log for this task and GCP trained will make a copy of your consent form and return this to you. The original will be put in the Investigator Site File which will be stored securely in the Dental Clinic Research Facility.

Name of participant:	
Signature of participant:	
Date	
Name of Researcher	
Signature of researcher	
Date	

Press submit to register for the study

Contact details of the researcher: Professor Lis Neubeck
Centre for Cardiovascular Health, School of Health and Social Care

EDINBURGH NAPIER UNIVERSITY
Room 4.B.28 | Sighthill Campus | Sighthill Court | Sighthill | Edinburgh | EH11 4BN
Email: l.neubeck@napier.ac.uk

12.10 Appendix 10: Participant debrief sheet (Version 2: 25/1/2022)

Please take time to read the following information, which explains the study that you have participated in. Please contact me if there is anything that is not clear or if you would like more information.

What was 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.

What will happen to the information that I have provided?
The results of the study may be published in healthcare journals and presented at conferences. Anonymised data may also be shared with other researchers for future analysis. 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.

Will I receive any individual feedback?
You will not normally receive any individual feedback.

How will I find out about the results?
A summary of the results will be available from the researcher (Lis Neubeck). If you would like to receive a copy of this summary via email, please email l.neubeck@napier.ac.uk and we will send you a summary once the research has been completed.

Have I been deceived in any way during the study?
No, you have not been deceived in any way during the study.

If I change my mind and wish to withdraw the information I have provided, how do I do this?
You are free to withdraw from the study at any time up until the point that your data has been analysed. This means that once your data has been analysed you are unable to withdraw the information that you have provided. To withdraw, please email l.neubeck@napier.ac.uk .

If you have further questions about the study, please contact:
Lis Neubeck email l.neubeck@napier.ac.uk

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

12.11 Appendix 11: Patient Screening Document Phase 1 (Version 3:16/8/2022)

Participant ID:	
Name	
Address	
Postcode (IMD):	
Date of Birth:	
Telephone Number:	
Registered GP:	
GP surgery address:	

What sex where you assigned at birth?

Male	
Female	

What age are you? ☐

What race/ethnic group do you consider yourself?

White British	
White Other	
Black Caribbean/Black Caribbean British	
Black African/Black African British	
Indian/Indian British	
Pakistani/Pakistani British	
Bangladeshi/Bangladeshi British	
Chinese/Chines British	
Filipino/Filipino British	
Maghreb / Middle Eastern	
Mixed Ethnicity	
Other (please specify)	

Do you have / a history of any of the following?

Heart Failure	
Hypertension (high blood pressure)	
Stroke/TIA/thromboembolism	
Vascular disease (prior MI, peripheral artery disease or aortic plaque)	
Diabetes	
Atrial fibrillation	

Are you taking any of the medication below?

Warfarin	
Dabigatran	
Rivaroxaban	
Edoxaban	
Apixaban	
Beta-blocker (ends in lol)	
Verapamil	
Diltiazem	
Amiodarone	
Flecainide	
Propafenone	
Digoxin	
Other (please specify)	

Do you have any of the following symptoms?

Heart palpitations	
Chest pain	
Dizziness	
Fatigue	
Light-headedness	
Shortness of breath	
Reduced ability to exercise	
None	

KardioMobile ECG Screening	**Screening Result**
Sinus rhythm	
AF not suspected by abnormal rhythm	
AF suspected	
AF known prior to screening	

Basic Periodontal Examination			**Result**		
Upper right	Upper anterior	Upper left			
Lower right	Lower anterior	Lower left			

12.12 Appendix 12: Follow up telephone screening (Version 2: 25/1/2022)

Participant ID:	

Since your screening have you been referred for a cardiology appointment?

Yes	
No	
Don't know	

If you were referred, have you attended your cardiology appointment?

Yes	
No	
Don't know	
Date in the future	

Have you had a 12 lead ECG since your screening?

Yes	
No	
Don't know	

Have you been prescribed any of the following medication since your screening?

Warfarin	
Dabigatran	
Rivaroxaban	
Edoxaban	
Apixaban	
Beta-blocker (ends in lol)	
Verapamil	
Diltiazem	
Amiodarone	
Flecainide	
Propafenone	
Digoxin	
Other (please specify)	

Have you been told you need?

Cardioversion	
Ablation	

12.13 Appendix 13: Telephone interview schedule Phase 2 (Version 2: 25/1/2022)

*Interview schedule – **Gain verbal consent at start of interview***

To explore the views of healthcare professionals (periodontal dentists, nurses and students, and GP involved in the study) **Initial information collected: profession, sex, length of time in profession.**	
Question	**Prompts**
1. Tell me about your experience of being involved in the Detect AF study	Warm up question – interviewer to give a brief description of the study if the participant is not clear, including the patient screening process and onward referral pathways. *Hospital staff:* How did you tell patients about the study? How keen were patients to participate? Why was this? What could be done better to engage more patients? *GPs:* How many letters did you receive about a patient with AF or an abnormal rhythm because of the study? What did you do when you received a letter about a patient from the study? What could be done to improve the information that your received about your patient (described if not used)?
2. What do think about the idea of opportunistically screening for AF during periodontal hospital appointments on a routine basis?	*Hospital staff:* How might AF screening be integrated into the appointment itself? Why is AF screening appropriate in this patient group? *GPs:* How do you feel about AF screening taking place in locations other than general practice? What effect do you think that this would have on your workload?
3. What do you think would facilitate the implementation of opportunistic single lead ECG/six lead screening for AF patients over ≥ 65 years in dental hospitals?	*Dental staff* What support tools would need to be in place to remind about screening What support would be needed to aid diagnosis?

	What would improve your confidence to implement an AF screening programme in periodontal appointments? Who would be responsible for screening? *GPs* How would you manage communication between the GP surgery and the hospital if screening was to be implemented in dental hospitals? How confident would you feel about a diagnosis given via this route?
4. What do you think are the barriers for implementing opportunistic single lead ECG/six lead AF screening for patients over ≥ 65 years in dental hospitals?	*Dental staff and GPs* How much time would screening take? What about funding? Which patients would be more likely to take part?
5. What would be the ideal onward referral pathway for: **a) A patient diagnosed with suspected AF during a periodontal appointment.** **b) A patient diagnosed with another abnormal ECG trace during a periodontal appointment.**	
6. Is there anything else about the potential for AF screening at hospital periodontal appointments that you wish to share before we finish?	

12.14 Appendix 14: Risk assessment (version 1: 20/12/2021)

Edinburgh Napier University
RISK ASSESSMENT FORM

SCHOOL/SERVICE: School of Health and Social Care	LOCATION: Sighthill	DATE: 21/12/2021

Description of event/activity: Cross-sectional and qualitative study.

No.	Hazards identified	People at risk from hazards	Existing control	Risk H	Risk M	Risk L	Further action / recommendations	Action by whom	Action by when	Completed
1	Risk Physical threat or abuse	Researcher	Patient research will take place in hospital environment so existing hospital operating procedures will be adhered to. Healthcare professional research is by telephone.			X	Planning research to minimise risks Effective means of communication If deemed high risk researcher must not work alone Dress appropriately Emergency plan in place Staff training in confrontation etc.	N/A		
2	Risk of physiological trauma	Researcher	Patient research will take place in hospital environment so existing hospital operating procedures will be adhered to. Healthcare professional			**X**	Planning research to minimise risks Effective means of communication University support mechanisms Use of consent forms Staff training etc.	**N/A**		

No.	Hazards identified	People at risk from hazards	Existing control	Risk			Further action / recommendations	Action by whom	Action by when	Completed
				H	M	L				
			research is by telephone.							
3	Driving	Researcher	Researchers may drive personal vehicle to the hospital or take public transport.			**X**	Compliance with road traffic legislation Adequate insurance for car business use – to be checked by PI	**N/A**		
	***Lone Working*-** **Miscellaneous Hazards** **Difficulties in summoning help when required**; risk of abuse/attack	Researcher	Patient research will take place in hospital environment so existing hospital operating procedures will be adhered to. Healthcare professional research is by telephone.			**X**	• Where possible carry a mobile phone. • Leave details of the field site and a work plan (include contact name and address) with colleagues in the department or at home prior to any trip. • Specify dates and times of departure and return. If your plans change, inform someone as soon as possible. • Do not carry valuables or large sums of money unless you need to. • Carry a personal alarm (This advice is directed to males as well as females - all are equally vulnerable when alone!) • Instigate a "check-in" system with a colleague or supervisor - Phone in at regular intervals. If you do not phone or return at a certain time arrange for suitable action to be taken.	**N/A**		

No.	Hazards identified	People at risk from hazards	Existing control	Risk			Further action / recommendations	Action by whom	Action by when	Completed
				H	M	L				
							• Trust your intuition - If you feel scared or uneasy, do not ignore it.			
	***Lone Working*-Travelling alone** **On foot** - risks of personal attack/abuse	Researcher	Researcher may travel alone by public transport and may walk between public transport stop and hospital			**X**	• Whenever possible avoid walking alone at night. • Keep to busy, well lit roads. • Avoid poorly lit or rarely used underpasses. • Walk facing on-coming traffic to avoid kerb-crawlers. • Do not use a personal stereo - you will be unable to hear anyone approaching from behind. • Plan your journey in advance - tell someone which route you mean to take and estimated time of arrival at your destination. • Walk with confidence and purpose - try not to look as if you are not sure of where you are going. • Make sure wallets, cameras, jewellery and expensive watches and other valuables are not on display. • Dress appropriately - try to fit in without attracting attention.	**N/A**		
	***Lone Working*-Travelling alone** **By Car**		Researchers may drive personal vehicle to the hospital or take public transport.			**x**	• Make sure the vehicle is in good working order before setting off. • Make sure you have change for a telephone in an emergency. • Plan your journey in advance - tell someone which route you	**N/A**		

No.	Hazards identified	People at risk from hazards	Existing control	Risk			Further action / recommendations	Action by whom	Action by when	Completed
				H	M	L				
							mean to take and estimated time of arrival at your destination. • Do not leave valuables visible in the car - even when you are in it. Keep bags etc. out of reach of open windows. • When parking in daylight, consider what the area will be like after dark. • When returning to the vehicle, quickly look around it to make sure there is no one waiting for you. • If you are forced to stop by another car, stay in the car, lock the doors and speak through a slightly open window. • Make sure you know what to do if the car breaks down. (i.e. who to phone; where to phone from etc.)			
	***Lone Working*-** **Staying in Hotels**		There is no overnight stays involved in this study			**x**		**N/A**		
	Other people's homes Risk of personal attack/abuse	•	No homes will be visited during this study			**x**		**N/A**		
	Aggressive Behaviour	•	Patient research will take place in hospital environment so existing hospital operating			**x**	• Do not underestimate the importance of body language. • Talk yourself out of problems; placate rather than provoke.	**N/A**		

No.	Hazards identified	People at risk from hazards	Existing control	Risk H	Risk M	Risk L	Further action / recommendations	Action by whom	Action by when	Completed
			procedures will be adhered to. Healthcare professional research is by telephone.				• Do not turn your back on someone who is behaving aggressively. • Stay Calm, speak gently and slowly. • Do not be enticed into an argument. • Avoid an aggressive stance. Crossed arms, hands on hips or raised hands will challenge and confront. • Keep your distance. • Never try to touch someone who is angry -this will not calm the situation. • Keep your eye on potential escape routes			
	Physical attack		Patient research will take place in hospital environment so existing hospital operating procedures will be adhered to. Healthcare professional research is by telephone.			**x**	• Try to get away as quickly as possible. Move towards a place where you know there will be other people. • Carry a personal alarm - set it off as close to the aggressor's ear as possible and then throw it out of reach. • Shout and scream - shout something practical like "call the police!" or "Fire!" - people rarely react to cries of "help!" or "rape!" • If grabbed and unable to break free - pretend to vomit. This will often have the desired effect!	**N/A**		

No.	Hazards identified	People at risk from hazards	Existing control	Risk			Further action / recommendations	Action by whom	Action by when	Completed
				H	M	L				
	Dealing with people		Patient research will take place in hospital environment so existing hospital operating procedures will be adhered to. Healthcare professional research is by telephone.			**x**	• Seek training in good interview techniques. • Where possible "vet" interviewees first over the phone. • Conduct interviews at neutral locations or public spaces or where neither party could be at risk. • Where possible conduct any interviews with an observer. • Seek advice and support from local groups. • Do not wear clothes that might cause offence. • Always carry your ID card and be prepared to identify yourself. • Consider your dress carefully - is it suitable for the location.	**N/A**		

Review Date:	**22/12/2021**	**Signature:**	**Coral Hanson**	**Job Title:**	**Research Fellow**

12.15 Appendix 15: Data management plan (Version 2: 05/07/22)

0. Proposal name

DEnTal Examination deteCTion of Atrial Fibrillation (DETECT-AF)

1. Description of the data

1.1 Type of study

1. Phase 1 includes a cross-sectional study of screening in dental clinics to identify undiagnosed AF in adults aged 65 years and over.
2. Phase 2 includes a qualitative study of healthcare professionals involved in the care of phase 1 study participants to explore factors that might influence sustainability of screening processes beyond the study setting.

1.2 Types of data

The study involves two phases.

Phase one will include primary quantitative data collected verbally from the subject comprised of medical history including pharmacotherapy and AF symptoms, date of birth, sex, ethnicity, address, postcode, telephone number and registered GP/GP surgery address and ECG cardiac rhythm using KardiaMobile ECG device. Additionally, a basic periodontal examination result will be collected from the patients NHS dental records via agreed NHS gatekeepers.

Phase two will include primary qualitative data collected via audio-recorded telephone semi-structured interviews of healthcare professionals involved in the care of study participants recruited in phase one. Topics will include experiences of the study, barriers and facilitators to AF screening in dental hospitals and views about follow up pathways.

1.3 Format and scale of the data

Phase one: Quantitative tabular data will be stored with metadata (variable labels, code labels, defined missing values and matrix of data) in SPSS (.sav) and excel (.xls) format.

Phase two: Qualitative data comprised of MS Word (.doc) transcripts will be stored in NVIVO (.nvp) format and audio files in MP3 or WAV format. Files will be converted to open file formats where possible for long term storage. It is not expected that data the project will require data storage of more than 10GB.

2. Data collection / generation

Phase one: Quantitative data collected from 1000 participants will provide data about proportion of screened participants with newly identified AF attending a dental clinic aged 65 years and older. Also, associations between stage of dental disease stage, age, sex, ethnicity, Index of Multiple Deprivation, and incidence of AF, and finally suitability and cost effectiveness of AF screening in a dental setting.

Phase 2: Qualitative data will be collected via telephone in audio-recorded semi-structured interviews with healthcare professionals (n=20) will

2.1 Data collection

The following methods will be used to collect data:

Phase one: a face-to-face screening interview to verbally collect personal data from the subject and the use of KardiaMobile ECG devices to collect ECG cardiac rhythm result. Additionally, periodontal examination results will be collected from NHS dental records via agreed NHS gatekeepers.

Phase two: primary qualitative data will be collected via telephone interview using an encrypted audio device.

2.2 Data quality and standards

Phase one: In order to be absolutely clear about the meaning of the data, the data set will have an overview document attached to it, covering the details that will facilitate their use by researchers.
Phase two: Interviews will be audio recorded on an Edinburgh Napier University encrypted device and transcribed with intelligent verbatim.

3. Data management, documentation and curation

Managing, storing and curating data.

3.1 Managing, storing and curating data.

Research data will be stored on the University's X drive. The University-managed data storage is resilient, with multiple copies stored in more than one physical location and protection against corruption. Daily backups are kept for 14 days and monthly backups for an additional year.

There will be no hard copies of data.

3.2 Metadata standards and data documentation

All research data will be organized as per the Universities metadata standards http://staff.napier.ac.uk/services/research-innovation-office/research-data/Pages/Organising.aspx

3.3 Data preservation strategy and standards

As per the Edinburgh Napier University Data Management Policy, research data will be retained after project completion if they substantiate research findings, are of potential long-term value or support a patent for at least 10 years. Long-term storage will be provided through the University data repository.

4. Data security and confidentiality of potentially disclosive information

4.1 Formal information/data security standards

4.2 Main risks to data security

Access to electronic data will be limited to study research group membership, which will be set up with information services support on the University X drive. The principal investigator will decide whether users require read-only or read write access. Off-campus access will be via University managed laptops. Data will not be stored on individual computers or laptops. Any portable electronic devices will be encrypted in

line with the university data protection policy. If any sensitive data needs to be transmitted electronically, this will be done via encrypted email.

5. Data sharing and access

5.1 Suitability for sharing

Data generated by the project will be made open after completion of the project after ensuring that there are no identifying details 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/for-organisations/documents/1061/anonymisation-code.pdf

5.2 Discovery by potential users of the research data

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 within six months following the first publication of findings based on the data.

5.3 Governance of access

The PI will make the decision about whether to supply research data to a potential new user. Before data is shared, a data-sharing agreement will be issued and signed by appropriate authorities as described in section 5.6.

5.4 The study team's exclusive use of the data

Data will be made available six months following the first publication of findings based on the data.

5.5 Restrictions or delays to sharing, with planned actions to limit such restrictions

Consent procedures will include provision for data sharing, while providing adequate safeguards for participants. Current and potential future associated risks will be clearly explained. Care will be taken to ensure that all data is anonymised or aggregated prior to sharing.

5.6 Regulation of responsibilities of users

External users will be bound by a data-sharing agreement that will prohibit any attempt to (a) identify study participants form the released data or otherwise breach confidentiality (b) make unapproved contact with any study participants. MRC Policy and Guidance on Sharing of Research Data from Population and Patient Studies will be adhered to: https://www.mrc.ac.uk/publications/browse/mrc-policy-and-guidance-on-sharing-of-research-data-from-population-and-patient-studies/

6. Responsibilities

The first point of contact for all queries in relation to these data is the principal investigator (Professor Lis Neubeck), who will also have overall responsibility for the larger project which this study forms part of. Preparation and upload of the data will be carried out by the team with the support of the University's Information Services staff.

7. Relevant institutional, departmental or study policies on data sharing and data security

Please complete, where such policies are (i) relevant to your study, and (ii) are in the public domain, e.g. accessible through the internet.

Add any others that are relevant

Policy	URL or Reference
Data Management Policy & Procedures	*http://staff.napier.ac.uk/services/research-innovation-office/Documents/Research%20Data%20Management%20Policy.pdf*
Data Security Policy	*http://staff.napier.ac.uk/services/cit/infosecurity/Pages/InformationSecurityPolicy.aspx*
Data Sharing Policy	*http://staff.napier.ac.uk/services/secretary/governance/DataProtection/Pages/DataSharing.aspx*
Institutional Information Policy	*http://staff.napier.ac.uk/services/research-innovation-office/Documents/Research%20Data%20Management%20Policy.pdf*
Other:	
Other	
8. Author of this Data Management Plan (Name) and, if different to that of the Principal Investigator, their **telephone & email contact details**	
Coral Hanson c.hanson@napier.ac.uk telephone: 0790 8861666	

12.16 Appendix 16: Participant: no further investigation letter (Version 1: 25/1/2022)

Dear Participant,

Following your participation in our research study to identify undiagnosed Atrial Fibrillation in older adults attending dental clinics; **"DEnTal Examination deTeCtion of Atrial Fibrillation (DETECT-AF)"** on (date to be added). I write to confirm that no further investigation is required.

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.

Thank you for taking the time to consider our study.

Professor Lis Neubeck
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School of Health and Social Care
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