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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).

There is very limited information on rates of AF in Australian Aboriginal people, and the only studies available have come from hospitalisation data after an event. These studies found a much higher age-standardised incidence of AF in Aboriginal than in non-Aboriginal patients. This is particularly marked in the younger age groups, with odds ratios of 3.6 for men and 5.4 for women Aboriginal people between ages 20-54. On average, Aboriginal people develop AF approximately 20 years earlier than their non-Aboriginal counterparts, and even more concerning is the high rate of associated co-morbidities found in this subset versus the wider Australian population (12, 13). Risk factors for AF such as hypertension, diabetes, obesity, chronic kidney disease are all more common in younger Aboriginal people than in non-Indigenous people (12, 13). This uneven burden of co-morbidity results in CHA_2DS_2VASc scores (a score developed to indicate risk of stroke) of ≥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).

There is some evidence in the literature for the efficacy of opportunistic screening in the sexual and reproductive health of Aboriginal people (16-19). 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 (20). Critically important is that opportunistic screening must include pathways for further assessment and treatment, and access must be actively facilitated where necessary (21). 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(22, 23). There are no studies of opportunistic screening of Aboriginal people for 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) (24) and is not reliably identified within the heath care setting; the population is also widely dispersed (25); 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 (26). 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. Screening will occur opportunistically within the course of usual duties for a range of qualified and unqualified Aboriginal health care workers who are termed iECG screeners in this paper. The study will also improve the health literacy of iECG screeners and patients about causes, prevention, symptoms and assessment of cardiovascular disease. Further the study will examine effective treatment pathways for cardiovascular disease, and patients

with a non-normal iECG result in order to reduce premature death and impairment, and improve quality of life. There is some evidence in the peer-reviewed literature for the efficacy of each of these elements with Aboriginal people (17, 19, 21, 27, 28).

The four aims of this study are to:

1) determine the acceptability of the portable iECG device to diagnose AF in Aboriginal people and facilitate access to further assessment and treatment;
2) estimate the prevalence of both known and unknown AF in Aboriginal people in Australia and the age distribution;
3) improve health literacy in Aboriginal people and iECG screeners; and
4) help prevent the effects of untreated AF in Aboriginal people, particularly ischemic stroke which may result in early death or impairment.

As there is limited evidence about the prevalence of AF in indigenous populations globally (15) this study should also contribute to the global picture of AF prevalence in indigenous peoples.

Methods and analysis

This is a mixed methods study. We will use quantitative methods to estimate the prevalence and age distribution of AF in Aboriginal people. Qualitative methods will be used to determine the acceptability of the iECG as a screening tool for Aboriginal people, and the effect of the intervention on improving health literacy. Qualitative methods will also be used to determine the effectiveness of the clinical pathways established for patients with a non-normal iECG result. In this context effectiveness refers to whether Aboriginal people seek follow up assessment and/or treatment, and whether they are able to access it.

The iECG has been chosen for this study as it is small (clips onto the back of most smartphones); can be used by anyone with minimal training; and records a single-lead ECG in approximately 30 seconds. A validated algorithm allows reliable detection of AF and other arrhythmias in real-time (14). This device enables cost-effective community-based screening, including rural and remote locations. The device is accurate and FDA and TGA approved (ARTG Identifier 208100) and has been used in studies to identify AF in Metropolitan Sydney (14) and Melbourne. After the ECG is completed, the data is transmitted to the password encrypted and HIPPAA compliant Kardia proprietary server. Another account will store de-identified ECG screening data for this study.

Participating health services will be supplied with the iECG device and smartphone for each health worker who will be undertaking screens in the study. The smartphone will have an activated Sim Card to enable the iECG software to transmit the ECG via the telephone data network. The participating health service will keep the iECG device after the completion of the study to benefit their health service.

The study will take place in communities in New South Wales, Northern Territory and Western Australia in collaboration with Aboriginal Community Controlled Health Services and other services which meet the needs of Aboriginal people in those communities (for example: hospital, dental service, pharmacy, and community centre). Each participating service will nominate local Aboriginal health or health-related workers with a good understanding of the local health care system and a willingness to participate in the study. The local Aboriginal health workforce have been identified to participate in the study

because they are likely to be trusted by Aboriginal people and have a high level of cultural competence, understand the local health system, and are likely to be able to facilitate and expedite access to the local health system. Cultural competence is well established in the literature as a critical factor in Aboriginal people participating in health care services (29-31). These workers will be termed iECG screeners in this study. The iECG screeners will receive training in the use of the iECG device, consent processes, cardiovascular health promotion and treatment, data collection and the clinical pathway for patients with a non-normal result.

This study will screen 1500 Aboriginal people, with each iECG screener conducting 50 screens on eligible patients in order to reach a total of 1500 screens. The eligibility criteria for this study are:

1. Aboriginal heritage;
2. Aged 45 years or more; and
3. Living in New South Wales, Northern Territory or Western Australia.

Eligible participants will be formally consented into the study and receive an information sheet explaining the study. All participants will also receive a plain English and pictorial information sheet setting out the risk factors for cardiovascular disease, the ways to reduce risk and promote heath, a straightforward explanation of the symptoms of a cardiovascular disease adverse event, and what to do if experiencing those symptoms.

The iECG has three possible results normal, possible AF or unclassified. Participants who record a result other than normal will be referred for a confirmatory 12-lead ECG and

individual management plan. This management plan will be supported by the iECG screener and will proceed according to the agreed pathway. The assessment and treatment pathways for patients with a non-normal result will be negotiated, agreed and documented with each community before commencing the study in that site. A Registered Nurse associated with the study will review all cases where a patient has a non-normal result within 24 hours of the screen and take all steps to ensure the participant has accessed further assessment and treatment where indicated.

Once the 1500 screens have been completed, data will be exported from the AliveCor server and analyzed to estimate the prevalence and age distribution of AF in Aboriginal people in Australia. The interviewer-assisted surveys will be conducted face to face or via telephone with the iECG screeners by a member of the research team. This will include, wherever possible, iECG screeners who did not complete 50 screens. The surveys will identify the enabling factors and barriers for: (i) Aboriginal workers using the iECG in the course of their practice; (ii) Aboriginal patients' receptiveness to the iECG; and (iii) the likelihood that patients screened using iECG seek out and/or access recommended follow up assessment and treatment.

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 and Aboriginal Australians. The study aims to estimate the prevalence and age distribution

of known and unknown AF in Aboriginal people in Australia; determine the acceptability of the portable iECG device to diagnose abnormal heart rhythm in Aboriginal people and facilitate access to further assessment and treatment; and improve the cardiovascular disease health literacy of Aboriginal people. The study will also contribute to the global

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 for this study is detailed in Figure 1.

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.

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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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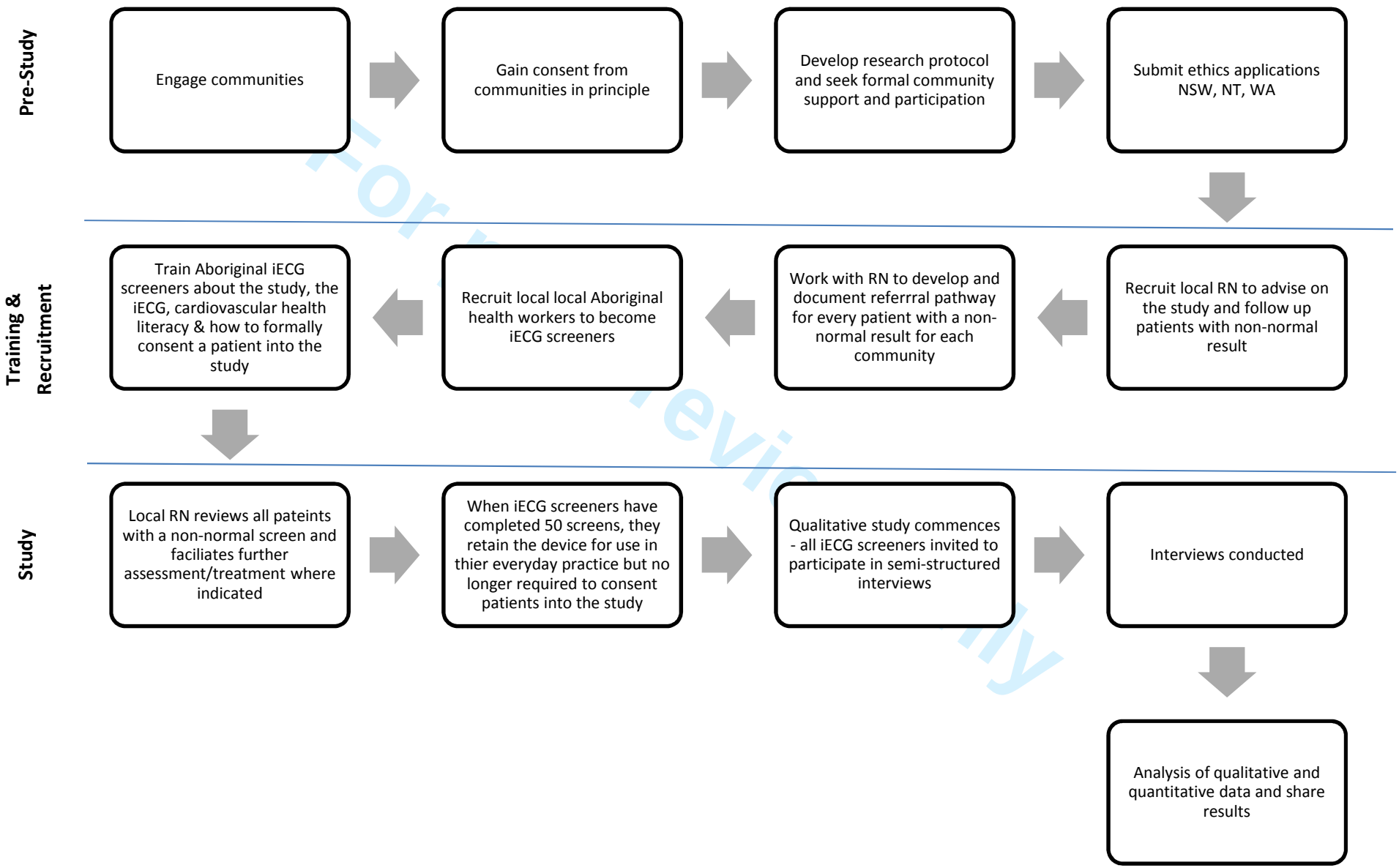

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Abstract

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-

12). The burden of stroke for Aboriginal people is considerable with Aboriginal people more likely than other Australians to suffer a stroke (12, 13). 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 (14). 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 (15, 16). 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 (17, 18).

AF prevalence in the Australian population is estimated to rise significantly over the next two decades (19). In people with AF, both stroke and death are greatly reduced by treatment with oral anticoagulant (by approximately 64% and 26% respectively) (17, 18). 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 (20, 21). To prevent strokes resulting from unknown AF, screening for asymptomatic AF could be helpful (22).

There is very limited information on rates of AF in Australian Aboriginal people, and the only studies available have come from hospitalisation data after an event. These studies found a much higher age-standardised incidence of AF in Aboriginal than in non-Aboriginal patients. This is particularly marked in the younger age groups, with ratios of age standardised

incidence rates of AF 3.6 for men and 5.4 for women for Aboriginal people compared to non-Aboriginal people between ages 20-54. On average, Aboriginal people develop AF approximately 20 years earlier than their non-Aboriginal counterparts, and even more concerning is the high rate of associated co-morbidities found in this subset versus the wider Australian population (20, 21). Risk factors for AF such as hypertension, diabetes, obesity, physical inactivity, chronic kidney disease, acute rheumatic fever, and rheumatic heart disease are all more common in Aboriginal people and at a younger age than in non-Indigenous people (20, 21) (23). This uneven burden of co-morbidity results in CHA_2DS_2VASc scores (a score developed to indicate risk of stroke) of ≥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 (20). Aboriginal people therefore face a double jeopardy of increased AF incidence at a younger age, and an increased risk of stroke when AF occurs (20, 21).

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. Aboriginal people 45 years and over make up just 18% of the Aboriginal population in Australia (24). By comparison the total Australian population aged 45 years and over is 39.6% (24). 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 (20, 21, 25).

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 heath 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).

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

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

As there is limited evidence about the prevalence of AF in indigenous populations globally (25) this study should also contribute to the global picture of AF prevalence in indigenous peoples.

Methods and analysis

Study Design

This is a mixed methods study. We will use quantitative methods to determine the proportion of participants with a non-normal result who presented for follow-up assessment and treatment, and to estimate the prevalence and age distribution of AF in Aboriginal people. Qualitative methods will be used to determine the acceptability of the iECG as a screening tool for iECG screeners and Aboriginal participants, and the effect of the intervention on improving health literacy.

The study will take place in communities in New South Wales, Northern Territory and Western Australia in collaboration with Aboriginal Community Controlled Health Services

and other services which meet the needs of Aboriginal people in those communities (for example: hospital, dental service, pharmacy, and community centre). Each participating service will nominate local Aboriginal health or health-related workers with a good understanding of the local health care system and a willingness to participate in the study.

The local Aboriginal health workforce have been identified to participate in the study because they are likely to be trusted by Aboriginal people and have a high level of cultural competence, understand the local health system, and are likely to be able to facilitate and expedite access to the local health system. Cultural competence is well established in the literature as a critical factor in Aboriginal people participating in health care services (39-41). These workers will be termed iECG screeners in this study. The iECG screeners will receive training in the use of the iECG device, consent processes, cardiovascular health promotion and treatment, data collection and the clinical pathway for patients with a non-normal result and will conduct the screens as part of their usual interactions with patients in the community, home or clinic. There is some evidence in the peer-reviewed literature for the efficacy of each of the study design elements with Aboriginal people (27, 29, 31, 42, 43).

Data collection method

The iECG has been chosen for this study because it has been success with other populations (22, 36-38), it is small (clips onto the back of most smartphones); can be used by anyone with minimal training; and records a single-lead ECG in approximately 30 seconds. A validated algorithm allows reliable detection of AF and other arrhythmias in real-time (22). This device enables cost-effective community-based screening, including rural and remote

locations. The device is accurate and FDA and TGA approved (ARTG Identifier 208100) and has been used in studies to identify AF in Metropolitan Sydney (22) and Melbourne. After the ECG is completed, the data is transmitted to the password encrypted and HIPPAA compliant Kardia proprietary server. Another account will store de-identified ECG screening data for this study.

Participating health services will be supplied with the iECG device and smartphone for each health worker who will be undertaking screens in the study. The smartphone will have an activated Sim Card to enable the iECG software to transmit the ECG via the telephone data network. The participating health service will keep the iECG device after the completion of the study to benefit their health service.

Gaining informed consent and conducting the screens will occur opportunistically within the course of usual duties for a range of qualified and unqualified iECG screeners. iECG screeners will invite consecutive patients to participate in the study which should reduce bias in the sample.

This study will screen 1500 Aboriginal people, which represents 1% of the total Aboriginal population aged 45 years and over (24). Thirty iECG screeners will conduct 50 screens on eligible patients in order to reach a total of 1500 screens. Given the additional time required to gain informed consent for patients to join the study and the wide-ranging roles and responsibilities of Aboriginal workers in the health care system, the study explicitly limits

each screener to 50 screens. Once they have completed the 50 screens for the study they can retain the device and use it in their usual practice.

The eligibility criteria for this study are:

1. Aboriginal heritage;
2. Aged 45 years or more; and
3. Living in New South Wales, Northern Territory or Western Australia.

Eligible participants will be formally consented into the study by an Aboriginal iECG screener. Participants will receive an information sheet explaining the study and a plain English and pictorial information sheet setting out the risk factors for cardiovascular disease, the ways to reduce risk and promote heath, a straightforward explanation of the symptoms of a heart disease and what to do if experiencing those symptoms.

The iECG has three possible results normal, possible AF or unclassified. Participants who record a result other than normal will be referred for a confirmatory 12-lead ECG and individual management plan. This management plan will be supported by the iECG screener and will proceed according to the agreed pathway. The assessment and treatment pathways for patients with a non-normal result will be negotiated, agreed and documented with each community before commencing the study in that site. A Registered Nurse associated with the study will review all cases where a patient has a non-normal result, within 24 hours of the screen, and take all steps to ensure the participant has accessed further assessment and treatment where indicated. The Registered Nurse will follow up with every patient with a non-normal result and facilitate access to further assessment and

treatment where this is indicated. The Registered Nurse will also record in a database whether or not the patient with a non-normal iECG attended for a 12-lead ECG, whether or not they had AF, and whether or not they knew they had AF prior to the screen. The fidelity of the intervention will be assessed quantitatively by recording the number of patients who do not complete the protocol and qualitatively through interviews with iECG screeners and the Registered Nurses.

Once the 1500 screens have been completed, data will be exported from the AliveCor server and analyzed to estimate the prevalence and age distribution of AF in Aboriginal people in Australia. The interviewer-assisted surveys will be conducted face to face or via telephone with the iECG screeners by a member of the research team. This will include, wherever possible, iECG screeners who did not complete 50 screens. The surveys will identify the enabling factors and barriers for: (i) Aboriginal workers using the iECG in the course of their practice and (ii) Aboriginal patients' receptiveness to the iECG.

Data analysis

1500 people represent 1% of the Aboriginal population in Australia aged 45 years and older and is therefore a reasonable sample to estimate prevalence. If we assume a prevalence of AF of 3% in this population, then the 95% CI of this would be 2.0%-4.0% with this sample size.

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.

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

and Aboriginal Australians 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.

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Data sharing

All de-identified data will be shared with all investigators on the study.

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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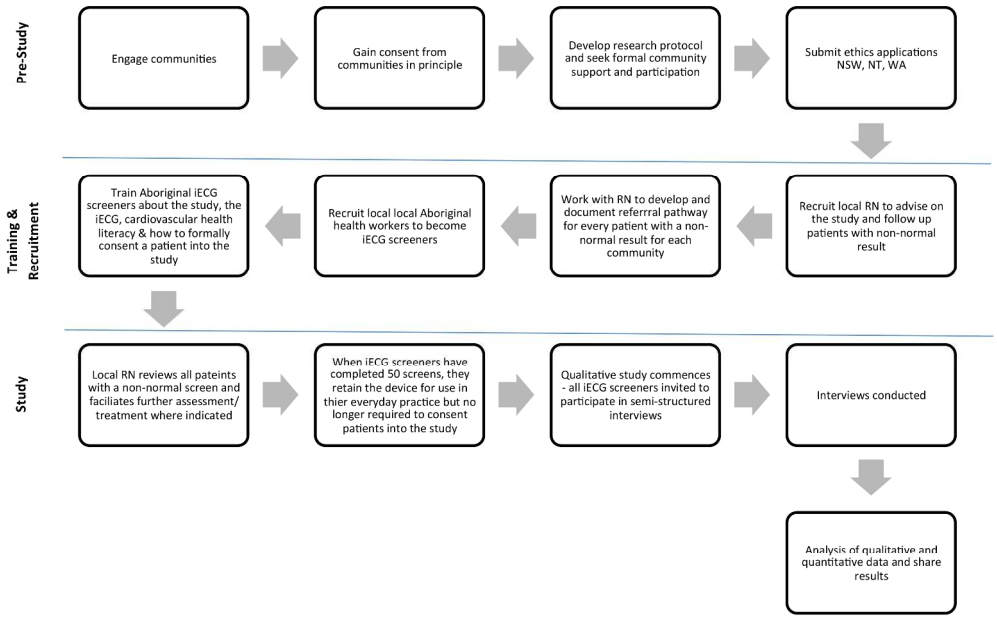

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Title

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

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. They will also be involved in data analysis, dissemination 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

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

(8, 9). Cardiovascular disease remains the leading cause of death for this population (10-12). The burden of stroke for Aboriginal people is considerable with Aboriginal people more likely than other Australians to suffer a stroke (12, 13). 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 (14). 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 (15, 16). 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 (17, 18).

AF prevalence in the Australian population is estimated to rise significantly over the next two decades (19). In people with AF, both stroke and death are greatly reduced by treatment with oral anticoagulant (by approximately 64% and 26% respectively) (17, 18). 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 (20, 21). To prevent strokes resulting from unknown AF, screening for asymptomatic AF could be helpful (22).

There is very limited information on rates of AF in Australian Aboriginal people, and the only studies available have come from hospitalisation data after an admission. These studies found a much higher age-standardised incidence of AF in Aboriginal than in non-Aboriginal

patients. This is particularly marked in the younger age groups, with ratios of age standardised incidence rates of AF 3.6 for men and 5.4 for women for Aboriginal people compared to non-Aboriginal people between ages 20-54. On average, Aboriginal people develop AF approximately 20 years earlier than their non-Aboriginal counterparts, and even more concerning is the high rate of associated co-morbidities found in this subset versus the wider Australian population (20, 21). Risk factors for AF such as hypertension, diabetes, obesity, physical inactivity, chronic kidney disease, acute rheumatic fever, and rheumatic heart disease are all more common in Aboriginal people and at a younger age than in non-Indigenous people (20, 21, 23). This uneven burden of co-morbidity results in CHA_2DS_2VASc scores (a score developed to indicate risk of stroke) of ≥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 (20). Aboriginal people therefore face a double jeopardy of increased AF incidence at a younger age, and an increased risk of stroke when AF occurs (20, 21).

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. Aboriginal people 45 years and over make up just 18% of the Aboriginal population in Australia (24). By comparison the total Australian population aged 45 years and over is 39.6% (24). 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 (20, 21, 25).

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 heath 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).

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

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

As there is limited evidence about the prevalence of AF in indigenous populations globally (25) this study should also contribute to the global picture of AF prevalence in indigenous peoples.

Methods and analysis

Study Design

This is a mixed methods study. We will use quantitative methods to determine the proportion of participants with a non-normal result who presented for follow-up assessment and treatment, and to estimate the prevalence and age distribution of AF in Aboriginal people. Qualitative methods will be used to determine the acceptability of the iECG as a screening tool for iECG screeners and Aboriginal participants, and the effect of the intervention on improving health literacy in Aboriginal patients.

The study will take place in communities in New South Wales, Northern Territory and Western Australia in collaboration with Aboriginal Community Controlled Health Services and other services which meet the needs of Aboriginal people in those communities (for example: hospital, dental service, pharmacy, and community centre). Each participating service will nominate local Aboriginal health or health-related workers with a good understanding of the local health care system and a willingness to participate in the study.

Data collection method

The local Aboriginal health workforce have been identified to participate in the study as data collectors because they are likely to be trusted by Aboriginal people and have a high level of cultural competence, understand the local health system, and are likely to be able to facilitate and expedite access to the local health system. Cultural competence is well established in the literature as a critical factor in Aboriginal people participating in health care services (39-41). These workers will be termed iECG screeners in this study. The iECG screeners will receive training in the use of the iECG device, consent processes, cardiovascular health promotion and treatment, data collection and the clinical pathway for patients with a non-normal result and will conduct the screens as part of their usual interactions with patients in the community, home or clinic. There is some evidence in the peer-reviewed literature for the efficacy of each of the study design elements with Aboriginal people (27, 29, 31, 42, 43).

The iECG has been chosen as the screening tool for this study because it has been success with other populations (22, 36-38), it is small (clips onto the back of most smartphones); can

be used by anyone with minimal training; and records a single-lead ECG in approximately 30 seconds. A validated algorithm allows reliable detection of AF and other arrhythmias in real-time (22). This device enables cost-effective community-based screening, including rural and remote locations. The device is accurate and FDA and TGA approved (ARTG Identifier 208100) and has been used in studies to identify AF in Metropolitan Sydney (22) and Melbourne. After the ECG is completed, the data is transmitted to the password encrypted and HIPPAA compliant Kardia proprietary server. Another account will store de-identified ECG screening data for this study.

Participating health services will be supplied with the iECG device and smartphone for each health worker who will be undertaking screens in the study. The smartphone will have an activated Sim Card to enable the iECG software to transmit the ECG via the telephone data network. The participating health service will keep the iECG device after the completion of the study to benefit their health service.

Sampling strategy

Gaining informed consent and conducting the screens will occur opportunistically within the course of usual duties for a range of qualified and unqualified iECG screeners. iECG screeners will invite consecutive patients to participate in the study which should reduce bias in the sample. 1500 people represent 1% of the Aboriginal population in Australia aged 45 years and older and is therefore a reasonable sample to estimate prevalence. If we assume a prevalence of AF of 3% in this population, then the 95% CI of this would be 2.0%-4.0% with this sample size.

Thirty iECG screeners will conduct 50 screens on eligible patients in order to reach a total of 1500 screens. Given the additional time required to gain informed consent for patients to join the study and the wide-ranging roles and responsibilities of Aboriginal workers in the health care system, the study explicitly limits each screener to 50 screens. Once they have completed the 50 screens for the study they can retain the device and use it in their usual practice.

The eligibility criteria for this study are:

1. Aboriginal heritage;
2. Aged 45 years or more; and
3. Living in New South Wales, Northern Territory or Western Australia.

Procedure

Eligible participants will be formally consented into the study by an Aboriginal iECG screener. Participants will receive an information sheet explaining the study and a plain English and pictorial information sheet setting out the risk factors for cardiovascular disease, the ways to reduce risk and promote heath, a straightforward explanation of the symptoms of a heart disease and what to do if experiencing those symptoms.

The iECG has three possible results normal, possible AF or unclassified. Participants who record a result other than normal will be referred for a confirmatory 12-lead ECG and individual management plan. This management plan will be supported by the iECG screener and will proceed according to the agreed pathway. The assessment and treatment

pathways for patients with a non-normal result will be negotiated, agreed and documented with each community before commencing the study in that site. A Registered Nurse associated with the study will review all cases where a patient has a non-normal result, within 24 hours of the screen, and take all steps to ensure the participant has accessed further assessment and treatment where indicated. The Registered Nurse will follow up with every patient with a non-normal result and facilitate access to further assessment and treatment where this is indicated. The Registered Nurse will also record in a database whether or not the patient with a non-normal iECG attended for a 12-lead ECG, whether or not they had AF, and whether or not they knew they had AF prior to the screen. The fidelity of the intervention will be assessed quantitatively by recording the number of patients who do not complete the protocol and qualitatively through interviews with iECG screeners and the Registered Nurses.

Once the 1500 screens have been completed, data will be exported from the AliveCor server and analyzed to estimate the prevalence and age distribution of AF in Aboriginal people in Australia. The interviewer-assisted surveys will be conducted face to face or via telephone with the iECG screeners by a member of the research team. This will include, wherever possible, iECG screeners who did not complete 50 screens. The surveys will identify the enabling factors and barriers for: (i) Aboriginal workers using the iECG in the course of their practice and (ii) Aboriginal patients' receptiveness to the iECG as perceived by the iECG screeners.

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.

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 sparse 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 reduce this we have instructed our screeners to be as systematic as possible. This will reduce the bias of

haphazard or selective sampling. Whilst consecutive sampling is not equivalent to random sampling it is appropriate for this population group. Our sample will not be completely representative of Aboriginal people across Australia as we are concentrating on rural and regional areas. The opportunistic sampling and its potential compromise to representativeness 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 and Aboriginal Australians 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.

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Data sharing

All de-identified data will be shared with all investigators on the study.

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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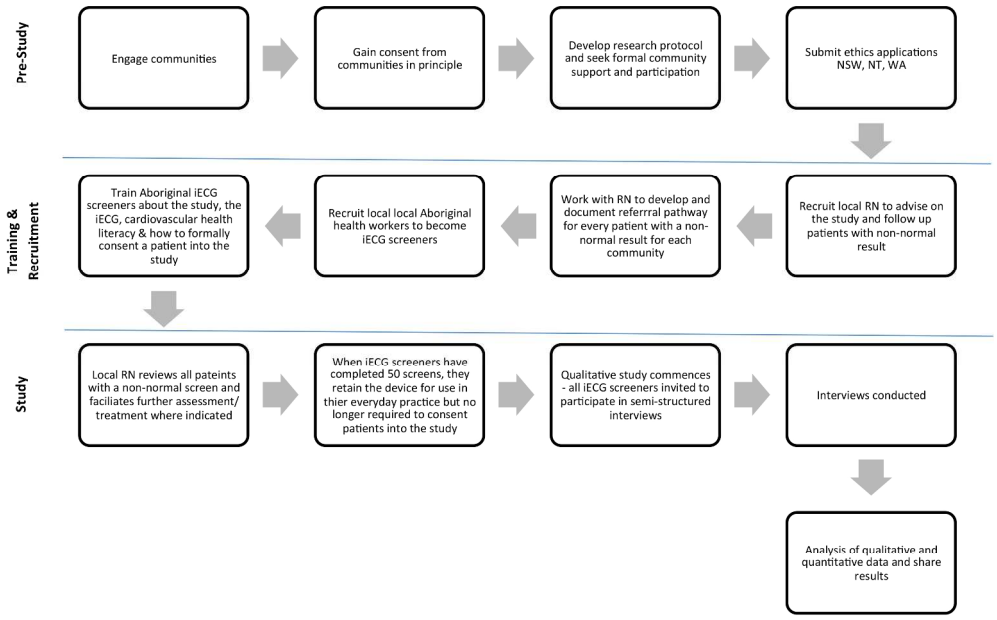

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