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## Opportunistic screening to detect Atrial Fibrillation in Aboriginal adults in Australia: study protocol.

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**Publication**

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**Title**

Opportunistic screening to detect Atrial Fibrillation in Aboriginal adults in Australia: study protocol.

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## Abstract

### Introduction

The leading cause of death for Aboriginal Australians is cardiovascular disease, including myocardial infarction and stroke. Although Atrial Fibrillation (AF) is a known precursor to stroke there are no published studies about the prevalence of AF for Aboriginal people and limited evidence about AF in indigenous populations globally. The purpose of the study is to estimate prevalence and age distribution of AF in Australian Aboriginal people.

### Methods and analysis

This mixed methods study will screen 1500 Australian Aboriginal people aged 45 years and older living in New South Wales, Northern Territory and Western Australia to estimate prevalence and age distribution of AF of the Australian Aboriginal population. In addition, the study will conduct semi-structured interviews with the Aboriginal people who conduct the screens to evaluate the effectiveness of opportunistic screening for AF using an iECG to facilitate timely assessment and treatment.

Study outcomes will determine the acceptability of the portable iECG device to diagnose AF in Aboriginal people and facilitate access to further assessment and treatment within an appropriate healthcare system; estimate the prevalence and age distribution of AF in Aboriginal people in Australia; improve cardiovascular health literacy in Aboriginal people and health workers; and if acceptable and widely adopted, may help prevent the effects of untreated AF including ischemic stroke and early deaths or impairment in Aboriginal people.

### **Ethics and dissemination**

This mixed methods study received ethics approval from the Aboriginal Health and Medical Research Council (1135/15) and the Australian Health Council of Western Australia (HREC706). Ethics approval is being sought in the Northern Territory. The findings of this study will be shared with Aboriginal communities, in peer reviewed publications and at conferences.

### **Clinical Trial Number**

The study has been registered as a clinical trial through ANZCTR (ACTRN12616000459426).

### **Keywords**

Opportunistic screening, Aboriginal, iECG, Atrial Fibrillation, Prevalence

## Introduction

Aboriginal Australians have very high rates of cardiovascular disease particularly myocardial infarction and stroke (1, 2). Cardiovascular disease remains the leading cause of death for this population (3-5). The burden of stroke for Aboriginal people is considerable with Aboriginal people more likely than other Australians to suffer a stroke (5, 6). Atrial Fibrillation (AF) is the most common sustained arrhythmia, with adults reaching the age of 40 having a one in four lifetime chance of developing the arrhythmia. The risk of AF increases with age and individuals affected by AF have a five times higher risk of ischemic stroke. Quality of life is also significantly worse for those with AF. One of the principal health issues is that AF is associated with approximately 1/3 of ischaemic strokes in Australia and Sweden (7, 8). Strokes from AF are in general more severe than those associated with other causes, with greater mortality and disability if non-fatal. But strokes associated with AF are preventable, with a 64% reduction if oral anticoagulant is prescribed.

AF prevalence in the Australian population is estimated to rise significantly over the next two decades (9). In people with AF, both stroke (approximately 60%) and death (approximately 10%) are greatly reduced by treatment with oral anticoagulant (10, 11). While AF can be associated with symptoms, it is frequently asymptomatic which may indicate that existing documented rates of AF in Australia are a significant underestimate of the scope of the problem (12, 13). To prevent strokes resulting from unknown AF, screening for asymptomatic AF could be helpful (14).

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3 There is very limited information on rates of AF in Australian Aboriginal people, and the only  
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5 studies available have come from hospitalisation data after an event. These studies found a  
6  
7 much higher age-standardised incidence of AF in Aboriginal than in non-Aboriginal patients.  
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9 This is particularly marked in the younger age groups, with odds ratios of 3.6 for men and  
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11 5.4 for women Aboriginal people between ages 20-54. On average, Aboriginal people  
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13 develop AF approximately 20 years earlier than their non-Aboriginal counterparts, and even  
14  
15 more concerning is the high rate of associated co-morbidities found in this subset versus the  
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17 wider Australian population (12, 13). Risk factors for AF such as hypertension, diabetes,  
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19 obesity, chronic kidney disease are all more common in younger Aboriginal people than in  
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21 non-Indigenous people (12, 13). This uneven burden of co-morbidity results in  
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CHA<sub>2</sub>DS<sub>2</sub>VASc scores (a score developed to indicate risk of stroke) of  $\geq 2$ , indicating risk sufficient to recommend anticoagulation in 53% of Aboriginal people aged below 55, and 73% in those aged 55-64, compared to only 14% and 28% respectively in non-Aboriginal people of the same age. Aboriginal people therefore face a double jeopardy of increased AF incidence at a younger age, and an increased risk of stroke when AF occurs (12, 13).

Accordingly, our study will take a preventative approach and opportunistically screen patients for AF at a younger age, starting at 45 years, before associated cardiovascular complications, like stroke, occur. Previous studies have assessed symptomatic AF in hospitalised patients, so our study is novel, in that no previous study has assessed the incidence of asymptomatic AF in Aboriginal people (12, 13, 15).

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3 There is some evidence in the literature for the efficacy of opportunistic screening in the  
4  
5 sexual and reproductive health of Aboriginal people (16-19). To be effective, opportunistic  
6  
7 screening must be undertaken in a culturally competent manner as the cultural competence  
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9 of the health service is associated with the likelihood that Aboriginal people access services  
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11 (20). Critically important is that opportunistic screening must include pathways for further  
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13 assessment and treatment, and access must be actively facilitated where necessary (21).  
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15 Further, opportunistic screening should include improving health literacy so that Aboriginal  
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17 people are better informed about their health and therefore more likely to identify potential  
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19 health issues earlier(22, 23). There are no studies of opportunistic screening of Aboriginal  
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21 people for AF.  
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29 Our study will estimate the prevalence and age distribution of asymptomatic AF in  
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31 Aboriginal Australians. There are a number of unique challenges in identifying Aboriginal  
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33 people with asymptomatic AF: the population is small (just under 3% of the Australian  
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35 population) (24) and is not reliably identified within the health care setting; the population is  
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37 also widely dispersed (25); less likely to access health care services; likely to have lower  
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39 health literacy; and less likely to seek health care assessment or treatment at the early signs  
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41 (26). This study explicitly addresses each of these issues through use of a portable single-  
42  
43 lead iECG device (Kardia) which can be used by a lay person with minimal training.  
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48 Screening will occur opportunistically within the course of usual duties for a range of  
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50 qualified and unqualified Aboriginal health care workers who are termed iECG screeners in  
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52 this paper. The study will also improve the health literacy of iECG screeners and patients  
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54 about causes, prevention, symptoms and assessment of cardiovascular disease. Further the  
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56 study will examine effective treatment pathways for cardiovascular disease, and patients  
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3 with a non-normal iECG result in order to reduce premature death and impairment, and  
4  
5 improve quality of life. There is some evidence in the peer-reviewed literature for the  
6  
7 efficacy of each of these elements with Aboriginal people (17, 19, 21, 27, 28).  
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10 The four aims of this study are to:

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12 1) determine the acceptability of the portable iECG device to diagnose AF in Aboriginal  
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14 people and facilitate access to further assessment and treatment;
- 15  
16 2) estimate the prevalence of both known and unknown AF in Aboriginal people in  
17  
18 Australia and the age distribution;
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20 3) improve health literacy in Aboriginal people and iECG screeners; and
- 21  
22 4) help prevent the effects of untreated AF in Aboriginal people, particularly ischemic  
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24 stroke which may result in early death or impairment.  
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30 As there is limited evidence about the prevalence of AF in indigenous populations globally  
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32 (15) this study should also contribute to the global picture of AF prevalence in indigenous  
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34 peoples.  
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#### 40 **Methods and analysis**

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42 This is a mixed methods study. We will use quantitative methods to estimate the  
43  
44 prevalence and age distribution of AF in Aboriginal people. Qualitative methods will be used  
45  
46 to determine the acceptability of the iECG as a screening tool for Aboriginal people, and the  
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48 effect of the intervention on improving health literacy. Qualitative methods will also be used  
49  
50 to determine the effectiveness of the clinical pathways established for patients with a non-  
51  
52 normal iECG result. In this context effectiveness refers to whether Aboriginal people seek  
53  
54 follow up assessment and/or treatment, and whether they are able to access it.  
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5 The iECG has been chosen for this study as it is small (clips onto the back of most  
6 smartphones); can be used by anyone with minimal training; and records a single-lead ECG  
7  
8 in approximately 30 seconds. A validated algorithm allows reliable detection of AF and other  
9  
10 arrhythmias in real-time (14). This device enables cost-effective community-based  
11  
12 screening, including rural and remote locations. The device is accurate and FDA and TGA  
13  
14 approved (ARTG Identifier 208100) and has been used in studies to identify AF in  
15  
16 Metropolitan Sydney (14) and Melbourne. After the ECG is completed, the data is  
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18 transmitted to the password encrypted and HIPAA compliant Kardia proprietary server.  
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20 Another account will store de-identified ECG screening data for this study.  
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29 Participating health services will be supplied with the iECG device and smartphone for each  
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31 health worker who will be undertaking screens in the study. The smartphone will have an  
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33 activated Sim Card to enable the iECG software to transmit the ECG via the telephone data  
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35 network. The participating health service will keep the iECG device after the completion of  
36  
37 the study to benefit their health service.  
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43 The study will take place in communities in New South Wales, Northern Territory and  
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45 Western Australia in collaboration with Aboriginal Community Controlled Health Services  
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47 and other services which meet the needs of Aboriginal people in those communities (for  
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49 example: hospital, dental service, pharmacy, and community centre). Each participating  
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51 service will nominate local Aboriginal health or health-related workers with a good  
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53 understanding of the local health care system and a willingness to participate in the study.  
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57 The local Aboriginal health workforce have been identified to participate in the study  
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3 because they are likely to be trusted by Aboriginal people and have a high level of cultural  
4 competence, understand the local health system, and are likely to be able to facilitate and  
5 expedite access to the local health system. Cultural competence is well established in the  
6 literature as a critical factor in Aboriginal people participating in health care services (29-31).  
7  
8 These workers will be termed iECG screeners in this study. The iECG screeners will receive  
9 training in the use of the iECG device, consent processes, cardiovascular health promotion  
10 and treatment, data collection and the clinical pathway for patients with a non-normal  
11 result.  
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25 This study will screen 1500 Aboriginal people, with each iECG screener conducting 50  
26 screens on eligible patients in order to reach a total of 1500 screens. The eligibility criteria  
27 for this study are:  
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- 31 1. Aboriginal heritage;
- 32 2. Aged 45 years or more; and
- 33 3. Living in New South Wales, Northern Territory or Western Australia.  
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42 Eligible participants will be formally consented into the study and receive an information  
43 sheet explaining the study. All participants will also receive a plain English and pictorial  
44 information sheet setting out the risk factors for cardiovascular disease, the ways to reduce  
45 risk and promote health, a straightforward explanation of the symptoms of a cardiovascular  
46 disease adverse event, and what to do if experiencing those symptoms.  
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55 The iECG has three possible results normal, possible AF or unclassified. Participants who  
56 record a result other than normal will be referred for a confirmatory 12-lead ECG and  
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3 individual management plan. This management plan will be supported by the iECG screener  
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5 and will proceed according to the agreed pathway. The assessment and treatment  
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7 pathways for patients with a non-normal result will be negotiated, agreed and documented  
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9 with each community before commencing the study in that site. A Registered Nurse  
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11 associated with the study will review all cases where a patient has a non-normal result  
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13 within 24 hours of the screen and take all steps to ensure the participant has accessed  
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15 further assessment and treatment where indicated.  
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23 Once the 1500 screens have been completed, data will be exported from the AliveCor server  
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25 and analyzed to estimate the prevalence and age distribution of AF in Aboriginal people in  
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27 Australia. The interviewer-assisted surveys will be conducted face to face or via telephone  
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29 with the iECG screeners by a member of the research team. This will include, wherever  
30  
31 possible, iECG screeners who did not complete 50 screens. The surveys will identify the  
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33 enabling factors and barriers for: (i) Aboriginal workers using the iECG in the course of their  
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35 practice; (ii) Aboriginal patients' receptiveness to the iECG; and (iii) the likelihood that  
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37 patients screened using iECG seek out and/or access recommended follow up assessment  
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39 and treatment.  
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47 Given the burden of cardiovascular disease borne by Aboriginal Australians and the  
48  
49 estimated significant rise of AF prevalence in Australia, this study is an important next step  
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51 in preventing premature death or impairment of Aboriginal people from stroke. This mixed  
52  
53 methods study brings together the best available evidence on AF, opportunistic screening  
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55 and Aboriginal Australians. The study aims to estimate the prevalence and age distribution  
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3 of known and unknown AF in Aboriginal people in Australia; determine the acceptability of  
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5 the portable iECG device to diagnose abnormal heart rhythm in Aboriginal people and  
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7 facilitate access to further assessment and treatment; and improve the cardiovascular  
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9 disease health literacy of Aboriginal people. The study will also contribute to the global  
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### 14 **Ethics and dissemination**

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19 Ethics approval has been granted for the NSW study through the Aboriginal Health and  
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21 Medical Research Council (1135/15) and Western Australia by the Australian Health Council  
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23 of Western Australia (HREC706). Ethics approval is being sought in the Northern Territory.  
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29 It is a requirement of the Ethics Committee of the Aboriginal Health and Medical Research  
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31 Council that Aboriginal communities are engaged prior to the study to inform the study  
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33 design. The process for this study is detailed in Figure 1.  
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39 Figure 1: Flow chart of the study.  
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45 The findings of this study will be shared with Aboriginal communities, the Aboriginal Health  
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47 and Medical Research Council, and in peer reviewed publications and at conferences. The  
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49 findings will also contribute to the global picture of AF prevalence and age distribution, and  
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51 if widely adopted will improve timely detection and treatment of AF in Aboriginal people.  
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### 56 **Strengths and limitations of the study**

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3 The strengths of the study are that it utilises technology which is proven to be effective in  
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5 the detection of AF, the study design was developed in collaboration Aboriginal health  
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7 organisations and is informed by the best available evidence about effective detection of  
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9 health issues and treatment of Australian Aboriginal people. However, the evidence for  
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11 effective detection and treatment of Aboriginal people is thin and there are no studies  
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13 about opportunistic screening of Aboriginal people for cardiovascular disease. The available  
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15 evidence indicates that Australian Aboriginal and New Zealand Maori populations  
16  
17 experience AF at a younger age than other populations. This study includes Aboriginal  
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19 people 45 and older. Depending on the findings of this study, future studies may include  
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21 younger people.  
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31  
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40  
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### 48 **Competing interests**

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50 Freedman: Research grants to conduct investigator-initiated studies by BMS/Pfizer, Bayer  
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52 Pharma, and Boehringer-Ingelheim, consultant for Bayer Pharma, BMS/Pfizer, Boehringer-  
53  
54 Ingelheim, Servier, Astra-Zeneca and Gilead, and speaker for Bayer Pharma, BMS/Pfizer,  
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56 AstraZeneca.  
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3 Neubeck: has received grants and honoraria from Pfizer BMS, Boehringer Ingelheim and  
4  
5 Bayer outside the submitted work.  
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### 10 11 **Author contributions**

12  
13 Study design – Gwynne, Freedman, Neubeck, Finlayson, McCowen, Martin, Flaskas

14  
15 Funding application – Gwynne, Flaskas, Freedman

16  
17 Ethics applications – Gwynne, Flaskas, Jeffries, O'Brien, Freedman

18  
19 Preparing manuscript – Gwynne

20  
21 Manuscript review and approval – All authors

22  
23 Registering as a trial - Gwynne  
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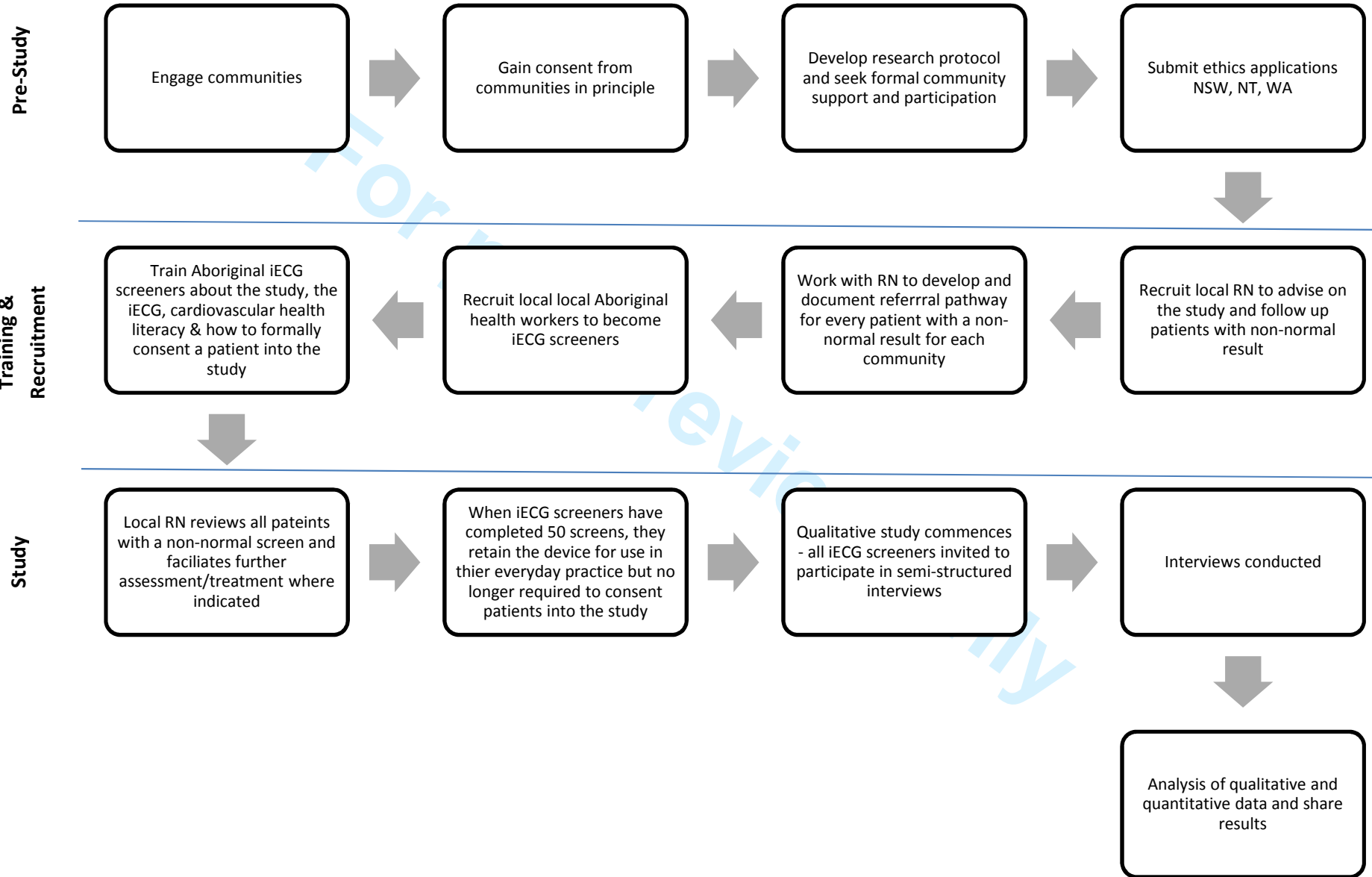
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# BMJ Open

## Opportunistic screening to detect Atrial Fibrillation in Aboriginal adults in Australia: study protocol.

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**Title**

Opportunistic screening to detect Atrial Fibrillation in Aboriginal adults in Australia: study protocol.

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## Abstract

### Introduction

There is a ten-year gap in life expectancy gap between Aboriginal and non-Aboriginal Australians. The leading cause of death for Aboriginal Australians is cardiovascular disease, including myocardial infarction and stroke. Although Atrial Fibrillation (AF) is a known precursor to stroke there are no published studies about the prevalence of AF for Aboriginal people and limited evidence about AF in indigenous populations globally. The purpose of the study is to estimate prevalence and age distribution of AF in Australian Aboriginal people.

### Methods and analysis

This mixed methods study will screen 1500 Australian Aboriginal people aged 45 years and older living in New South Wales, Northern Territory and Western Australia to estimate prevalence and age distribution of AF of the Australian Aboriginal population determine the acceptability of the portable iECG device to diagnose AF in Aboriginal people and facilitate access to further assessment and treatment; and improve cardiovascular health literacy in Aboriginal people and health workers. If the device and approach are acceptable and widely adopted, it may help prevent the effects of untreated AF including ischemic stroke and early deaths or impairment in Aboriginal people.

### **Ethics and dissemination**

This mixed methods study received ethics approval from the Aboriginal Health and Medical Research Council (1135/15) and the Australian Health Council of Western Australia (HREC706). Ethics approval is being sought in the Northern Territory. The findings of this study will be shared with Aboriginal communities, in peer reviewed publications and at conferences. There are Aboriginal investigators in each state/territory where the study is being conducted who have been actively involved in the study design. They will also be involved in data analysis, dissemination of results and research translation.

### **Strengths and limitations of this study**

- There is a ten-year life expectancy gap between Aboriginal and non-Aboriginal Australians and cardiovascular disease is a leading cause of early death and impairment.
- The study intends to estimate the prevalence and age distribution of known and unknown AF in Aboriginal people in Australia and determine the acceptability of the portable iECG device.
- This study utilises technology which is proven to be effective in the detection of AF, was designed in collaboration Aboriginal health organisations and is informed by the best available evidence about effective detection and treatment of health issues in Australian Aboriginal people.
- The study is novel as there are no studies about the prevalence of AF in Aboriginal people and the study design utilises Aboriginal health workers to conduct consecutive opportunistic screens using the iECG in the course their usual duties.

- The study will contribute to the global evidence on indigenous peoples and AF.

### Clinical Trial Number

The study has been registered as a clinical trial through ANZCTR (ACTRN12616000459426).

### Keywords

Opportunistic screening, Aboriginal, iECG, Atrial Fibrillation, Prevalence

### Note

The term **Aboriginal** in this paper includes Aboriginal and/or Torres Strait Islander peoples.

The term **indigenous** includes indigenous people globally.

## Introduction

Aboriginal Australians die on average ten years earlier than other Australians. With significantly higher rates of infant mortality, suicide and chronic disease, improving health outcomes in this population is a key priority for health care providers and governments (1). Many Aboriginal Australians access the health care system in the late stages of the disease process or in emergencies due to fear, racism and service access (2, 3). The Australian Government has a national strategy, Closing the Gap, which has established goals to close the gap in life expectancy for Aboriginal Australians within a generation. The strategy includes social determinants as well as specific health related targets. The Prime Minister of Australia reports annually on progress toward meeting the Closing the Gap targets (1).

Free health care is available in Australia (4). In addition, Aboriginal Community Controlled Health Services were established from 1971 to provide culturally specific primary health care services (5) and all public health care services have explicit obligations with respect to meeting the needs to Aboriginal patients (3, 6). Aboriginal employees in the health care system, including Aboriginal Health Workers, play a key role in the provision of culturally competent health care for Aboriginal people. Aboriginal Health Workers provide primary health care and health literacy, and often act as brokers for Aboriginal people accessing health care services (7).

Despite significant efforts to improve Aboriginal health outcomes, Aboriginal Australians have very high rates of cardiovascular disease particularly myocardial infarction and stroke (8, 9). Cardiovascular disease remains the leading cause of death for this population (10-

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3 12). The burden of stroke for Aboriginal people is considerable with Aboriginal people more  
4 likely than other Australians to suffer a stroke (12, 13). Atrial Fibrillation (AF) is the most  
5 common sustained arrhythmia, with adults reaching the age of 40 having a one in four  
6 lifetime chance of developing the arrhythmia (14). The risk of AF increases with age and  
7 individuals affected by AF have a five times higher risk of ischemic stroke. Quality of life is  
8 also significantly worse for those with AF. One of the principal health issues is that AF is  
9 associated with approximately 1/3 of ischaemic strokes in Australia and Sweden (15, 16).  
10 Strokes from AF are in general more severe than those associated with other causes, with  
11 greater mortality and disability if non-fatal. But strokes associated with AF are preventable,  
12 with a 64% reduction if oral anticoagulant is prescribed (17, 18).  
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30 AF prevalence in the Australian population is estimated to rise significantly over the next  
31 two decades (19). In people with AF, both stroke and death are greatly reduced by  
32 treatment with oral anticoagulant (by approximately 64% and 26% respectively) (17, 18).  
33  
34 While AF can be associated with symptoms, it is frequently asymptomatic which may  
35 indicate that existing documented rates of AF in Australia are a significant underestimate of  
36 the scope of the problem (20, 21). To prevent strokes resulting from unknown AF, screening  
37 for asymptomatic AF could be helpful (22).  
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50 There is very limited information on rates of AF in Australian Aboriginal people, and the only  
51 studies available have come from hospitalisation data after an event. These studies found a  
52 much higher age-standardised incidence of AF in Aboriginal than in non-Aboriginal patients.  
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54 This is particularly marked in the younger age groups, with ratios of age standardised  
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3 incidence rates of AF 3.6 for men and 5.4 for women for Aboriginal people compared to  
4 non-Aboriginal people between ages 20-54. On average, Aboriginal people develop AF  
5 approximately 20 years earlier than their non-Aboriginal counterparts, and even more  
6 concerning is the high rate of associated co-morbidities found in this subset versus the  
7 wider Australian population (20, 21). Risk factors for AF such as hypertension, diabetes,  
8 obesity, physical inactivity, chronic kidney disease, acute rheumatic fever, and rheumatic  
9 heart disease are all more common in Aboriginal people and at a younger age than in non-  
10 Indigenous people (20, 21) (23). This uneven burden of co-morbidity results in CHA<sub>2</sub>DS<sub>2</sub>VASc  
11 scores (a score developed to indicate risk of stroke) of  $\geq 2$ , indicating risk sufficient to  
12 recommend anticoagulation in 53% of Aboriginal people aged below 55, and 73% in those  
13 aged 55-64, compared to only 14% and 28% respectively in non-Aboriginal people of the  
14 same age (20). Aboriginal people therefore face a double jeopardy of increased AF incidence  
15 at a younger age, and an increased risk of stroke when AF occurs (20, 21).  
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37 Accordingly, our study will take a preventative approach and opportunistically screen  
38 patients for AF at a younger age, starting at 45 years, before associated cardiovascular  
39 complications, like stroke, occur. Aboriginal people 45 years and over make up just 18% of  
40 the Aboriginal population in Australia (24). By comparison the total Australian population  
41 aged 45 years and over is 39.6% (24). Previous studies have assessed symptomatic AF in  
42 hospitalised patients, so our study is novel, in that no previous study has assessed the  
43 incidence of asymptomatic AF in Aboriginal people (20, 21, 25).  
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3 There is some evidence in the literature for the efficacy of opportunistic screening in the  
4 sexual and reproductive health of Aboriginal people (26-29). To be effective, opportunistic  
5 screening must be undertaken in a culturally competent manner as the cultural competence  
6 of the health service is associated with the likelihood that Aboriginal people access services  
7 (30). Critically important is that opportunistic screening must include pathways for further  
8 assessment and treatment, and access must be actively facilitated where necessary (31).  
9  
10 Further, opportunistic screening should include improving health literacy so that Aboriginal  
11 people are better informed about their health and therefore more likely to identify potential  
12 health issues earlier (32, 33). There are no studies of opportunistic screening of Aboriginal  
13 people for cardiovascular disease or AF.  
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29 Our study will estimate the prevalence and age distribution of asymptomatic AF in  
30 Aboriginal Australians. There are a number of unique challenges in identifying Aboriginal  
31 people with asymptomatic AF: the population is small (just under 3% of the Australian  
32 population) (1) and is not reliably identified within the health care setting; the population is  
33 also widely dispersed (34); less likely to access health care services; likely to have lower  
34 health literacy; and less likely to seek health care assessment or treatment at the early signs  
35 (35). This study explicitly addresses each of these issues through use of a portable single-  
36 lead iECG device (Kardia) which can be used by a lay person with minimal training. The iECG  
37 device has been successfully used by non-physician health personnel in non-Aboriginal  
38 populations in Australia (22, 36-38).  
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3 The overall goal of the study is to help prevent the effects of untreated AF in Aboriginal  
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5 people, particularly ischemic stroke which may result in early death or impairment. The  
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7 study has three aims, to:  
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- 10 1) determine the acceptability of the portable iECG device to diagnose AF in Aboriginal  
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12 people and facilitate access to further assessment and treatment;
- 13 2) estimate the prevalence of both known and unknown AF in Aboriginal people in  
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15 Australia and the age distribution;
- 16  
17 3) improve health literacy in Aboriginal people and iECG screeners.  
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23 As there is limited evidence about the prevalence of AF in indigenous populations globally  
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25 (25) this study should also contribute to the global picture of AF prevalence in indigenous  
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27 peoples.  
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### 33 **Methods and analysis**

#### 34 Study Design

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37 This is a mixed methods study. We will use quantitative methods to determine the  
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39 proportion of participants with a non-normal result who presented for follow-up  
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41 assessment and treatment, and to estimate the prevalence and age distribution of AF in  
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43 Aboriginal people. Qualitative methods will be used to determine the acceptability of the  
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45 iECG as a screening tool for iECG screeners and Aboriginal participants, and the effect of the  
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47 intervention on improving health literacy.  
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55 The study will take place in communities in New South Wales, Northern Territory and  
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57 Western Australia in collaboration with Aboriginal Community Controlled Health Services  
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3 and other services which meet the needs of Aboriginal people in those communities (for  
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5 example: hospital, dental service, pharmacy, and community centre). Each participating  
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7 service will nominate local Aboriginal health or health-related workers with a good  
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9 understanding of the local health care system and a willingness to participate in the study.  
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15 The local Aboriginal health workforce have been identified to participate in the study  
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17 because they are likely to be trusted by Aboriginal people and have a high level of cultural  
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19 competence, understand the local health system, and are likely to be able to facilitate and  
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21 expedite access to the local health system. Cultural competence is well established in the  
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23 literature as a critical factor in Aboriginal people participating in health care services (39-41).  
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25 These workers will be termed iECG screeners in this study. The iECG screeners will receive  
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27 training in the use of the iECG device, consent processes, cardiovascular health promotion  
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29 and treatment, data collection and the clinical pathway for patients with a non-normal  
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31 result and will conduct the screens as part of their usual interactions with patients in the  
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33 community, home or clinic. There is some evidence in the peer-reviewed literature for the  
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35 efficacy of each of the study design elements with Aboriginal people (27, 29, 31, 42, 43).  
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#### 44 Data collection method

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46 The iECG has been chosen for this study because it has been success with other populations  
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48 (22, 36-38), it is small (clips onto the back of most smartphones); can be used by anyone  
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50 with minimal training; and records a single-lead ECG in approximately 30 seconds. A  
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52 validated algorithm allows reliable detection of AF and other arrhythmias in real-time (22).  
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54 This device enables cost-effective community-based screening, including rural and remote  
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3 locations. The device is accurate and FDA and TGA approved (ARTG Identifier 208100) and  
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5 has been used in studies to identify AF in Metropolitan Sydney (22) and Melbourne. After  
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7 the ECG is completed, the data is transmitted to the password encrypted and HIPAA  
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9 compliant Kardia proprietary server. Another account will store de-identified ECG screening  
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11 data for this study.  
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17 Participating health services will be supplied with the iECG device and smartphone for each  
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19 health worker who will be undertaking screens in the study. The smartphone will have an  
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21 activated Sim Card to enable the iECG software to transmit the ECG via the telephone data  
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23 network. The participating health service will keep the iECG device after the completion of  
24  
25 the study to benefit their health service.  
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31 Gaining informed consent and conducting the screens will occur opportunistically within the  
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33 course of usual duties for a range of qualified and unqualified iECG screeners. iECG  
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35 screeners will invite consecutive patients to participate in the study which should reduce  
36  
37 bias in the sample.  
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44 This study will screen 1500 Aboriginal people, which represents 1% of the total Aboriginal  
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46 population aged 45 years and over (24). Thirty iECG screeners will conduct 50 screens on  
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48 eligible patients in order to reach a total of 1500 screens. Given the additional time required  
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50 to gain informed consent for patients to join the study and the wide-ranging roles and  
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52 responsibilities of Aboriginal workers in the health care system, the study explicitly limits  
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3 each screener to 50 screens. Once they have completed the 50 screens for the study they  
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5 can retain the device and use it in their usual practice.  
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10 The eligibility criteria for this study are:

- 11 1. Aboriginal heritage;
- 12 2. Aged 45 years or more; and
- 13 3. Living in New South Wales, Northern Territory or Western Australia.  
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20 Eligible participants will be formally consented into the study by an Aboriginal iECG  
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22 screener. Participants will receive an information sheet explaining the study and a plain  
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24 English and pictorial information sheet setting out the risk factors for cardiovascular disease,  
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26 the ways to reduce risk and promote health, a straightforward explanation of the symptoms  
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28 of a heart disease and what to do if experiencing those symptoms.  
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34 The iECG has three possible results normal, possible AF or unclassified. Participants who  
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36 record a result other than normal will be referred for a confirmatory 12-lead ECG and  
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38 individual management plan. This management plan will be supported by the iECG screener  
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40 and will proceed according to the agreed pathway. The assessment and treatment  
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42 pathways for patients with a non-normal result will be negotiated, agreed and documented  
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44 with each community before commencing the study in that site. A Registered Nurse  
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46 associated with the study will review all cases where a patient has a non-normal result,  
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48 within 24 hours of the screen, and take all steps to ensure the participant has accessed  
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50 further assessment and treatment where indicated. The Registered Nurse will follow up  
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52 with every patient with a non-normal result and facilitate access to further assessment and  
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3 treatment where this is indicated. The Registered Nurse will also record in a database  
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5 whether or not the patient with a non-normal iECG attended for a 12-lead ECG, whether or  
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7 not they had AF, and whether or not they knew they had AF prior to the screen. The fidelity  
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9 of the intervention will be assessed quantitatively by recording the number of patients who  
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11 do not complete the protocol and qualitatively through interviews with iECG screeners and  
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13 the Registered Nurses.  
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20 Once the 1500 screens have been completed, data will be exported from the AliveCor server  
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22 and analyzed to estimate the prevalence and age distribution of AF in Aboriginal people in  
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24 Australia. The interviewer-assisted surveys will be conducted face to face or via telephone  
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26 with the iECG screeners by a member of the research team. This will include, wherever  
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28 possible, iECG screeners who did not complete 50 screens. The surveys will identify the  
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30 enabling factors and barriers for: (i) Aboriginal workers using the iECG in the course of their  
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32 practice and (ii) Aboriginal patients' receptiveness to the iECG.  
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#### 40 Data analysis

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42 1500 people represent 1% of the Aboriginal population in Australia aged 45 years and older  
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44 and is therefore a reasonable sample to estimate prevalence. If we assume a prevalence of  
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46 AF of 3% in this population, then the 95% CI of this would be 2.0%-4.0% with this sample  
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48 size.  
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3 The qualitative analysis will be based on published methods for qualitative research in  
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5 health care (44). All interviews will be transcribed in full and downloaded into Nvivo11 for  
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7 analysis.  
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### 10 11 12 **Ethics and dissemination** 13

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16 Ethics approval has been granted for the NSW study through the Aboriginal Health and  
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18 Medical Research Council (1135/15) and Western Australia by the Australian Health Council  
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20 of Western Australia (HREC706). Ethics approval is being sought in the Northern Territory.  
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25 It is a requirement of the Ethics Committee of the Aboriginal Health and Medical Research  
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27 Council that Aboriginal communities are engaged prior to the study to inform the study  
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29 design. The process of working with communities to design the study such that they could  
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31 write letters of support took approximately nine months. The process for this study is  
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33 detailed in Figure 1.  
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Figure 1: Flow chart of the study.

The findings of this study will be shared with Aboriginal communities, the Aboriginal Health and Medical Research Council, and in peer reviewed publications and at conferences. The findings will also contribute to the global picture of AF prevalence and age distribution, and if widely adopted will improve timely detection and treatment of AF in Aboriginal people.



### Strengths and limitations of the study

The strengths of the study are that it utilises technology which is proven to be effective in the detection of AF, the study design was developed in collaboration Aboriginal health organisations and is informed by the best available evidence about effective detection of health issues and treatment of Australian Aboriginal people. However, the evidence for effective detection and treatment of Aboriginal people is thin and there are no studies about opportunistic screening of Aboriginal people for cardiovascular disease. The available evidence indicates that Australian Aboriginal and New Zealand Maori populations experience AF at a younger age than other populations. This study includes Aboriginal people 45 and older. Depending on the findings of this study, future studies may include younger people.

We are conducting opportunistic screening for known and unknown AF in people accessing health care services and are recruiting predominantly from rural and remote parts of Australia, with some regional sites. This will inevitably bias our sample. To try and reduce this we have instructed our screeners where possible to conduct consecutive sampling. While it is random it may not be completely representative of Aboriginal people across Australia as we are concentrating on rural and regional areas. The study is opportunistic rather than systematic and this is a limitation of the study.

Given the burden of cardiovascular disease borne by Aboriginal Australians and the estimated significant rise of AF prevalence in Australia, this study is an important next step in preventing premature death or impairment of Aboriginal people from stroke. This mixed methods study brings together the best available evidence on AF, opportunistic screening

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3 and Aboriginal Australians to estimate the prevalence and age distribution of known and  
4  
5 unknown AF in Aboriginal people in Australia and determine the acceptability of the  
6  
7 portable iECG device.  
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9

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13  
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22  
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### 30 31 **Data sharing**

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33 All de-identified data will be shared with all investigators on the study.  
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### 39 40 **Competing interests**

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42 Freedman: Research grants to conduct investigator-initiated studies by BMS/Pfizer, Bayer  
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44 Pharma, and Boehringer-Ingelheim, consultant for Bayer Pharma, BMS/Pfizer, Boehringer-  
45  
46 Ingelheim, Servier, Astra-Zeneca and Gilead, and speaker for Bayer Pharma, BMS/Pfizer,  
47  
48 AstraZeneca.  
49

50  
51 Neubeck: has received grants and honoraria from Pfizer BMS, Boehringer Ingelheim and  
52  
53 Bayer outside the submitted work.  
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**Author contributions**

Study design – Gwynne, Freedman, Neubeck, Finlayson, McCowen, Martin, Flaskas

Funding application – Gwynne, Flaskas, Freedman

Ethics applications – Gwynne, Flaskas, Jeffries, O’Brien, Freedman

Preparing manuscript – Gwynne

Manuscript review and approval – All authors

Registering as a trial - Gwynne

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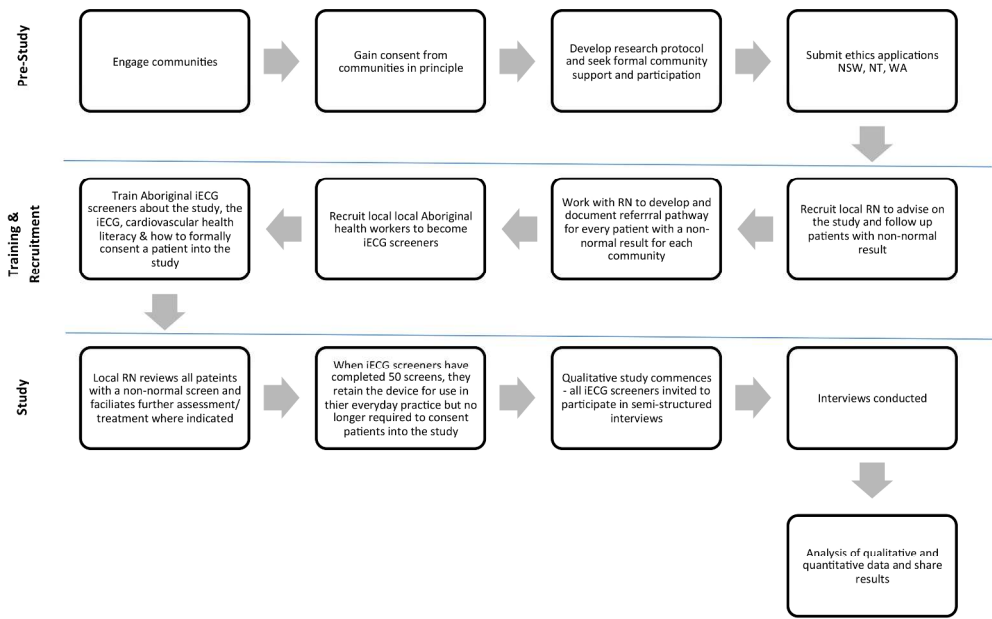
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# BMJ Open

## Opportunistic screening to detect Atrial Fibrillation in Aboriginal adults in Australia: study protocol.

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**Title**

Opportunistic screening to detect Atrial Fibrillation in Aboriginal adults in Australia: study protocol.

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## Abstract

### Introduction

There is a ten-year gap in life expectancy gap between Aboriginal and non-Aboriginal Australians. The leading cause of death for Aboriginal Australians is cardiovascular disease, including myocardial infarction and stroke. Although Atrial Fibrillation (AF) is a known precursor to stroke there are no published studies about the prevalence of AF for Aboriginal people and limited evidence about AF in indigenous populations globally.

### Methods and analysis

This mixed methods study will recruit and train Aboriginal health workers to utilise an iECG device attached to a smartphone to consecutively screen 1500 Aboriginal people aged 45 years and older. The study will quantify the proportion of people who presented for follow up assessment and/or treatment following a non-normal screening and then estimate the prevalence and age distribution of AF of the Australian Aboriginal population. The study includes semi-structured interviews with the Aboriginal health workers about the effectiveness of the iECG device in their practice as well as their perceptions of the acceptability of the device for their patients. Thematic analysis will be undertaken on the qualitative data collected in the study. If the device and approach are acceptable to Aboriginal people and widely adopted, it may help prevent the effects of untreated AF including ischemic stroke and early deaths or impairment in Aboriginal people.

### Ethics and dissemination

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3 This mixed methods study received ethics approval from the Aboriginal Health and Medical Research  
4 Council (1135/15) and the Australian Health Council of Western Australia (HREC706). Ethics  
5 approval is being sought in the Northern Territory. The findings of this study will be shared  
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8 with Aboriginal communities, in peer reviewed publications and at conferences. There are  
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12 Aboriginal investigators in each state/territory where the study is being conducted who  
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15 have been actively involved in the study. They will also be involved in data analysis,  
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18 dissemination and research translation.  
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### 22 **Strengths and limitations of this study**

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- The study intends to estimate the prevalence and age distribution of known and  
unknown AF in Aboriginal people in Australia and determine the acceptability of the  
portable iECG device.
- This study utilises technology which is proven to be effective in the detection of AF,  
was designed in collaboration Aboriginal health organisations and is informed by the  
best available evidence about effective detection and treatment of health issues in  
Australian Aboriginal people.
- The study is novel as there are no studies about the prevalence of AF in Aboriginal  
people and the study design utilises Aboriginal health workers to conduct  
consecutive opportunistic screens using the iECG in the course their usual duties.
- The study will contribute to the global evidence on indigenous peoples and AF.

**Clinical Trial Number**

The study has been registered as a clinical trial through ANZCTR (ACTRN12616000459426).

**Keywords**

Opportunistic screening, Aboriginal, iECG, Atrial Fibrillation, Prevalence

For peer review only

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## Introduction

Aboriginal and/or Torres Strait Islander peoples (hereafter Aboriginal) are the indigenous people of Australia and die on average ten years earlier than other Australians. With significantly higher rates of infant mortality, suicide and chronic disease, improving health outcomes in this population is a key priority for health care providers and governments (1). Many Aboriginal Australians access the health care system in the late stages of the disease process or in emergencies due to fear, racism and service access (2, 3). The Australian Government has a national strategy, Closing the Gap, which has established goals to close the gap in life expectancy for Aboriginal Australians within a generation. The strategy includes social determinants as well as specific health related targets. The Prime Minister of Australia reports annually on progress toward meeting the Closing the Gap targets (1).

Free health care is available in Australia (4). In addition, Aboriginal Community Controlled Health Services were established from 1971 to provide culturally specific primary health care services (5) and all public health care services have explicit obligations with respect to meeting the needs to Aboriginal patients (3, 6). Aboriginal employees in the health care system, including Aboriginal Health Workers, play a key role in the provision of culturally competent health care for Aboriginal people. Aboriginal Health Workers provide primary health care and health literacy, and often act as brokers for Aboriginal people accessing health care services (7).

Despite significant efforts to improve Aboriginal health outcomes, Aboriginal Australians have very high rates of cardiovascular disease particularly myocardial infarction and stroke

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3 (8, 9). Cardiovascular disease remains the leading cause of death for this population (10-  
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6 12). The burden of stroke for Aboriginal people is considerable with Aboriginal people more  
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8 likely than other Australians to suffer a stroke (12, 13). Atrial Fibrillation (AF) is the most  
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10 common sustained arrhythmia, with adults reaching the age of 40 having a one in four  
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12 lifetime chance of developing the arrhythmia (14). The risk of AF increases with age and  
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14 individuals affected by AF have a five times higher risk of ischemic stroke. Quality of life is  
15  
16 also significantly worse for those with AF. One of the principal health issues is that AF is  
17  
18 associated with approximately 1/3 of ischaemic strokes in Australia and Sweden (15, 16).  
19  
20 Strokes from AF are in general more severe than those associated with other causes, with  
21  
22 greater mortality and disability if non-fatal. But strokes associated with AF are preventable,  
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24 with a 64% reduction if oral anticoagulant is prescribed (17, 18).  
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32 AF prevalence in the Australian population is estimated to rise significantly over the next  
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34 two decades (19). In people with AF, both stroke and death are greatly reduced by  
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36 treatment with oral anticoagulant (by approximately 64% and 26% respectively) (17, 18).  
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39 While AF can be associated with symptoms, it is frequently asymptomatic which may  
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41 indicate that existing documented rates of AF in Australia are a significant underestimate of  
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43 the scope of the problem (20, 21). To prevent strokes resulting from unknown AF, screening  
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45 for asymptomatic AF could be helpful (22).  
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52 There is very limited information on rates of AF in Australian Aboriginal people, and the only  
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54 studies available have come from hospitalisation data after an admission. These studies  
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56 found a much higher age-standardised incidence of AF in Aboriginal than in non-Aboriginal  
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3 patients. This is particularly marked in the younger age groups, with ratios of age  
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5 standardised incidence rates of AF 3.6 for men and 5.4 for women for Aboriginal people  
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7 compared to non-Aboriginal people between ages 20-54. On average, Aboriginal people  
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9 develop AF approximately 20 years earlier than their non-Aboriginal counterparts, and even  
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11 more concerning is the high rate of associated co-morbidities found in this subset versus the  
12  
13 wider Australian population (20, 21). Risk factors for AF such as hypertension, diabetes,  
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15 obesity, physical inactivity, chronic kidney disease, acute rheumatic fever, and rheumatic  
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17 heart disease are all more common in Aboriginal people and at a younger age than in non-  
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19 Indigenous people (20, 21, 23). This uneven burden of co-morbidity results in CHA<sub>2</sub>DS<sub>2</sub>VASc  
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21 scores (a score developed to indicate risk of stroke) of  $\geq 2$ , indicating risk sufficient to  
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23 recommend anticoagulation in 53% of Aboriginal people aged below 55, and 73% in those  
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25 aged 55-64, compared to only 14% and 28% respectively in non-Aboriginal people of the  
26  
27 same age (20). Aboriginal people therefore face a double jeopardy of increased AF incidence  
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29 at a younger age, and an increased risk of stroke when AF occurs (20, 21).  
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39 Accordingly, our study will take a preventative approach and opportunistically screen  
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41 patients for AF at a younger age, starting at 45 years, before associated cardiovascular  
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43 complications, like stroke, occur. Aboriginal people 45 years and over make up just 18% of  
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45 the Aboriginal population in Australia (24). By comparison the total Australian population  
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47 aged 45 years and over is 39.6% (24). Previous studies have assessed symptomatic AF in  
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49 hospitalised patients, so our study is novel, in that no previous study has assessed the  
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51 incidence of asymptomatic AF in Aboriginal people (20, 21, 25).  
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There is some evidence in the literature for the efficacy of opportunistic screening in the sexual and reproductive health of Aboriginal people (26-29). To be effective, opportunistic screening must be undertaken in a culturally competent manner as the cultural competence of the health service is associated with the likelihood that Aboriginal people access services (30). Critically important is that opportunistic screening must include pathways for further assessment and treatment, and access must be actively facilitated where necessary (31). Further, opportunistic screening should include improving health literacy so that Aboriginal people are better informed about their health and therefore more likely to identify potential health issues earlier (32, 33). There are no studies of opportunistic screening of Aboriginal people for cardiovascular disease or AF.

Our study will estimate the prevalence and age distribution of asymptomatic AF in Aboriginal Australians. There are a number of unique challenges in identifying Aboriginal people with asymptomatic AF: the population is small (just under 3% of the Australian population) (1) and is not reliably identified within the health care setting; the population is also widely dispersed (34); less likely to access health care services; likely to have lower health literacy; and less likely to seek health care assessment or treatment at the early signs (35). This study explicitly addresses each of these issues through use of a portable single-lead iECG device (Kardia) which can be used by a lay person with minimal training. The iECG device has been successfully used by non-physician health personnel in non-Aboriginal populations in Australia (22, 36-38).



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6 The overall goal of the study is to help prevent the effects of untreated AF in Aboriginal  
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8 people, particularly ischemic stroke which may result in early death or impairment. The  
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10 study has three aims, to:

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13 1) determine the acceptability of the portable iECG device to diagnose AF in Aboriginal  
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15 people and facilitate access to further assessment and treatment;
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18 2) estimate the prevalence and age distribution of both known and unknown AF in  
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20 Aboriginal people in Australia;
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23 3) improve health literacy in Aboriginal people and iECG screeners.

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25 As there is limited evidence about the prevalence of AF in indigenous populations globally  
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27 (25) this study should also contribute to the global picture of AF prevalence in indigenous  
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29 peoples.  
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## 35 36 **Methods and analysis**

### 37 38 Study Design

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41 This is a mixed methods study. We will use quantitative methods to determine the  
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43 proportion of participants with a non-normal result who presented for follow-up  
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45 assessment and treatment, and to estimate the prevalence and age distribution of AF in  
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47 Aboriginal people. Qualitative methods will be used to determine the acceptability of the  
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49 iECG as a screening tool for iECG screeners and Aboriginal participants, and the effect of the  
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51 intervention on improving health literacy in Aboriginal patients.  
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3 The study will take place in communities in New South Wales, Northern Territory and  
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5 Western Australia in collaboration with Aboriginal Community Controlled Health Services  
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7 and other services which meet the needs of Aboriginal people in those communities (for  
8  
9 example: hospital, dental service, pharmacy, and community centre). Each participating  
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11 service will nominate local Aboriginal health or health-related workers with a good  
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13 understanding of the local health care system and a willingness to participate in the study.  
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### 20 Data collection method

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22 The local Aboriginal health workforce have been identified to participate in the study as  
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24 data collectors because they are likely to be trusted by Aboriginal people and have a high  
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26 level of cultural competence, understand the local health system, and are likely to be able to  
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28 facilitate and expedite access to the local health system. Cultural competence is well  
29  
30 established in the literature as a critical factor in Aboriginal people participating in health  
31  
32 care services (39-41). These workers will be termed iECG screeners in this study. The iECG  
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34 screeners will receive training in the use of the iECG device, consent processes,  
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36 cardiovascular health promotion and treatment, data collection and the clinical pathway for  
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38 patients with a non-normal result and will conduct the screens as part of their usual  
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40 interactions with patients in the community, home or clinic. There is some evidence in the  
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42 peer-reviewed literature for the efficacy of each of the study design elements with  
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44 Aboriginal people (27, 29, 31, 42, 43).  
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52 The iECG has been chosen as the screening tool for this study because it has been success  
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54 with other populations (22, 36-38), it is small (clips onto the back of most smartphones); can  
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3 be used by anyone with minimal training; and records a single-lead ECG in approximately 30  
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5 seconds. A validated algorithm allows reliable detection of AF and other arrhythmias in real-  
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7 time (22). This device enables cost-effective community-based screening, including rural and  
8  
9 remote locations. The device is accurate and FDA and TGA approved (ARTG Identifier  
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11 208100) and has been used in studies to identify AF in Metropolitan Sydney (22) and  
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13 Melbourne. After the ECG is completed, the data is transmitted to the password encrypted  
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15 and HIPAA compliant Kardia proprietary server. Another account will store de-identified  
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17 ECG screening data for this study.  
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24 Participating health services will be supplied with the iECG device and smartphone for each  
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26 health worker who will be undertaking screens in the study. The smartphone will have an  
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28 activated Sim Card to enable the iECG software to transmit the ECG via the telephone data  
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30 network. The participating health service will keep the iECG device after the completion of  
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32 the study to benefit their health service.  
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### 38 Sampling strategy

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40 Gaining informed consent and conducting the screens will occur opportunistically within the  
41  
42 course of usual duties for a range of qualified and unqualified iECG screeners. iECG  
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44 screeners will invite consecutive patients to participate in the study which should reduce  
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46 bias in the sample. 1500 people represent 1% of the Aboriginal population in Australia aged  
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48 45 years and older and is therefore a reasonable sample to estimate prevalence. If we  
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50 assume a prevalence of AF of 3% in this population, then the 95% CI of this would be 2.0%-  
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52 4.0% with this sample size.  
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3 Thirty iECG screeners will conduct 50 screens on eligible patients in order to reach a total of  
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5 1500 screens. Given the additional time required to gain informed consent for patients to  
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7 join the study and the wide-ranging roles and responsibilities of Aboriginal workers in the  
8  
9 health care system, the study explicitly limits each screener to 50 screens. Once they have  
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11 completed the 50 screens for the study they can retain the device and use it in their usual  
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13 practice.  
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20 The eligibility criteria for this study are:

- 21 1. Aboriginal heritage;
  - 22 2. Aged 45 years or more; and
  - 23 3. Living in New South Wales, Northern Territory or Western Australia.
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### 33 Procedure

34 Eligible participants will be formally consented into the study by an Aboriginal iECG  
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36 screener. Participants will receive an information sheet explaining the study and a plain  
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38 English and pictorial information sheet setting out the risk factors for cardiovascular disease,  
39  
40 the ways to reduce risk and promote health, a straightforward explanation of the symptoms  
41  
42 of a heart disease and what to do if experiencing those symptoms.  
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51 The iECG has three possible results normal, possible AF or unclassified. Participants who  
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53 record a result other than normal will be referred for a confirmatory 12-lead ECG and  
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55 individual management plan. This management plan will be supported by the iECG screener  
56  
57 and will proceed according to the agreed pathway. The assessment and treatment  
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3 pathways for patients with a non-normal result will be negotiated, agreed and documented  
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5 with each community before commencing the study in that site. A Registered Nurse  
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7 associated with the study will review all cases where a patient has a non-normal result,  
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9 within 24 hours of the screen, and take all steps to ensure the participant has accessed  
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11 further assessment and treatment where indicated. The Registered Nurse will follow up  
12  
13 with every patient with a non-normal result and facilitate access to further assessment and  
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15 treatment where this is indicated. The Registered Nurse will also record in a database  
16  
17 whether or not the patient with a non-normal iECG attended for a 12-lead ECG, whether or  
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19 not they had AF, and whether or not they knew they had AF prior to the screen. The fidelity  
20  
21 of the intervention will be assessed quantitatively by recording the number of patients who  
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23 do not complete the protocol and qualitatively through interviews with iECG screeners and  
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25 the Registered Nurses.  
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35 Once the 1500 screens have been completed, data will be exported from the AliveCor server  
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37 and analyzed to estimate the prevalence and age distribution of AF in Aboriginal people in  
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39 Australia. The interviewer-assisted surveys will be conducted face to face or via telephone  
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41 with the iECG screeners by a member of the research team. This will include, wherever  
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43 possible, iECG screeners who did not complete 50 screens. The surveys will identify the  
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45 enabling factors and barriers for: (i) Aboriginal workers using the iECG in the course of their  
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47 practice and (ii) Aboriginal patients' receptiveness to the iECG as perceived by the iECG  
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49 screeners.  
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### Data analysis

Descriptive statistics (means and proportions including their confidence intervals) will be analysed using SPSS software, version 22 (SPSS Inc, Chicago Ill, USA). The chi-square test will be used to examine demographic differences including age and sex.

The qualitative analysis will be based on published methods for qualitative research in health care (44). All interviews will be transcribed in full and downloaded into Nvivo11 for analysis.

### **Ethics and dissemination**

Ethics approval has been granted for the NSW study through the Aboriginal Health and Medical Research Council (1135/15) and Western Australia by the Australian Health Council of Western Australia (HREC706). Ethics approval is being sought in the Northern Territory.

It is a requirement of the Ethics Committee of the Aboriginal Health and Medical Research Council that Aboriginal communities are engaged prior to the study to inform the study design. The process of working with communities to design the study such that they could write letters of support took approximately nine months. The process for this study is detailed in Figure 1.

Figure 1: Flow chart of the study.

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6 The findings of this study will be shared with Aboriginal communities, the Aboriginal Health  
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8 and Medical Research Council, and in peer reviewed publications and at conferences. The  
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10 findings will also contribute to the global picture of AF prevalence and age distribution, and  
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12 if widely adopted will improve timely detection and treatment of AF in Aboriginal people.  
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### 15 16 17 18 **Strengths and limitations of the study** 19

20  
21 The strengths of the study are that it utilises technology which is proven to be effective in  
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23 the detection of AF, the study design was developed in collaboration Aboriginal health  
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25 organisations and is informed by the best available evidence about effective detection of  
26  
27 health issues and treatment of Australian Aboriginal people. However, the evidence for  
28  
29 effective detection and treatment of Aboriginal people is sparse and there are no studies  
30  
31 about opportunistic screening of Aboriginal people for cardiovascular disease. The available  
32  
33 evidence indicates that Australian Aboriginal and New Zealand Maori populations  
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35 experience AF at a younger age than other populations. This study includes Aboriginal  
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37 people 45 and older. Depending on the findings of this study, future studies may include  
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39 younger people.  
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50 We are conducting opportunistic screening for known and unknown AF in people accessing  
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52 health care services and are recruiting predominantly from rural and remote parts of  
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54 Australia, with some regional sites. This will inevitably bias our sample. To reduce this we  
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56 have instructed our screeners to be as systematic as possible. This will reduce the bias of  
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3 haphazard or selective sampling. Whilst consecutive sampling is not equivalent to random  
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5 sampling it is appropriate for this population group. Our sample will not be completely  
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7 representative of Aboriginal people across Australia as we are concentrating on rural and  
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9 regional areas. The opportunistic sampling and its potential compromise to  
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11 representativeness is a limitation of the study.  
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18 Given the burden of cardiovascular disease borne by Aboriginal Australians and the  
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20 estimated significant rise of AF prevalence in Australia, this study is an important next step  
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22 in preventing premature death or impairment of Aboriginal people from stroke. This mixed  
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24 methods study brings together the best available evidence on AF, opportunistic screening  
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26 and Aboriginal Australians to estimate the prevalence and age distribution of known and  
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28 unknown AF in Aboriginal people in Australia and determine the acceptability of the  
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30 portable iECG device.  
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38  
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40  
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42  
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44  
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46  
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### 54 **Data sharing**

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56 All de-identified data will be shared with all investigators on the study.  
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### Competing interests

Freedman: Research grants to conduct investigator-initiated studies by BMS/Pfizer, Bayer Pharma, and Boehringer-Ingelheim, consultant for Bayer Pharma, BMS/Pfizer, Boehringer-Ingelheim, Servier, Astra-Zeneca and Gilead, and speaker for Bayer Pharma, BMS/Pfizer, AstraZeneca.

Neubeck: has received grants and honoraria from Pfizer BMS, Boehringer Ingelheim and Bayer outside the submitted work.

### Author contributions

Study design – Gwynne, Freedman, Neubeck, Finlayson, McCowen, Martin, Flaskas

Funding application – Gwynne, Flaskas, Freedman

Ethics applications – Gwynne, Flaskas, Jeffries, O'Brien, Freedman

Preparing manuscript – Gwynne

Manuscript review and approval – All authors

Registering as a trial - Gwynne

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1  
2  
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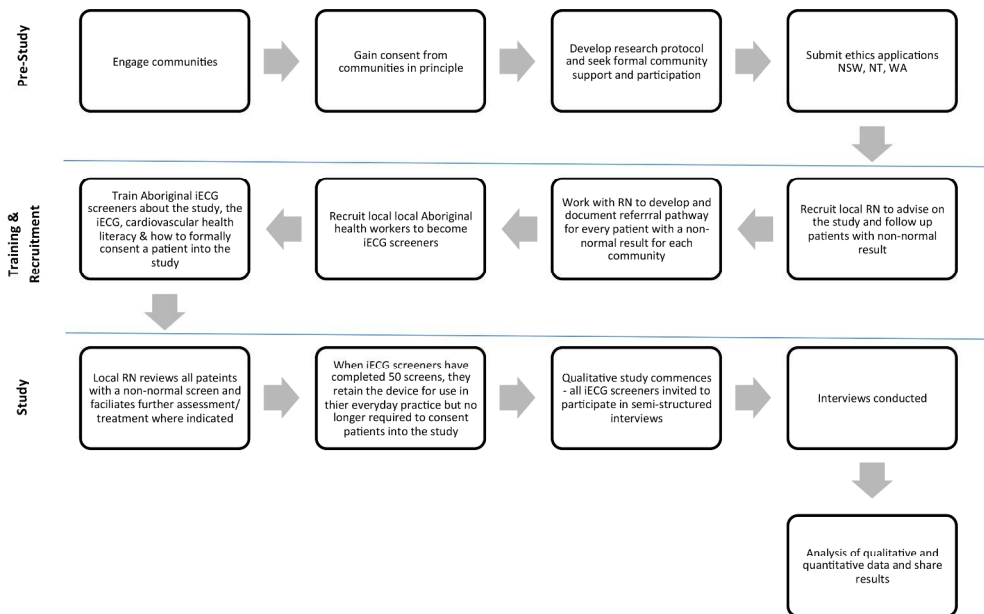
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