ISRCTN10135302 https://doi.org/10.1186/ISRCTN10135302

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

Submission date
05/03/2021

Recruitment status
No longer recruiting

Registration date
08/03/2021

Overall study status
Completed

Last Edited
03/11/2022

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
279087

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

Scotland

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
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Sponsor information

Organisation
Edinburgh Napier University

ROR
https://ror.org/03zjvnn91

Funder(s)

Funder type
Government

Funder Name
Chief Scientists Office, Scotland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically 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?
HRA research summary			28/06/2023	No	No
Participant information sheet	version v3	22/01/2021	01/04/2021	No	Yes
Participant information sheet	version v2	22/01/2021	01/04/2021	No	Yes
Protocol file	version v1	07/12/2020	01/04/2021	No	No