

# Does a mobile app help people with atrial fibrillation take their medication?

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<b>Registration date</b> 08/03/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/11/2022	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and aims:

Atrial fibrillation (AF) is a heart condition that causes an irregular and often abnormally fast heart rate. AF affects over 1.4 million people in the UK, requires frequent hospital admissions and increases the risk of stroke five-fold. AF-related strokes are more likely to be fatal or severely disabling compared to other types of stroke. Oral anticoagulation medication reduces stroke risk in AF by two-thirds but in Scotland only 35% of people with AF still take this medication after 18 months. Missing just 1-2 doses increases stroke risk. People with AF often take many medications and may need help to remember to take them at the right time. Mobile health apps are one way of supporting people to manage their medications. This study will test a new app among people who have AF and identify the best way to test whether people are taking their medication as planned. We will use this information to plan a larger study.

### Who can participate?

Adults who have atrial fibrillation and are taking anticoagulant medication.  
Healthcare professionals who help to recruit participants

### What does the study involve?

#### Adults with atrial fibrillation:

If you take part you will be randomly allocated to either use the app or to receive normal care. Both groups will be asked to complete telephone questionnaires and have a blood test at the start of the study, after 12 weeks and after 24 weeks. Those in the app group will download the app onto their mobile phone, be shown how to use it and then use it for 12 weeks. If you are in this group you may also be asked to take part in a telephone interview about your experience of using the app.

#### Healthcare professionals

If you take part in the study, you will be asked to complete a telephone interview with a researcher about your experience of being involved in the study.

### Where is the study run from?

Edinburgh Napier University (UK)

When is the study starting and how long is it expected to run for?  
July 2019 to March 2023

Who is funding the study?  
Chief Scientists Office, Scotland (UK)

Who is the main contact?  
Professor Lis Neubeck, l.neubeck@napier.ac.uk

## Contact information

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

279087

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

IRAS 279087

## Study information

**Scientific Title**

Increasing medication adherence among adults with atrial fibrillation: an mHealth digital intervention feasibility RCT study

**Study objectives**

Aims/Primary Objectives:

1. Can we recruit clinicians/centres to take part in the study?
2. Can we recruit and retain participants to the study and is access equitable?
3. Can participants complete the outcome assessments?
4. What is the most valid, reliable and practical measure of adherence in this population?
5. What estimates of effect size/variability should be used in the design of the full trial?
6. What are patients' and providers' experiences of the complete intervention?

Secondary Objectives:

1. What are patient barriers and facilitators to engaging with an app based intervention?
2. What, if any, improvements are seen in patient quality of life following use of the intervention?

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 20/01/2021, NHS South East Scotland Research Ethics Committee (2nd Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, UK; no telephone number provided; Sandra.Wyllie@nhslothian.scot.nhs.uk), ref: 21/SS/0001

**Study design**

A multi centre pilot feasibility randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

See additional files

**Health condition(s) or problem(s) studied**

Atrial fibrillation

**Interventions**

This study is a pilot and feasibility study where participants will be randomly allocated to one of two groups, the intervention or control group. Randomisation will be carried out via secure web-based system provided by Tayside Clinical Trials Unit. This will be on 1:1 basis, using minimisation on key variables including age and setting (cardiology or GP practice). Where appropriate an estimate of the intra-cluster correlation will be obtained for each setting to inform the sample size estimate of the subsequent definitive trial.

Control Group: Participants will undergo all routine care including but not limited to GP appointments, nurse-led clinics or cardiology outpatient appointments +/- elective or emergency hospital procedures. No changes will be made to existing treatment plans unless clinically indicated within their usual healthcare team.

Intervention Group: As well as usual care, participants will be provided the use of a mobile app designed to promote self-management and increase medication adherence. No changes will be made to existing treatment plans unless clinically indicated within their usual healthcare team.

All participants (control group and intervention group) will be asked to undertake a baseline demographic questionnaire (including age, sex, ethnicity, education level, employment status, Scottish Index of Multiple Deprivation (SIMD) calculated from postcode, relevant medical history and medication regimen). At baseline, 12 weeks and 24 weeks participants will also need to

complete three validated health questionnaires:

1. Medication Adherence Rating Scale (MARS)
2. Beliefs About Medicines questionnaire (BMQ)
3. Quality of life questionnaire (SF-12)

We will ask patients to self-report AF morbidity data (e.g. AF related hospitalization) at 12 weeks and 24 weeks. Additionally at 12 weeks a satisfaction with care score will be included. Due to Covid-19 restrictions these questionnaires will be facilitated via telephone. A blood test (Anti-Xa blood Assay or International Normalised Ratio blood assays) will also be taken at all three time points. For those allocated to the intervention group, participants (n=20) will be invited to a semi-structured telephone interview to discuss their experiences with using the mobile app. Participants who dropped out of the intervention group will also be asked to undertake an interview to provide additional understanding and context around the acceptability of a mobile app intervention.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Measured at week 1, 12 and 24:

1. Medication adherence measured using blood assay measures (Anti-Xa or International Normalised Ratio)
2. Medication adherence measured using the Medication Adherence Rating Scale
3. Beliefs about Medications Questionnaire scores

## **Secondary outcome measures**

1. Quality of life assessed via (SF-12 questionnaire) at baseline, 12 weeks and 24 weeks
2. AF morbidity (e.g. AF related hospitalization) assessed via a self-reported healthcare questionnaire at 12 weeks and 24 weeks
3. Patient barriers and facilitators to using a mobile health app to manage their AF assessed via semi-structured interviews after 12 weeks
4. Healthcare professional experiences of implementing a mobile health app to increase medication adherence between 12 and 24 weeks

## **Overall study start date**

01/07/2019

## **Completion date**

31/03/2023

# **Eligibility**

## **Key inclusion criteria**

Patients:

1. Adults diagnosed with atrial fibrillation
2. Prescribed oral anticoagulant therapy
3. Able to provide written informed consent in English
4. Participants must have access to a personal device (e.g. mobile or tablet)

Health care professionals:

1. Healthcare professionals working at study recruitment sites who have had involvement in

recruitment of study participants

2. Healthcare professionals working at study recruitment sites who have had involvement in taking blood samples for study participants

**Participant type(s)**

Mixed

**Age group**

Adult

**Sex**

Both

**Target number of participants**

76 (53 from secondary care and 23 from primary care)

**Total final enrolment**

70

**Key exclusion criteria**

Patients:

1. Patients with unstable atrial fibrillation or newly initiated on warfarin
2. Patients with atrial fibrillation who are not prescribed oral anticoagulant therapy
3. Patients who are unable to provide written informed consent in English
4. Patients who do not have access to a personal device (e.g. mobile or tablet)

Health care professionals:

1. Healthcare professionals working at study recruitment sites who have not had involvement in recruitment of study participants or taken blood samples for study participants

**Date of first enrolment**

01/10/2021

**Date of final enrolment**

06/09/2022

**Locations**

**Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**

**Royal Infirmary Edinburgh**

51 Little France Crescent

Old Dalkeith Road

Edinburgh  
United Kingdom  
EH16 4SA

**Study participating centre**  
**NRS Primary Care Network**  
Mackenzie Building  
Kirsty Semple Way  
Dundee  
United Kingdom  
DD2 4BF

**Study participating centre**  
**The Scottish Health Research Register and Biobank**  
School of Medicine, Mailbox 12, Level 5  
Population Health and Genomics  
Ninewells Hospital & Medical School  
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## **Sponsor information**

**Organisation**  
Edinburgh Napier University

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University/education

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<https://www.napier.ac.uk/>

**ROR**  
<https://ror.org/03zjvnn91>

# Funder(s)

## Funder type

Government

## Funder Name

Chief Scientists Office, Scotland

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

## Intention to publish date

30/11/2023

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. Data generated by the project will be made open after completion of the project once appropriate changes (e.g., all participants assigned a unique identifier and any identifying details have been removed) have been made to honour assurances of confidentiality and anonymity. The Information Commissioner's Office Anonymisation: managing data protection risk code of practice will be adhered to: <https://ico.org.uk/media/for-organisations/documents/1061/anonymisation-code.pdf>. Datasets will be allocated a DOI and stored on the Edinburgh Napier University Open Access Research Repository in accordance with the University research data deposit process. The DOI and the datasets will be made available to the UK Data Service ReShare repository within six months following the first publication of findings based on the data.

## IPD sharing plan summary

Stored in publicly available repository

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version v3	22/01/2021	01/04/2021	No	Yes
<a href="#">Participant information sheet</a>	version v2	22/01/2021	01/04/2021	No	Yes
<a href="#">Protocol file</a>	version v1	07/12/2020	01/04/2021	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No