

BMJ Open Atrial fibrillation (AF) pilot screening programme in primary care in Ireland: an implementation study protocol

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ABSTRACT

Introduction Atrial fibrillation (AF) is a major risk factor for stroke. There is a fivefold increase in stroke risk in the presence of AF. The irregular beating of the heart enables blood stasis which allows clots to form. These can migrate to the brain causing a stroke. AF is common and its incidence increases with age. AF is often asymptomatic and early detection enables effective preventive treatment reducing stroke risk by up to two-thirds.

Stroke contributes significantly to morbidity and mortality globally. In Ireland, it is the leading cause of acquired disability and second leading cause of death. The cost associated with stroke is significant. Stroke risk increases with age and is a public health priority.

Internationally, there is consensus among experts that AF screening is valuable. In Ireland, the National Cardiovascular Policy recommended establishing a screening programme. However, there are many ways to screen for AF including pulse palpation, mobile ECG devices, 12-lead ECG and personal health monitoring devices.

This study aims to investigate the acceptability, feasibility and impact of AF screening in primary care using a handheld mobile ECG device.

Methods and analysis General practitioners (GPs) and practice nurses in the South of Ireland will opportunistically screen patients aged ≥65 years for AF at routine consultation using a handheld one-lead ECG device, KardiaMobile. This study will screen up to 4000 patients. Blood pressure and smoking status will be checked concurrently. A mixed-method evaluation will be undertaken including a partial economic evaluation. Anonymised data will be collected from participating practices and qualitative interviews will be conducted with GP, nurse and patient participants.

Ethics and dissemination Ethical approval has been granted by the Clinical Research Ethics Committee in University College Cork. Dissemination will involve publication in peer-reviewed journals and presentation at national and international conferences.

INTRODUCTION

Atrial fibrillation (AF), a cardiac arrhythmia, is a major risk factor for stroke.¹ AF is defined as a supraventricular tachyarrhythmia with uncoordinated atrial electrical activation resulting in ineffective atrial contraction.²

Strengths and limitations of this study

- This mixed-methods study will comprehensively assess the use of a mobile device for atrial fibrillation (AF) screening in primary care.
- The study spans the COVID-19 global pandemic making initial recruitment difficult and pausing the study temporarily.
- The study is being carried out in a defined geographical location in the South of Ireland and, thus, generalisation to the entire population may be limited.
- The results can be used to inform future AF screening policies.

AF is the most common cardiac arrhythmia globally. It affects a substantial proportion of the population, approximately 33.5 million people worldwide.³ AF affects approximately 11% of adults aged ≥65 years in Ireland.⁴ The condition is more common in males and the risk of developing AF increases significantly with age. By the age of 55 years the lifetime risk of AF is 37%.⁵ It is a condition that is often asymptomatic and is frequently diagnosed when a patient presents with a stroke.⁶ AF is estimated to be responsible for approximately 20%–30% of ischaemic strokes and 10% of haemorrhagic strokes.² Early diagnosis of AF allows effective preventive treatment to be offered, thereby reducing AF stroke risk by up to two-thirds.^{7,8}

There is a fivefold increase in stroke risk in the presence of AF.¹ Stroke is a major global public health issue that has a significant impact on morbidity and mortality. It remains one of the leading causes of death globally responsible for approximately 5.5 million deaths worldwide annually.⁹ Stroke is the second biggest contributor to disability-adjusted life-years globally.¹⁰ In Ireland, it is the leading cause of acquired disability¹¹ and the second leading cause of death¹² imposing a significant burden on the healthcare system. It is estimated there are approximately 30 000

individuals in Ireland living with disabilities due to stroke in the community.¹¹ The cost of stroke to both the individual and to the economy is significant and a report in 2010 estimated the cost to the Irish economy to be in the region of €557million annually.¹³

Stroke risk increases with age and with an ageing population, stroke prevention is a key priority.¹⁴ Stroke caused by AF is preventable in approximately 64% of cases with appropriate oral anticoagulant (OAC) therapy, which can reduce AF-related stroke risk.⁷ Opportunistic screening increases detection, yet 37% of the Irish population with AF remain undetected prestroke.^{15,16} Patients with AF may be managed in different ways according to their medical condition. The range of treatment options include oral anticoagulation, cardioversion, cardio-ablation and lifestyle changes such as increasing physical activity, weight loss, consuming a healthy well-balanced diet and smoking cessation.^{2,16} Keele University in the UK, in conjunction with the National Institute for Health and Care Excellence (NICE), have developed a decision support tool for healthcare professionals to aid appropriate prescribing of oral anticoagulation therapy to patients with AF to prevent stroke. The tool uses a combination of guidelines, CHA₂DS₂-VASc score (Congestive heart failure, Hypertension, Age ≥75 years, Diabetes mellitus, Stroke, Vascular disease, Age 65-74, Sex Category (female)), to assess stroke risk and HAS-BLED score (Hypertension, Abnormal renal and liver function, Stroke, Bleeding, Labile INR's, Elderly, Drugs and alcohol), to assess bleeding risk for patients commencing on or currently being treated with oral anticoagulation as recommended by NICE¹⁷ (figure 1).

There are a number of ways to detect AF including pulse palpation, mobile ECG devices and 12-lead ECG and a range of personal health monitoring devices.¹⁸ One-lead mobile ECG devices have been found to be

more accurate than pulse palpation in detecting AF.¹⁹ This technology has been found to be effective in similar studies in other locations such as rural Australia.^{20,21} AF-SCREEN, an international collaboration of clinicians, allied healthcare professionals, public health specialists and health economists concluded in a White Paper on AF screening that mobile ECG devices provide the preferred screening tool.²² Current ESC guidelines recommend a 12-lead ECG to establish a diagnosis of AF.²

AF screening meets many of the Wilson Jungner Criteria for screening. AF is an important health problem, there is acceptable treatment and facilities for diagnosis available and a suitable test which is acceptable to the population exists.²³

AF screening is now recommended by international expert consensus and clinical practice guidelines.^{2,22,24} However, the optimal mode, location and target population for AF screening remains the topic of discussion. AF-SCREEN concluded that AF screening is valuable but needs to be relevant for the particular healthcare system and adopt a pathway for appropriate diagnosis and management of the condition.²² In Ireland, the National Cardiovascular Health Policy 2010 recommended that a screening programme for AF be established for people aged ≥65 years.²⁵ In response to this recommendation, a national Health Technology Assessment (HTA) was undertaken and published in 2015. This HTA concluded that annual opportunistic pulse palpation for those aged ≥65 years would be expected to lead to reductions in the incidence and severity of AF-related strokes.^{26,27} The report estimates a 1.9% reduction in the incidence of first-ever stroke in the first 5 years.²⁶ AF screening has been found to be more cost-effective than routine practice in the ≥65 age category.² AF SCREEN recommend that the ideal target population for AF screening is individuals

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Keele University

Decision Support
Anticoagulation therapy for the prevention of stroke and systemic embolism in atrial fibrillation.

Patient Profile

Do you wish to store patient details? YES NO

Date of Birth DD MM YYYY

First Name Gender MALE FEMALE

Last Name Weight Select

Patient ID

Suspected or diagnosed non-valvular atrial fibrillation? YES NO

Proceed

Last updated on 23rd November 2017. Version 1.1.0.
Developed as part of a joint working group initiative comprising the National Institute for Health and Care Excellence (NICE), Boehringer Ingelheim Ltd and
anticoagulation-dst.co.uk/home on Support Ltd at the Centre for Medicines Optimisation, Keele University.

Boehringer Ingelheim

Figure 1 Screenshot showing patient profile of Keele University decision support tool.

aged ≥ 65 years and primary care or community setting is recommended as the most appropriate setting.²²

In 2019, the Chronic Disease Management (CDM) Programme in Ireland was established to include re-imbursement for general practitioners (GPs) who undertake opportunistic case finding for AF in the community. Partial implementation of this commenced in January 2020 and will be implemented over a 4-year period.^{28 29} This CDM programme currently includes patients aged ≥ 75 years who have cover under the publicly funded national health insurance scheme. It has not been executed in full to date, is extended only to those aged ≥ 75 years who are covered under the scheme. The mode of detection in this programme is pulse palpation. The publicly funded national health insurance scheme covers approximately 80% of the population aged ≥ 70 years, the CDM programme currently covers those aged ≥ 75 years and will be extended to those aged ≥ 70 years over the 4-year period.²⁸

A feasibility study of opportunistic AF screening in primary care via pulse palpation was previously undertaken in a rural population in the West of Ireland.⁴ The study concluded that opportunistic pulse palpation in a rural population is effective in identifying new cases of previously undetected AF.⁴ This study was conducted before the launch of the one-lead ECG devices. The current project being conducted in the South of Ireland will build on previous knowledge to assess the implementation of an AF screening pilot comprising AF screening using a mobile one-lead ECG device, KardiaMobile. The study aims to investigate the yield, acceptability and feasibility of AF screening in primary care using a mobile one-lead ECG device, Kardia (figure 2).

METHODS AND ANALYSIS

This observational study is a mixed-methods study involving opportunistic recruitment of patients via GPs and practice nurses recruited to a pilot AF screening programme. The study will report the outcomes of AF screening in the primary care setting including yield, feasibility and acceptability. This study is being carried out in primary care at the practices of the participating

GPs. It involves opportunistic AF screening using a mobile one-lead ECG device, KardiaMobile, along with blood pressure monitoring and assessment of smoking status. The study aims to investigate if AF screening in primary care in Ireland using the KardiaMobile device is feasible and acceptable. This will be reflected by the experience of the participants (screeners and patients and health-care system) and the acceptability will be reflected by the numbers who attend for screening and their experience.

The target population for the initiative is 4000 patients aged ≥ 65 years residing in a defined geographical area, that is, the counties of Cork and Kerry in the South of Ireland. The initial target population was a defined area in the northside of Cork city which was subsequently extended to Cork and Kerry to increase participation. The total population for this area, Cork and Kerry, is approximately 773 000 with approximately 107 000 in the ≥ 65 years old category.^{30–32}

Recruitment

General practitioners

At the time of writing, May 2021, approximately 70 GPs from practices across the Cork and Kerry region in the South of Ireland have been recruited to participate in the study. The target population at the start of the study in January 2020 was the northside of Cork city, but due to the COVID-19 global pandemic recruitment to the study was low and the target population was expanded to include the entire counties of Cork and Kerry to maximise participation rates. A list of GPs from the relevant geographical area was obtained from the Health Service Executive (HSE), Ireland's national body for the provision of health services and all practising GPs in the relevant geographical area were invited to participate in the study. An invitation letter followed by a webinar invited all practising GPs from the Cork and Kerry region to participate in the study. The first invitation was sent to 50 GPs in the northside of Cork city in January 2020 and was subsequently extended to 370 GPs across the Cork/Kerry region who were invited to participate in March 2021. Participating GPs invite all eligible patients aged ≥ 65 years, who are attending for a routine appointment to also undergo an AF screening consultation. Examples of routine visits include the



Figure 2 Picture of Kardia device with ECG reading display.

annual influenza vaccine, COVID-19 vaccine, medication review, chronic disease review, blood tests, etc (this list is not exhaustive). Participating GPs are reimbursed and will be paid a one-off fee for each patient who partakes in the screening. The fee is to cover the cost of the visit and associated costs including completing the relevant study documentation and patient follow-up.

Participating GPs are required to sign an agreement, memorandum of understanding (online supplemental file 1), with regard to the collection and handling of patient data pertaining to the study consistent with current data protection legislation.³³

Patients

Patients are being recruited into the study by their GP or practice nurse when they attend as outlined above. The patients are provided with an invitation letter and a participant information leaflet (online supplemental file 2) outlining the study procedures. Consenting patients are invited to attend for an AF screening consultation with their GP at their convenience. Patients sign a consent form (online supplemental file 2) before screening can commence.

Patient eligibility

All patients aged ≥ 65 years who present to any of the participating practices are eligible for participation in the study unless they have a current recorded diagnosis of AF, decline to participate or are unable or unwilling to provide informed consent.

Sample size

A total of 420 GPs were invited to participate in the study, with an aim of recruiting approximately 70 GPs in total recruited to participate in the screening. It is anticipated that each participating GP will invite an average of 60 patients (8000 patients in all) and that up to 50% of those invited will partake in the study (4000 participant patients).

Preintervention: study information evening and training

All participating GPs in the North Lee area of Cork city were invited to an information evening on the study by the study team in January 2020. The GPs were provided with a KardiaMobile device and trained in its use. A step-by-step demonstration on downloading the Kardia app and use of the device was provided. The GPs were also provided with the necessary documentation required to participate in the study including the study proposal (an earlier version of the study protocol), the standard operating procedure (online supplemental file 3), the memorandum of understanding (MoU) (online supplemental file 1), the clinical report form (online supplemental file 4), the patient invitation letter and consent form (online supplemental file 2). All GPs who agreed to participate provided a completed MoU and a copy of their medical indemnity. Due to the COVID-19 global pandemic, the start date of the study was paused for some months while contingencies were put in place. As a result, all the study

documentation was revised and contingencies around COVID-19 were included. A follow-up webinar, at which the changes to the study procedures were highlighted, was conducted in March 2021 with participating GPs and the newly recruited GPs from the wider Cork and Kerry area.

Screening intervention protocol

Screening will be conducted at participating practices until the target of 4000 patients screened has been reached. A review of recruitment is taking place monthly. Staff, including GPs or practice nurses in each participating practice identify eligible patients when they attend for annual influenza vaccine, COVID-19 vaccine, medication review, chronic disease review, blood test or other consultation. At the AF screening consultation, participants are screened for AF using a hand-held one-lead ECG device (KardiaMobile). The device provides three potential outcomes once the reading is complete: 'possible AF', 'normal' and 'unclassified'. Patients in whom AF is suspected, 'possible AF' on Kardia device, undergo a 12-lead ECG, at the practice. Optimal oral anticoagulation is complex in older patients with multimorbidity and polypharmacy. Patients with newly diagnosed AF are assessed for suitability to commence anticoagulant medication as per current National Institute for Health and Care Excellence (NICE) guidelines³³ using the Keele University decision support tool.¹⁷ The Keele University decision support tool was developed in conjunction with NICE to support healthcare professionals in providing anticoagulation treatment recommendations for patients with AF to reduce stroke risk and to support communication and shared decision-making with patients. The tool uses a combination of the NICE recommended guidelines for stroke risk in AF, CHA₂DS₂-VASc score and HAS-BLED score to assess bleeding risk for patients commencing on or currently being treated with oral anticoagulation.¹⁷ Patients with newly diagnosed AF are provided with an information booklet, 'Live Well with Atrial Fibrillation', supplied by the Irish Heart Foundation.³⁴ Patient treatment and follow-up is at the discretion of the GP. Patients commenced on any treatment (anticoagulants, antihypertensives or smoking cessation) will have any required follow-up blood work and any further monitoring of their condition(s) per current guidelines and usual practice. All newly diagnosed cases of AF are referred for an ECG. Patients may also be referred to a cardiologist if deemed necessary by their GP. Patients identified as having an 'unclassified' diagnosis via the KardiaMobile ECG test have a 12-lead ECG to further investigate. These patients are also followed up at the discretion of their GP. Patients who receive a 'normal' reading via the Kardia device are not required to have any further follow-up as part of the study (figure 3). The one-lead ECGs will be interpreted by the GPs which in the context of the study the device is being used as a screening tool and not a diagnostic tool. GPs in Ireland are specialist physicians whose training

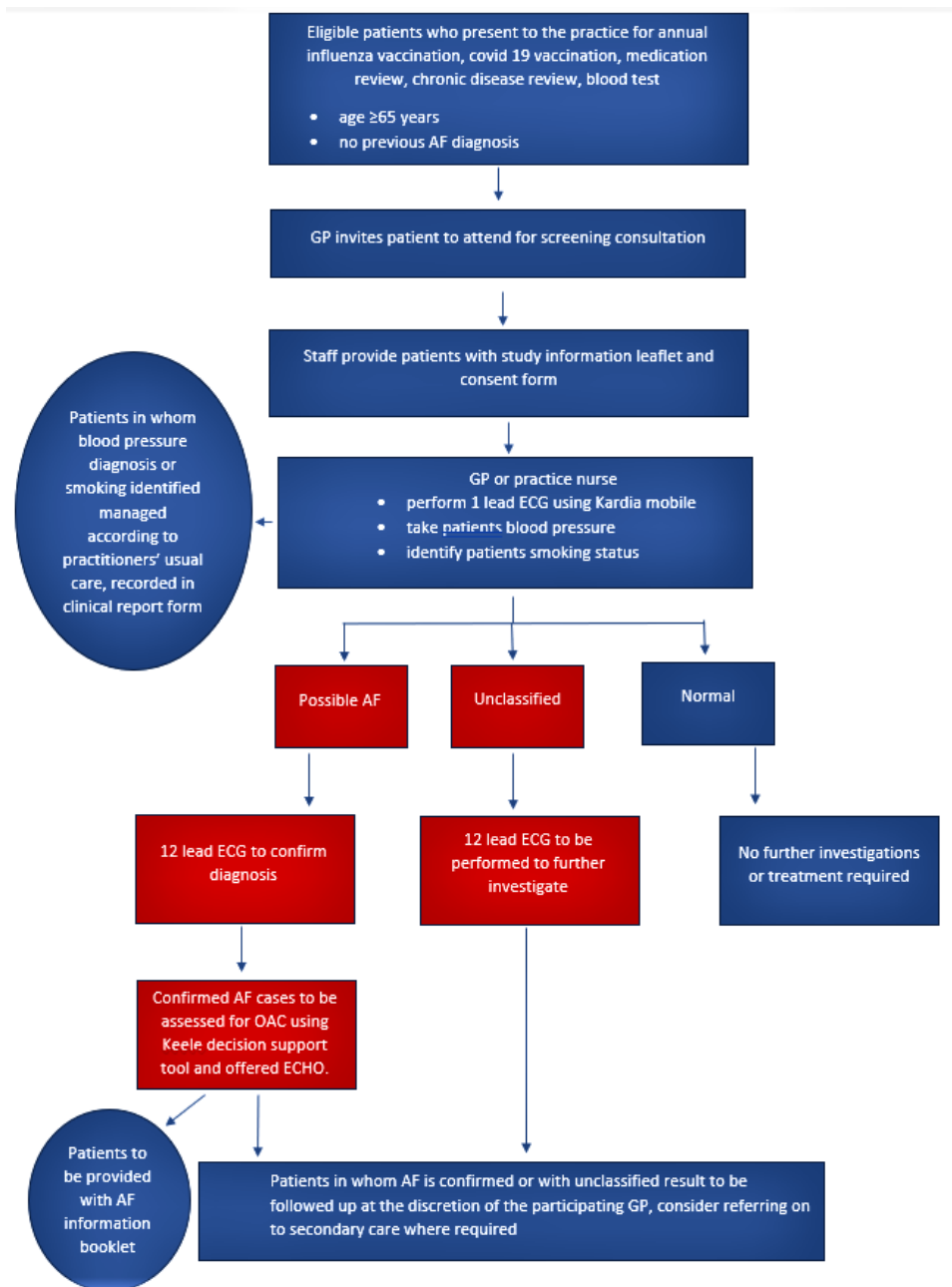


Figure 3 Flow chart of process of atrial fibrillation (AF) screening. GP, general practitioner; OAC, oral anticoagulant.

includes ECG interpretation. All newly identified cases of AF will be followed up as per the protocol outlined above.

At the initial screening consultation, all participants also have their blood pressure checked using a standardised sphygmomanometer and their smoking status determined. Patients with high blood pressure and/or who are smokers are to be managed as per the practitioner's usual practice.

Data collection

Quantitative

Participating GPs will supply anonymised data to the study team to evaluate the pilot screening programme. These data will be collected via a clinical report form (online supplemental file 4) and participating practices

will receive payment on return of data on study outcomes listed as follows:

- ▶ Number, age and gender of all patients attending for AF screening consultation.
- ▶ Number of patients and age and gender breakdown found to have possible AF (per KardiaMobile device), elevated blood pressure and current smoker status.
- ▶ Number and age and gender breakdown of patients in whom AF is confirmed per 12-lead ECG.
- ▶ Number and age and gender breakdown of patients commenced on oral anticoagulation therapy and the specific anticoagulation medication(s) prescribed.
- ▶ Number and age and gender breakdown of patients currently on and commenced on antihypertensive

medication and the specific antihypertensive medication(s) prescribed.

- ▶ Number and age and gender breakdown of patients commenced on smoking cessation therapy (counselling and/or medication).
- ▶ Number and age and gender breakdown of patients in whom AF is confirmed who have further investigation (eg, ECG) and who are referred to a cardiologist.
- ▶ Height, weight, body mass index, blood pressure, medical history and current medication of all participating patients.

Qualitative

Qualitative data will be collected by researchers on the study team who will undertake interviews with a sample of participants. Qualitative descriptive (QD) methodology will be adopted for this element of the study. QD is useful for exploring healthcare phenomena which are descriptive in nature.³⁵

Patients will be invited to participate in one-to-one interviews with a member of the research team. They will be asked to indicate at the time of screening if they are willing to participate in a qualitative interview and will be recruited via their GP or practice nurse. A topic guide (online supplemental file 5) has been designed to collect qualitative data on the patient participants' experiences of the screening. The GP will record on the clinical report form if the patient is willing to participate in the interview. Those patients who consent will form the sampling frame. Sampling for the interviews will be stratified from the pool of participants to include a mix of male and female participants, older and younger participants and those with and without comorbidities.

Participating GPs and practice nurses will also be invited to participate in a qualitative interview once screening has been completed. A further topic guide (online supplemental file 6) has been designed to collect qualitative data on the GPs and practice nurses' experiences of the screening. The GPs and practice nurses will be asked at recruitment to complete a consent form should they consent to participate in the interview and will form a separate sampling frame. They will be stratified to include a mix of male and female participants, older and younger GPs and participants in rural and urban practice. The stratification is intended to maximise diversity in the sample.

The interviews will be audio-recorded and transcribed verbatim by members of the study team. Framework analysis will be used to analyse the data. Framework analysis is an approach commonly used in health services research. The method is commonly used for the thematic analysis of semi-structured interview transcripts.³⁶ It is a suitable approach for studies with prespecified objectives while also allowing unexpected themes to emerge.³⁷ The number of the final sample to be recruited for the interviews will depend on when data saturation has been reached. Data analysis will be performed as interviews are conducted and data saturation will be determined when

no new themes emerge. It is anticipated that between 12 and 20 interviews may be required.

Data management

The data management plan for the project is designed in compliance with research data management policy at University College Cork (UCC).^{38 39} All data collected will be stored on encrypted investigator devices that will be set to automatically lock during periods of inactivity and will be subject to the university's data protection regulations. The files will be systematically and consistently named to aid data archiving and reuse. Researchers on the project have completed general data protection regulations General Data Protection Regulation (GDPR) training which relates to personal data protection and privacy. All data collected during the study will be retained for a period of 10 years as indicated by UCC's research data management policy. The raw data will not be made publicly available, anonymised data may be made available subject to prior request stating how it will be used. While data for health services research is not usually made available, with agreement from the participants we will create a suitable data repository as per UCC's policies and procedures for research data management. Variables will be recorded in data table formats and files will be systematically and consistently named.

Analysis

Quantitative

Quantitative data will be analysed by standard, primarily descriptive, statistical methods in STATA statistical package. Descriptive statistics such as frequencies, means, medians, percentiles, variance and SD will be used to summarise the characteristics in the population screened including gender, age, weight, height, etc. Continuous and categorical variables will be assessed differently. The researchers will use the data to quantitatively assess the proportion of new AF cases detected in the population screened; the proportion of patients in whom AF is diagnosed that are commenced on anticoagulants and the proportion of patients who are already on OAC, antihypertensive medication and/or smoking cessation therapy; and the proportion of patients who have further investigations (such as ECG) or secondary care referral.

Qualitative

One-to-one interviews will be carried out by researchers with a sample of patients, who receive the screening, and healthcare professionals (GPs and practice nurses), who provide the screening. Topic guides have been developed to guide content of the interviews (online supplemental files 5; 6). The researchers will collect data from participants relating to feasibility and acceptability of the screening process. The interviews will be audio-recorded, transcribed and codified using NVivo software. Qualitative data will be analysed using thematic analysis. Thematic analysis has been described by Braun and Clarke as a method to identify, analyse and report themes

within data.³⁷ Members of the research team will follow a framework developed by Braun and Clarke to guide the data analysis. This will involve data familiarisation, generating initial codes, looking for, reviewing and defining the emerging themes and finally writing up the findings.⁴⁰

Economic evaluation

A partial economic evaluation of AF screening in primary care using a handheld mobile ECG device will be conducted. Herein, a cost analysis will be performed to estimate the economic cost of the screening and resulting further investigations. In line with national guidelines for conducting economic evaluations from the Health Information and Quality Authority,⁴¹ microcosting techniques will be employed to identify, measure and value the resources involved in implementing the screening and initial further investigations, from the health service provider perspective. Direct costs will be considered, which will include any healthcare resource use at primary care and secondary care including visits to clinicians, diagnostics, medications etc.

A full economic evaluation considers both the costs and consequences of an intervention and at least one alternative, whereby in the incremental costs of the intervention versus alternative (or control) can be compared with the incremental benefits to determine if it is cost-effective. In this instance, we will conduct a partial economic analysis that will only consider costs of the intervention and initial further investigations arising from the intervention. In this study, a full economic evaluation is not feasible as there is no comparator or control group. Neither are health outcomes, quality of life or other effectiveness measures.

PATIENT AND PUBLIC INVOLVEMENT

A patient representative from the Irish Heart Foundation was present at the launch event to include the patient perspective in the conducting of the study. The representative participated in discussion at the event and subsequently provided the 'Live Well with Atrial Fibrillation' booklets to be distributed to newly confirmed cases of AF detected through screening.

ETHICS AND DISSEMINATION

Ethical approval has been granted by the Clinical Research Ethics Committee in UCC, review reference number: ECM 4 (e) 13/08/19. The study will be conducted in Cork city and Kerry and will be administered by UCC (School of Public Health and Department of General Practice). Dissemination will be across various forums including publication in peer-reviewed journals and presentation at national and international conferences. Results of the study will also be reported back to the participants at regular intervals over the course of the study.

Limitations

In the context of the qualitative interviews selection bias may be present. All participants both GPs and practice

nurses and patients will consent to interview. Those who self-select to participate in the interviews may have inherently different characteristics to those who do not consent to participate.

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Contributors DQ, CMB and CPB conceived the project. DQ, CMB, CPB and AC contributed to the study design. AC, DQ, SO'S, CMB and CPB developed the protocol. AC drafted the manuscript. DQ, CMB, CPB and PMK are providing PhD supervision for AC and supporting data analysis. AM provided economic expertise. DQ, SO'S, CPB, PMK, AM and CMB contributed to revision and drafting of the final manuscript.

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Competing interests None declared.

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