Patient-Led Mass Screening for Atrial Fibrillation in the Older Population Using Handheld Electrocardiographic Devices Integrated with a Clinician-Coordinated Remote Central Monitoring System

Short title: The Mass Atrial Fibrillation Screening (MAFS)

STATISTICAL ANALYSIS PLAN

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(Principal Investigator)

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1.0 Modification history

Version	Version date	Primary author	Significant change(s) from the previous version
V1.0	15th March 2023	Kam Wong	Restructured, reviewed, and approved by the team.

2.0 Introduction

There is lack of data regarding the feasibility, effectiveness, and acceptability of patient-led atrial fibrillation (AF) screening by remote patient self-recording of single-lead electrocardiograms (ECGs) with centralized clinician-supported monitoring in older community-dwelling people. The Mass AF screening program is designed for implementation among community-dwelling people aged ≥75 years. It comprises the provision of a handheld ECG device and training of participants to self-screen on weekdays and transmit ECGs for review by a central monitoring team. We aim to implement and evaluate this AF self-screening program in which older people in the community are empowered to perform repeated heart rhythm monitoring using a single-lead handheld ECG device and connected with health care providers who review and support the diagnosis of AF and management by primary care and specialist services. We hypothesize that the proposed self-screening model of care may lead to several positive outcomes, including a feasible and scalable model for implementing patient-led AF screening in community-dwelling older people, improved patient satisfaction by empowering them with the relevant knowledge and skills to perform self-screening.

This document describes the statistical methodology and intended analyses of the Mass Atrial Fibrillation Screening Study (see the published protocol: Wong et al 2022). The study objectives, design, outcomes, sample size, randomisation, data collection and management, and planned analysis are described. The proposed layouts of tables and figures are included.

3.0 Objectives

Our study objectives are to (1) compare AF ascertainment rates in the intervention and control groups; (2) evaluate the feasibility of the intervention, including assessing participant satisfaction, acceptability, barriers, and enablers; and (3) assess agreements between the ECG device automatic algorithm and clinician interpretation.

4.1 Study design

This is an open-label randomised controlled trial among community-dwelling people aged ≥75 years. The intervention is a program of patient-led screening for atrial fibrillation (AF) using AliveCor handheld single-lead ECG devices. Control participants are 'wait-listed'and they receive usual care from their general practitioners for the first 6 months and receive the intervention program for the subsequent 6 months. Participants' ECGs were monitored by clinicians remotely. Participants and their GPs are notified of AF and other clinically significant ECG abnormalities.

4.2 Sample size

The sample size was determined by considering the primary feasibility outcome, i.e. participant satisfaction score and primary clinical outcome i.e. AF detection, illustrated as follows:

- In computing the sample size required to assess the primary feasibility outcome, we will evaluate the proportion of participants reporting being satisfied or very satisfied that their heart rhythm was monitored in the past six months in the intervention group versus the control group. We arbitrarily set that 50% of the participants in the control group would be satisfied or very satisfied. With reference to the literature that reported a proportion of 67% to 82% of older people were satisfied or very satisfied with the use of technology-enabled monitoring at home, we postulate that there will be an absolute 30% increase in satisfaction in the intervention group compared with the control group. Our study will have 80% power, using a 5% significance level, to detect an absolute difference of 30% in satisfaction between the two groups. A sample size of 100 participants aged ≥75 years is required to assess the primary feasibility outcome.
- To calculate the sample size required to evaluate the primary clinical outcome of the AF detection, we set an AF detection of 10% in the intervention group and 1% in the control group, according to a recent study (Gladstone DJ et al 2021). At 80% power, a 2-sided test, and α 0.05, we estimate that a sample of 200 participants will be needed to detect a significant difference in AF detection between the intervention and control groups. Therefore, 200 participants will be recruited for this trial to assess the primary clinical outcome.

The larger sample size (200) was adopted to cover both the primary feasibility and clinical outcomes.

4.3 Randomisation

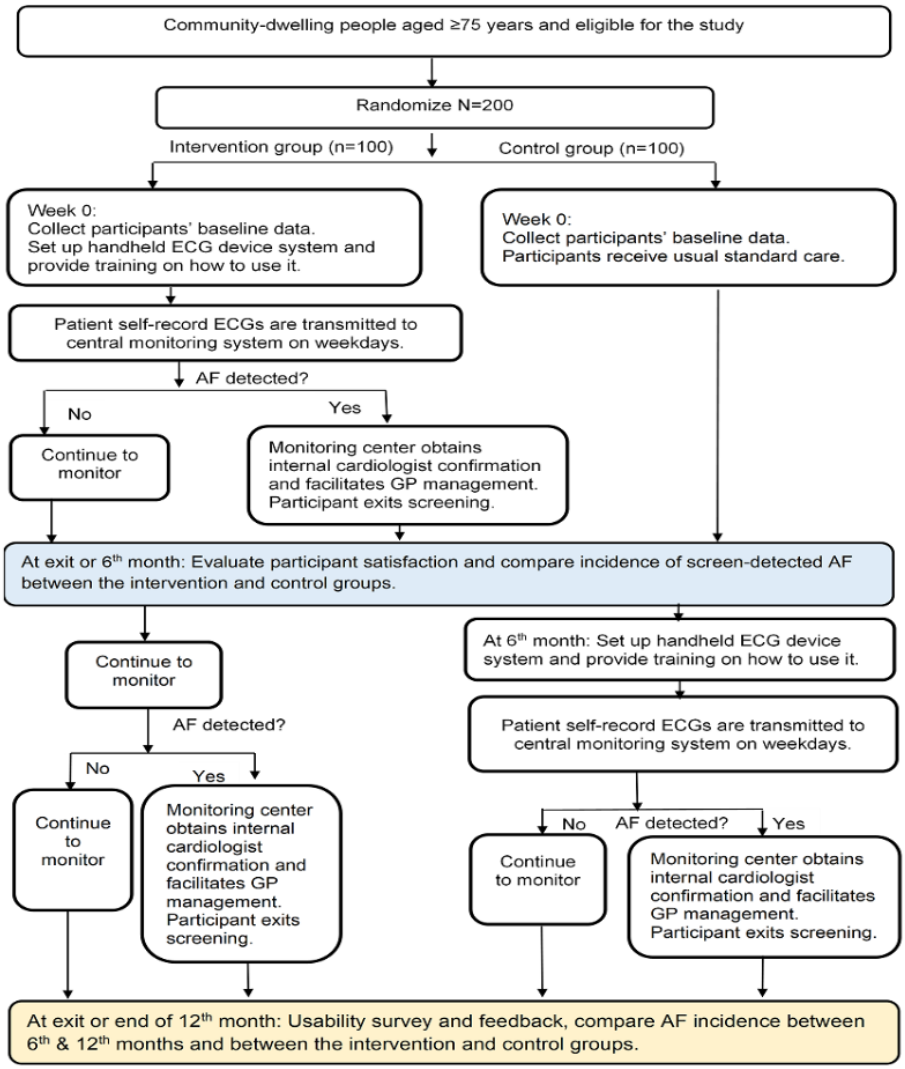
Participants are randomised in a 1:1 (intervention: control) ratio and stratified by participant frailty status (frail or non-frail). Participant frailty is determined using the "Fatigue, Resistance, Ambulation, Illnesses, and Loss of Weight" (FRAIL) scale based on five components: fatigue, resistance (inability to climb stairs), ambulation (inability to walk a certain distance), illness, and loss of weight.

4.4 Blinding

This is an open-label trial. Participants are told that they are waitlisted for six months before commencing the ECG monitoring program in the subsequent six months. The principal investigator and statistician are blinded to randomisation until the completion of the trial.

4.5 Study flow

The steps involved for enrolment, randomisation, intervention, control and exit from the program are outlined in the following study flowchart which was included in the published protocol (Wong et al 2022).



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4.6 Data collection and data management

Data collection is conducted virtually (by telephone) because of COVID-19 pandemic restrictions.

Participant data

Participants are eligible individuals according to the inclusion and exclusion criteria of the protocol. Participant data collected and stored in the REDCap system which included the demographic data and medications.

ECG central monitoring data

Participants' ECG data are transmitted to the Kardia Pro central monitoring system. The authorised research team members (PhD student investigator (KCW), cardiac technicians (ST and AI), research assistants (MB, RW) and project manager (VG)) have access to the central monitoring system. The ECG data are extracted from the central monitor system using R-program via an application program interface. The ECG data include:

- ECG rhythm traces with date and time
- ECG device (AliveCor Kardia) automatic interpretations
- Participants' pulse rates

4.7 Outcomes definition

The outcomes are categorised into clinical and feasibility outcomes.

Clinical outcomes:

New Atrial Fibrillation - AF is a medical diagnosis i.e., AF is confirmed by a clinician using ECGs including single-lead rhythm traces confirmed by a cardiologist.

Feasibility outcomes:

(a) participant satisfaction score: Participants are asked about their satisfaction that their heart rhythm was monitored.

(b) participant usability score evaluates the following: ease of use of the device, time efficiency in using the device, anxious about using the device and sharing health information, interruption to daily routine, confidence in using the device, satisfaction with the device, device effectiveness in detecting irregular heart rhythm and intention to continue using the device.

(c) participants' engagement was measured by their number of "active days" transmitting ECGs

4.8 Management of changes

Changes to the conduct of the study will be recorded as process variations. They will be discussed in the project management meeting.

Changes in the conduct of the study

This document is established with reference to the protocol version 3.0 dated 3rd November 2021 approved by the Human Research Ethics Committee at the University of Sydney. If changes were to occur during the trial, they would be recorded in the "Modification history" in this document.

Changes in the planned analyses

Changes in the planned analyses will be discussed in the project meeting and reviewed by the statistician. The changes are subject to the approval of the principal investigator, and they will be documented in the "Modification history".

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5.0 Statistical methods

This section describes the general methodology applied to analyse various variables and management of premature exits and missing data.

5.1 General methodology

Histograms and boxplots will be constructed to examine the distributions of continuous variables. Outliers will be reviewed and discussed in the research team meeting. Outliers due to data entry errors will be corrected. If the outliers were not data entry errors, they remain in the analysis. Sensitivity analysis will be performed to examine whether the outliers had affected the robustness of the findings.

The normality of the distribution of continuous variables will be assessed with the Shapiro-Wilk test and histograms. Normally distributed continuous variables will be presented as mean and standard deviation (SD) and evaluated using the t-test. Non-normally distributed data will be presented as median with interquartile range (IQR) and assessed using the Mann-Whitney test. Categorical variables will be presented as frequencies and percentages and evaluated using the chi-square test or Fisher exact test as appropriate.

All statistical tests will be 2-tailed with $P<0.05$ as statistically significant. Unless otherwise specified, all intervention evaluations will be performed on the principle of 'intention to treat'.

Mock tables are included to show the expected layout of the analysis.

SPSS and R statistical software will be used to analyze the data.

5.2 Handling of dropouts

Dropout refers to a participant who exits the study prematurely. Dropouts are handled as follows:

- The cause of premature exit from the study is examined and documented
- There is no coercion to persuade any participant to stay in the study
- There is no replacement for dropout

5.3 Handling of missing data

Missing data are incomplete data that can occur at various stages of the study. The pattern of missing data, that is, the randomness of the missing data and its causes will be examined, and appropriate remedial actions will be taken as follows:

- Incomplete participant demographic data and baseline data – The research team will contact participants to clarify and obtain the missing data, document the cause for the missing data and make a note in the "Patient Contact Form" in REDCap.
- Missing ECG for three consecutive working days – The research team will contact participants, find out the cause and help participants address the cause if possible and record the communications in an Excel spreadsheet. Participants will resume ECG recording and transmission. There is no replacement for the missing ECG data.

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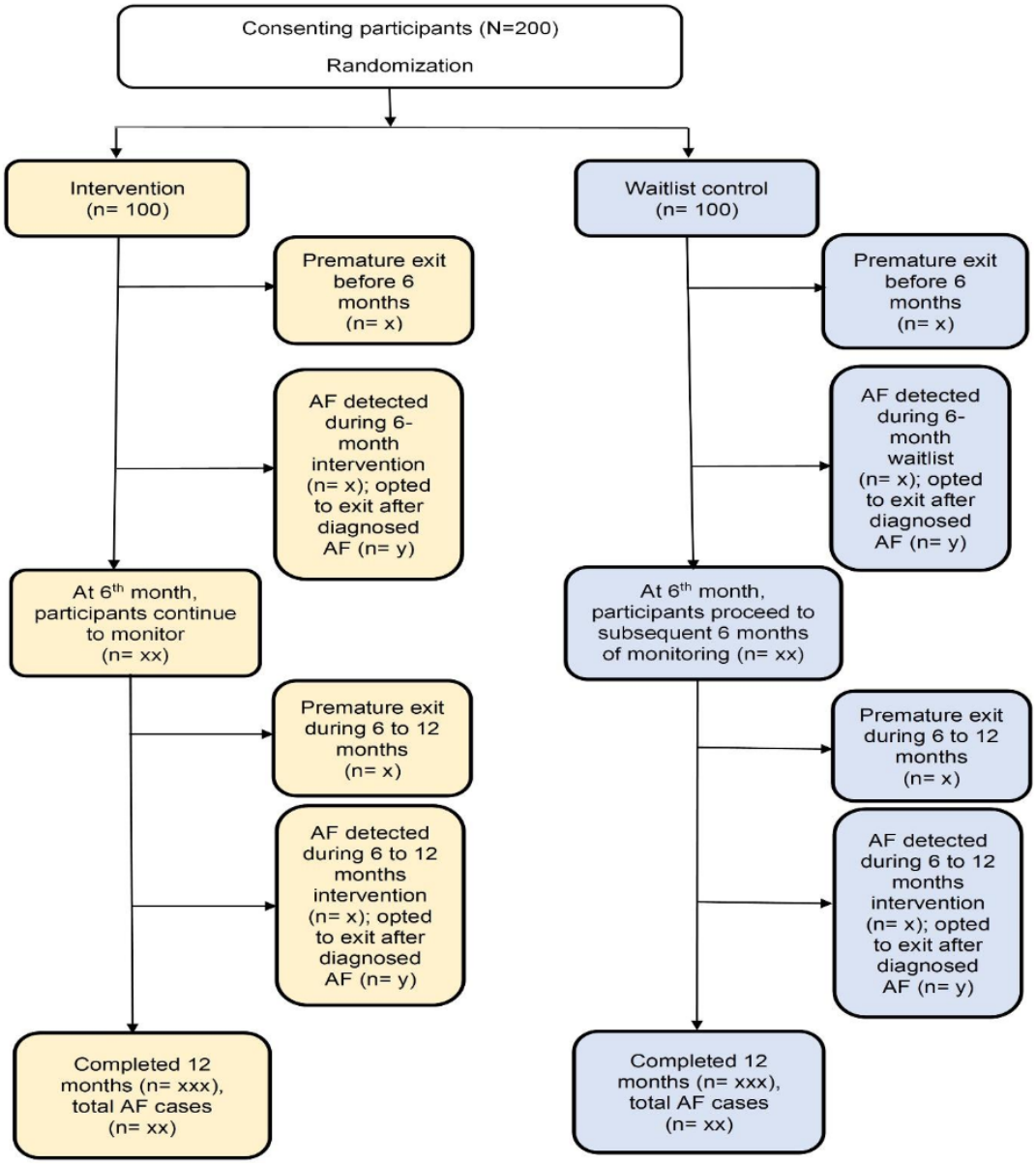
6.0 Statistical analysis

At the completion of the trial, i.e. the last patient has completed the monitoring program and the Study Completion Form is completed in REDCap, the authorized research team members (PhD student investigator (KCW), project manager (VG) and research officers (MB & RW) will check and confirm that the data is complete. The dataset will be locked (i.e. no further amendment), and it will be downloaded for analysis using SPSS and R software.

6.1 Participant disposition

Participant disposition referred to screening participant eligibility, randomizing them into intervention and waitlist control groups and documenting the reasons for their exclusion and discontinuation. Information about enrolled and randomized participants in the study are recorded in the REDCap. Information about participants who declined to participate and who did not meet the inclusion criteria and the reasons are recorded in an Excel spreadsheet in the shared drive. These sources of information will be described and summarized in Figure 1 "Participant randomization and disposition".

Figure 1. Participant randomization and disposition.



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6.2 Participant recruitment

Participant recruitment rate is computed from the number of participants recruited over time. The recruitment data is recorded in an Excel spreadsheet. A cumulative frequency graph will be plotted (Figure 2. Participant recruitment cumulative frequency graph) and the number of participants recruited by each recruitment source will be tabulated (Table 1. The number of participants by each recruitment source).

Table 1. The number of participants recruited by each recruitment source.

Recruitment source	**Total = 200; n (%)**
General practitioners	xx (xx)
Peers and family:	xx (xx)
Friends & participants in the study	xx
Family/ Partner	xx
Face-to-face community recruitment talks:	xx (xx)
Bicycle club & various community clubs	xx
Retirement residences (urban)	xx
Flyers (self-referred)	xx (xx)
Media (a rural newspaper)	xx (x)
Others	xx (xx)

6.3 Participant baseline characteristics

Table 2. Participant baseline characteristics by intervention and waitlist-controlled groups.

Characteristics	Intervention n (%)	Control n (%)	Total n (%)
Participants enrolled	100 (50.0)	100 (50.0)	200 (100.0)
Age, mean (SD), years	yy (SD)	yy (SD)	yy (SD)
Female	xx (xx.x)	xx (xx.x)	xx (xx.x)
Male	xx (xx.x)	xx (xx.x)	xx (xx.x)
Location:			
Major city	xx (xx.x)	xx (xx.x)	xx (xx.x)
Regional/ Rural	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity:			
Caucasian	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asian	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)
Education			
None	xx (xx.x)	xx (xx.x)	xx (xx.x)
Primary school	xx (xx.x)	xx (xx.x)	xx (xx.x)
High school	xx (xx.x)	xx (xx.x)	xx (xx.x)
Higher education	xx (xx.x)	xx (xx.x)	xx (xx.x)
Smoking			
Never	xx (xx.x)	xx (xx.x)	xx (xx.x)
Current	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ex-smoker	xx (xx.x)	xx (xx.x)	xx (xx.x)
Alcohol consumption	xx (xx.x)	xx (xx.x)	xx (xx.x)
Reported weight, kg	xx (xx.x)	xx (xx.x)	xx (xx.x)
Reported height, m	xx (xx.x)	xx (xx.x)	xx (xx.x)
BMI	xx (xx.x)	xx (xx.x)	xx (xx.x)
Physical activity level	xx (xx.x)	xx (xx.x)	xx (xx.x)
Chronic health conditions:			
Hypertension	xx (xx.x)	xx (xx.x)	xx (xx.x)
Coronary heart disease	xx (xx.x)	xx (xx.x)	xx (xx.x)
Peripheral artery disease	xx (xx.x)	xx (xx.x)	xx (xx.x)
Aortic atherosclerosis	xx (xx.x)	xx (xx.x)	xx (xx.x)
Stroke/TIA	xx (xx.x)	xx (xx.x)	xx (xx.x)
Heart failure	xx (xx.x)	xx (xx.x)	xx (xx.x)
Diabetes	xx (xx.x)	xx (xx.x)	xx (xx.x)
COPD	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asthma	xx (xx.x)	xx (xx.x)	xx (xx.x)
Arthritis	xx (xx.x)	xx (xx.x)	xx (xx.x)
Kidney disease	xx (xx.x)	xx (xx.x)	xx (xx.x)
Dyslipidaemia	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)
CHA2DS2-VASc score*	xx (xx.x)	xx (xx.x)	xx (xx.x)
Have seen a cardiologist	xx (xx.x)	xx (xx.x)	xx (xx.x)
Frailty:**			
FRAIL scale <3	xx (xx.x)	xx (xx.x)	xx (xx.x)
FRAIL scale ≥3	xx (xx.x)	xx (xx.x)	xx (xx.x)
ADL disability:			
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)

No	xx (xx.x)	xx (xx.x)	xx (xx.x)

Social isolation:			
Friendship scale*** ≤15	xx (xx.x)	xx (xx.x)	xx (xx.x)
Friendship scale 16-24	xx (xx.x)	xx (xx.x)	xx (xx.x)
Baseline medications			
Antihypertensive medications:			
Beta-blocker	xx (xx.x)	xx (xx.x)	xx (xx.x)
Calcium-channel blocker	xx (xx.x)	xx (xx.x)	xx (xx.x)
ACE Inhibitor	xx (xx.x)	xx (xx.x)	xx (xx.x)
Angiotensin receptor inhibitor	xx (xx.x)	xx (xx.x)	xx (xx.x)
Diuretic	xx (xx.x)	xx (xx.x)	xx (xx.x)
Statin	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antiplatelet	xx (xx.x)	xx (xx.x)	xx (xx.x)
Anticoagulant	xx (xx.x)	xx (xx.x)	xx (xx.x)
Diabetes medications:			
Insulin	xx (xx.x)	xx (xx.x)	xx (xx.x)
Others:	xx (xx.x)	xx (xx.x)	xx (xx.x)

* **CHA2DS2-VASc score:** congestive heart failure (score 1), hypertension (score 1), age ≥75 (score 2), diabetes (score 1), stroke (score 2), vascular disease (score 1), age 65 to 74 (score 1) and sex (female score 1).

****FRAILTY**- Fatigue: "How much of the time during the past 4 weeks did you feel tired?" 1 = All of the time, 2 = Most of the time, 3 = Some of the time, 4 = A little of the time, 5 = None of the time. Responses of "1" or "2" are scored as 1 and all others as 0.

Resistance: "By yourself and not using aids, do you have any difficulty walking up 10 steps without resting?" 1 = Yes, 0 = No.

Ambulation: By yourself and not using aids, do you have any difficulty walking 1km?" 1 = Yes, 0 = No.

Illnesses: from the list of chronic conditions above, 0 - 4 = 0 and ≥5 conditions = 1

Loss of weight: ask the participants their current weight and their weight in the previous year. If ≥ 5% loss of weight, scored as 1 and < 5% as 0

If they do not remember their weight, ask "Have you recently lost weight such that your clothing has become looser?", if Yes, scored as 1.

Friendship scale: In the past 4 weeks, I found it easy to get on with others: 1= almost always, 2= most of the time, 3= about half of the time, 4= occasionally, 5= not at all

I had someone to share my feelings with: 1= almost always, 2= most of the time, 3= about half of the time, 4= occasionally, 5= not at all

I found it easy to make contact with others: 1= almost always, 2= most of the time, 3= about half of the time, 4= occasionally, 5= not at all

I felt lonely: 5= almost always, 4= most of the time, 3= about half of the time, 2= occasionally, 1= not at all

I felt I was a burden to others: 5= almost always, 4= most of the time, 3= about half of the time, 2= occasionally, 1= not at all

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6.4 Primary analysis

Table 3. Primary and secondary outcomes at 6th month.

	Intervention n (%)	Control n (%)	P value for difference
Primary outcomes:			
AF diagnosis	xx (xx.x)	x (x.x)	x.x
"Very satisfied or satisfied"	xx (xx.x)	xx (xx.x)	x.x
Secondary outcomes:			
Very satisfied	xx (xx.x)	xx (xx.x)	x.x
Satisfied	xx (xx.x)	xx (xx.x)	
Somewhat satisfied	xx (xx.x)	xx (xx.x)	
Not satisfied	xx (xx.x)	xx (xx.x)	

Subgroup analysis:

The primary clinical outcome (i.e., AF diagnosis) at 6 months will be explored for each of the baseline covariates listed below, exploring the interaction of these subgroups with the intervention group. A logistic regression will be fitted, adjusting for:

- Intervention group
- Covariate measured at baseline
- Interaction term of the covariate and intervention group

If the interaction p-value is less than 0.05 then subgroup analyses will be conducted for that covariate. The baseline covariates to be examined are:

- Gender
- Location (urban/ rural)
- Frailty

The odds ratio for each group will be calculated from the above-mentioned models, including interaction p-value, and presented in a forest plot.

The primary feasibility outcome (i.e., participant satisfaction) at 6 months will be explored for each of the baseline covariates listed below, exploring the interaction of these subgroups with the intervention group. A logistic regression will be fitted, adjusting for:

- Intervention group
- Covariate measured at baseline
- Interaction term of the covariate and intervention group

If the interaction p-value is less than 0.05 then subgroup analyses will be conducted for that covariate. The baseline covariates to be examined are:

- Gender
- Location (urban/ rural)
- Frailty

The odds ratio for each group will be calculated from the above-mentioned models, including interaction p-value, and presented in a forest plot.

Table 4. Additional analysis of secondary outcomes: cardio-protective medication and health service utilisation at 6 months.

	Intervention n (%)	Control n (%)	Odd ratio (95% CI)	P value
Cardio-protective medications: [a]				
Anticoagulants	xx (xx.x)	xx (xx.x)	y.y(z-z)	x.x
Antiplatelet medications	xx (xx.x)	xx (xx.x)	y.y(z-z)	
Blood pressure lowering medications	xx (xx.x)	xx (xx.x)	y.y(z-z)	
Cholesterol lowering medications	xx (xx.x)	xx (xx.x)	y.y(z-z)	
Health service utilization: [b]				
Seen GP:				x.x
None	xx (xx.x)	xx (xx.x)	y.y(z-z)	
1 time	xx (xx.x)	xx (xx.x)	y.y(z-z)	
2 times	xx (xx.x)	xx (xx.x)	y.y(z-z)	
≥3 times	xx (xx.x)	xx (xx.x)	y.y(z-z)	
Seen specialist: Yes	xx (xx.x)	xx (xx.x)	y.y(z-z)	x.x
Attended ED: Yes	xx (xx.x)	xx (xx.x)	y.y(z-z)	x.x

(a) Logistic regression adjusted for baseline medication.
(b) Chi-square or Fisher exact test

Table 5. Adverse events as reported at the completion of the study (12 month follow-up).

Adverse Event	Yes (Y)/ No (N)	Remark
Death		
Stroke/ Transient Ischemic Attack ("temporary stroke")		
Clinically significant bleeds (bleeding that required medical treatment)		
Deep vein thrombosis/ pulmonary embolism ("blood clots")		
Other cardiovascular disease (Other heart disease)		
Respiratory disease (Lung disease)		
Other neurological disease (Other disease in the nerve system)		
Orthopedic/musculoskeletal disease (disease in the bones or muscles)		
Fall		
Gastroenterological disease (disease in the digestive system)		
Renal/urologic disease (disease in kidneys & urinary system)		
Other disease		

6.5 Additional analysis

The characteristics of the participants with AF diagnosed by the study and the time to AF diagnosis is tabulated in Table 6.

Table 6. Participants with atrial fibrillation diagnosed by the study.

Participant (ID, sex, CHA2DS2-VASc score)	Time to AF diagnosis (days)*	Pulse rate when AF was diagnosed	Paroxysmal AF / Persistent AF**	Anticoagulant Yes/No ***
Pxx, F, 4	xx	xx	Paroxysmal AF	No
Pyy, M, 3	yy	yy	Persistent AF	Yes

*The time to AF diagnosis: the "first ECG transmitted to the central monitoring" to the "first ECG with AF confirmed by a cardiologist".

**Persistent AF (>consecutive 7 days).

***Anticoagulant status at the end of the study.

Factors that impact on participant satisfaction scores at 6 months
The four-point Likert scale of satisfaction score will be collapsed into binary "very satisfied & satisfied" and "somewhat satisfied and not satisfied". Logistic regression will be performed to assess potential factors associated with the binary satisfaction scores (Table 7).

Table 7 Logistic regression of potential factors associated with participants' satisfaction.

	Univariate analysis Unadjusted OR for being "Very satisfied or satisfied." (95%CI)	P	Multivariate analysis Adjusted OR for being "Very satisfied or satisfied." (95%CI)	P
Age	xx.x (xx.x, xx.x)	y.yy	xx.x (xx.x, xx.x)	y.yy
Women	xx.x (xx.x, xx.x)	y.yy	xx.x (xx.x, xx.x)	y.yy
Education status	xx.x (xx.x, xx.x)	y.yy	xx.x (xx.x, xx.x)	y.yy
Ethnicity	xx.x (xx.x, xx.x)	y.yy	xx.x (xx.x, xx.x)	y.yy
Location (urban/ rural)	xx.x (xx.x, xx.x)	y.yy	xx.x (xx.x, xx.x)	y.yy
Frailty	xx.x (xx.x, xx.x)	y.yy	xx.x (xx.x, xx.x)	y.yy
ADL disability	xx.x (xx.x, xx.x)	y.yy	xx.x (xx.x, xx.x)	y.yy
Social isolation	xx.x (xx.x, xx.x)	y.yy	xx.x (xx.x, xx.x)	y.yy
Multimorbidity	xx.x (xx.x, xx.x)	y.yy	xx.x (xx.x, xx.x)	y.yy
CHA2DS2-VASc Score	xx.x (xx.x, xx.x)	y.yy	xx.x (xx.x, xx.x)	y.yy
Randomisation group	xx.x (xx.x, xx.x)	y.yy	xx.x (xx.x, xx.x)	y.yy

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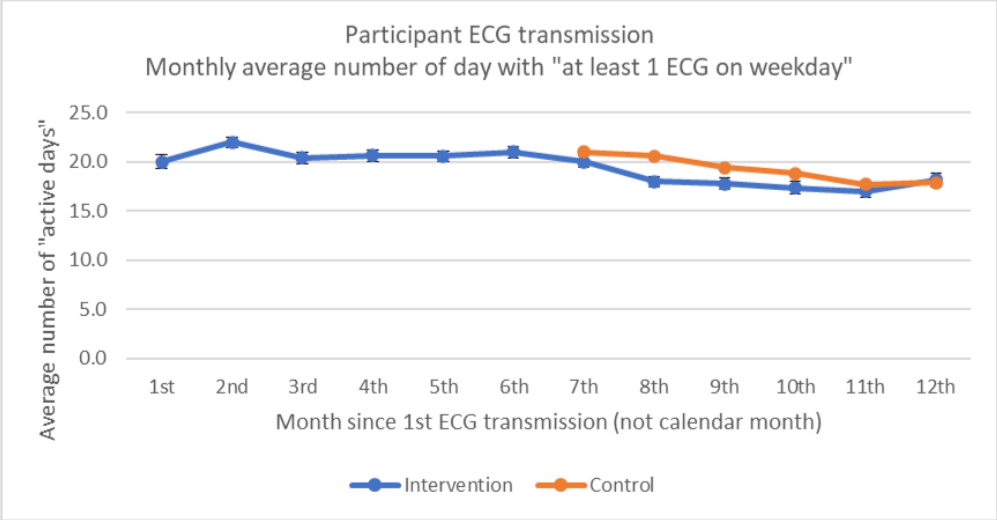
Table 8. Participants' responses to the usability survey questionnaire at 12th month.

	Intervention n	Control n	Total n
1. How easy was the use of this device?	Proportions of each scale 1 to 5	Proportions of each scale 1 to 5	Proportions of each scale 1 to 5
2. In term of the time taken to acquire an ECG tracing, how efficient was this device?	Proportions of each scale 1 to 5	Proportions of each scale 1 to 5	Proportions of each scale 1 to 5
3(a) When you first received the device - How anxious were you in using this device?	Proportions of each scale 1 to 5	Proportions of each scale 1 to 5	Proportions of each scale 1 to 5
3(b) How anxious are you currently in using this device? (In the past month)	Proportions of each scale 1 to 5	Proportions of each scale 1 to 5	Proportions of each scale 1 to 5
4. How comfortable were you in sharing your personal information and ECG with the research team?	Proportions of each scale 1 to 5	Proportions of each scale 1 to 5	Proportions of each scale 1 to 5
5. To what extent did the use of this device restrict your usual activities?	Proportions of each scale 1 to 5	Proportions of each scale 1 to 5	Proportions of each scale 1 to 5
6. How confident were you in your ability to use this device correctly?	Proportions of each scale 1 to 5	Proportions of each scale 1 to 5	Proportions of each scale 1 to 5
7. How satisfied were you with the use of this device?	Proportions of each scale 1 to 5	Proportions of each scale 1 to 5	Proportions of each scale 1 to 5
8. Do you agree that this screening method helps detect irregular heart rhythms in the community?	Proportions of each scale 1 to 5	Proportions of each scale 1 to 5	Proportions of each scale 1 to 5
9. Would you like to continue using this device if you have the choice?	Proportions of each scale 1 to 5	Proportions of each scale 1 to 5	Proportions of each scale 1 to 5

6.6 Process measures:

Figure 3. Participants' number of active days transmitting ECGs by intervention and waitlist-controlled groups. *(The following diagram is based on mock data)*



Note: An active day is counted when a participant transmits at least one ECG to the central monitor.

The engagement rate (a measure of adherence to the study protocol with respect to self-recording ECG using handheld device) is defined as the total number of "active days" of all active participants divided by the "total number of active participants" in a month. On average, participants are expected to transmit at least one ECG per day in 20 days in a typical month (excluding weekends and public holidays). When participants transmitted more than one ECG a day, only the first ECG will be included in the computation of engagement rate.

Table 9. Number of participants missed transmitting ECG for three consecutive days and the reasons.

Missed transmitting ECGs for 3 consecutive weekdays" for:	Number of participants, n
One time	xx
Two times	xx
Three times	xx
Four times	xx
Five times	xx
More than five times	xx

Reasons for missing ECGs for ≥3 times:
Travelling…
Yyyyyyyyy

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Table 10. Diagnostic accuracy of the handheld electrocardiographic device's automatic algorithm versus clinicians' interpretation of electrocardiograms.

Kardia Interpretation (n)	**Clinician diagnosis (n)**		
	AF	**No AF**	**Total**
AF			
No AF			
Total			

Breakdown statistics of various rhythms: (Kappa statistics)

Kardia Interpretation (n)	**Clinician Interpretation (n)**							
	AF	**SR**	**SBrady**	**STachy**	**SArrhy**	**SVT**	**Unreadable*** **	**Total**
AF								
SR								
SBrady								
STachy								
Too_short*								
Unclassified**								
Unreadable* **								
Total								

* Too short means the ECG trace is less than 30 seconds.

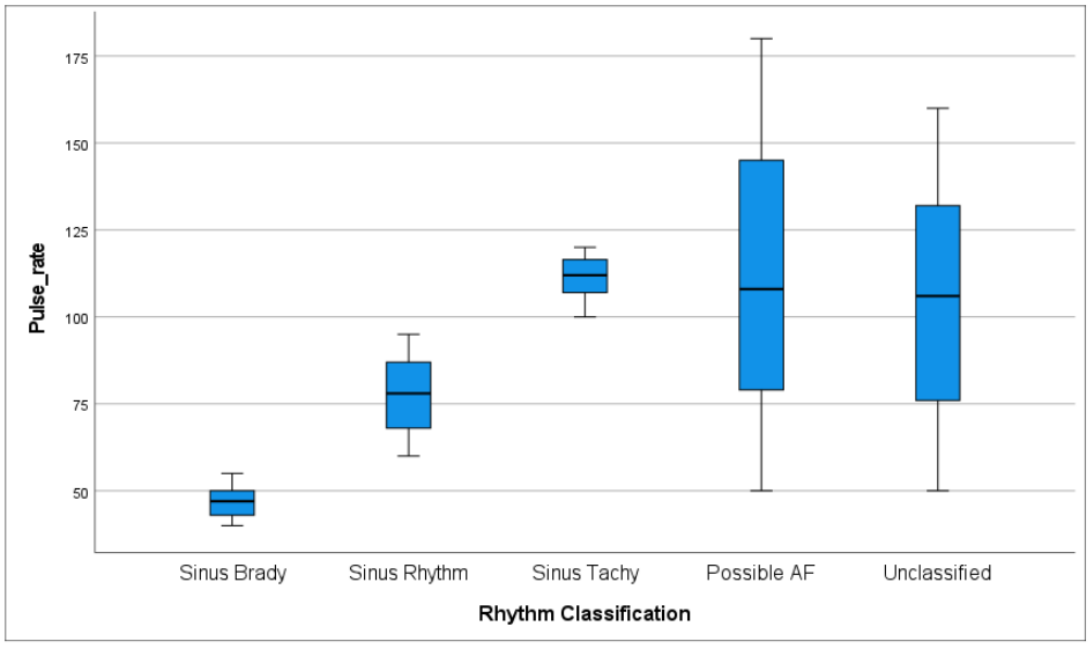
** Unclassified means the device is unable to determine a result.

*** Unreadable means the device is unable to read the ECG trace due to interferences.

Note: Recompute the Kappa statistics by restricting the analysis to the following:

- Excluding ECG traces that were labelled "Too short"
- Excluding ECG traces that were labelled "Unreadable"
- Excluding ECG traces that were labelled "Unclassified"
- Excluding ECG traces that were labelled "Too short", "Unreadable" and "Unclassified.

Figure 4. Distribution of participants' pulse rates by the type of electrocardiogram classification automatically determined by the devices. *(mock data)*



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