Participant information sheet

Increasing medication adherence among adults with atrial fibrillation: A digital health intervention feasibility study

You are invited to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact me if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

What is the purpose of the study?
The aim of the study is to evaluate the effectiveness of a newly developed mobile app designed to help increase medication adherence and knowledge for people living with atrial fibrillation. Adherence to medication refers to how individuals take their medications compared to what their prescription recommends. This involves several factors, for example remembering to take the medication, taking the medication at the recommended time, understanding why a medication must be taken and whether prescriptions are filled when empty. This study has been designed to pilot an app designed to help individuals adhere to their atrial fibrillation medications and test how easy it is to use and that the functions work. All information gathered will be used to inform a larger research study about the use of the mobile app to support those with atrial fibrillation to manage their medication.

Why have I been asked to take part?
We are interested in making sure the app appeals to as many groups of people as possible from different backgrounds. You have been asked to take part because your cardiology outpatient service or GP surgery has agreed to be part of the study and has helped us identify individuals who have a diagnosis of atrial fibrillation.

Do I have to take part?
No, it is up to you to decide whether to take part. Your decision will not affect your future medical care. If you decide to take part, please keep this information sheet and return the signed the consent form to: *a.pearsons@napier.ac.uk* or by post to *Alice Pearsons, Room 4.B.29, Sighthill Campus, Edinburgh Napier University, Sighthill, Edinburgh, EH11 4BN* If you decide to take part, you are still free to withdraw at any time.

What will happen if I take part?
If you agree to participate and have given written consent your details will be passed onto a researcher at Edinburgh Napier University who will then contact you to discuss your participation in the study. It is important that we are able to measure whether using the app has any benefits. Therefore you will be randomly allocated into one of two groups (Figure 1) via a secure web-based system provided by Tayside Clinical Trials Unit.

Group a) will follow usual care with no use of the mobile app. Group b) will follow usual care plus use of the mobile app.

For those people allocated to group B, you will be asked to download the mobile app onto your own personal device. We ask that you use the mobile app for 12 weeks.

Both groups will be required to fill in three different health questionnaires before the study starts, after 12 weeks and after 24 weeks. A researcher will phone to complete these remotely with you. We estimate it will take 20-30 minutes to complete each questionnaire at each time point. To monitor anticoagulation therapy we also require a blood test at these

three times at your GP surgery or cardiology outpatient department. The data collected will provide evidence as to the effectiveness of the atrial fibrillation mobile app.

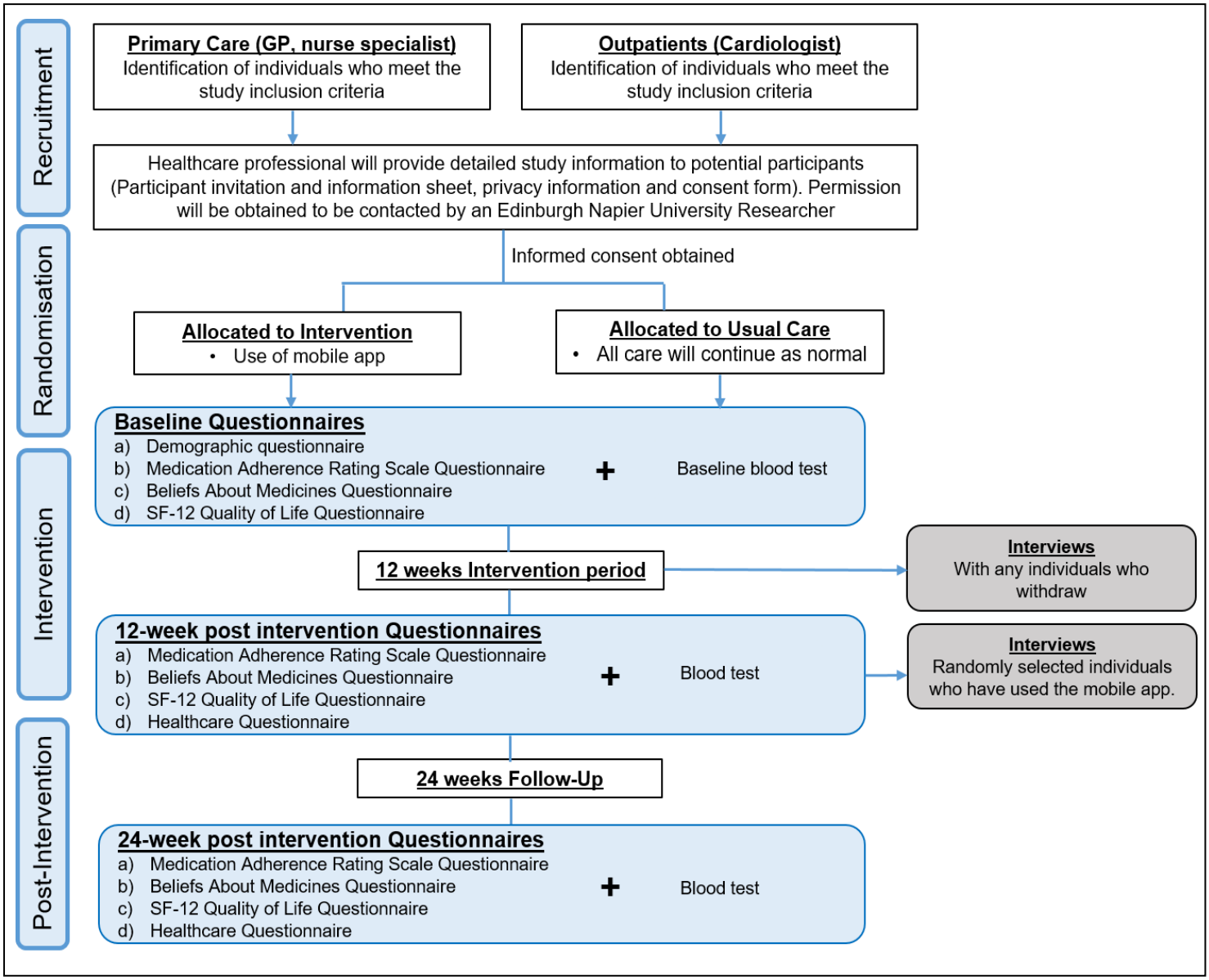

Figure 1. Overview of how the full study will run for participants

If you decide to withdraw from the study we will not try and persuade you to continue. It is important that we are able to understand reasons for withdrawing therefore you will be asked your reason for dropping out, and whether you would mind being contacted for a short telephone interview to discuss these reasons in further detail. You do not have to do this if you do not want to.

We will also ask some participants from group B to take part in a telephone interview to discuss their experiences of using the app. This will be after the 12 week trial period. We will select participants so that we can talk to a range of different people (for example, men and women of different ages, those who continued to use the app, and those who did not). You may, or may not, be asked to take part in this part of the study. The telephone interviews will be recorded and the conversation will be transcribed into a written document. All personally

identifiable information will be removed and conversations will be analysed to see who the app works for, and how.

Due to the study being a feasibility study it may be necessary to contact you for additional information that has not been included in the original study protocol.

The Mobile App- Nurse Ali

The interactive app features a nurse based avatar (Figure 2) named Nurse Ali. This avatar will be there to support you throughout the app.

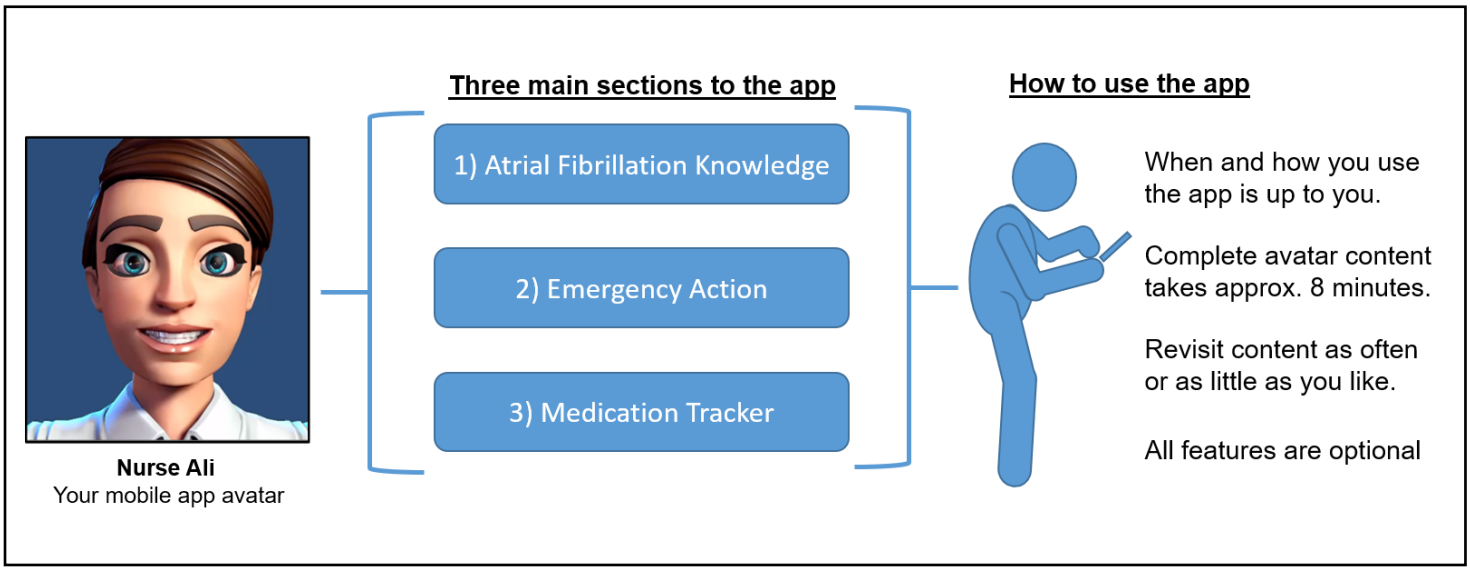

Figure 2. Content of the mobile app- Nurse Ali

The mobile app contains three distinct sections

a) **Atrial Fibrillation Knowledge-** This section contains detailed knowledge regarding atrial fibrillation, stroke risk and information about the different types of medications you may have been prescribed relating to your diagnosis.
b) **Emergency Action**- There may be times when you wish to seek about any atrial fibrillation related concerns e.g. if you experience palpitations. This section provides advice on when someone should seek help and where you are able to get this help from.
c) Medication Tracker- This section has been designed to help you easily manage all you medications (not only those medications prescribed for your AF). Chose if and when you want reminders, get appointment reminders and tick off when you have taken your medications to keep track.

It is estimated that the avatar content of the app is 8 minutes. However, with additional features the app start to finish is approximately 20-30 minutes. All sections are optional and you are able to revisit individual sections as often as you like.

What are the possible benefits of taking part?

There may be no benefit to you as a participant from being involved with this study. However potential benefits may include:

1) Improved medication management helping to reduce any missed or forgotten doses. By improving adherence to anticoagulation medication this could reduce your risk of atrial fibrillation related stroke.
2) Improved understanding of atrial fibrillation. By improving your knowledge of atrial fibrillation you may experience better symptom management and a decrease in stress and anxiety related to the diagnosis.
3) Remote support. The app has been designed in response to questions and concerns raised by people diagnosed with atrial fibrillation. It may feel personalised and help you may feel more supported.

What are the possible disadvantages and risks of taking part?

The mobile health app is not being used to replace your normal medical care. The content included in the app is from reliable, evidence based sources and check by health professionals for reliability. Therefore participating in the study will not pose any additional risks to your health. The time commitment to the study is 24 weeks: 12 weeks for the initial study with a follow up 12 weeks later. Filling out the questionnaires may feel time consuming, but should not take more than 30 minutes per questionnaire. To lessen this burden and to respond to the challenges COVID-19 presents us, we will complete the questionnaires with you via telephone at a prearranged time. You may also be asked to take part in a telephone interview after 12 weeks to discuss your experiences of using the app. We expect that this will take no more than 45 minutes. We hope that this will help make the process more convenient to you.

Will my taking part in the study be kept confidential?
All personal identification information collected during the course of the research will be kept confidential and there are strict laws that safeguard your privacy at every stage. Your name and any other identifiable information will be removed from the data so that you cannot be recognised. Care will be taken to make sure that any data are non-identifiable if used in the presentation of findings.

What happens when the study is finished?
At the end of the research, the data you have provided will be stored once all personally identifiable data has been removed. These anonymised data may be made available to other researchers for further analysis once the results of the research have been published. This would only be after an official request, consideration of suitability for sharing, and subject to a data sharing agreement between Edinburgh Napier University and the researcher requesting the data. The data will be stored for at least 10 years.

What will happen to the results of the study?
The results of the study will be used in inform a larger research study, which may run after the completion of this pilot study. Pilot trials are very important for ensuring the success of a larger trial therefore it is possible that this pilot study will also be written up as a report and the findings may be published in healthcare journals and presented at conferences. Data from withdrawn participants will be included unless explicitly asked to be removed by the participant. We will be unable to delete data from withdrawn participants if analysis has meant researchers are no longer able to ascertain who the data belongs to.

Who is organising the research and why?
The principal investigator organising the study is Professor Lis Neubeck, a Professor of Nursing at Edinburgh Napier University. Lis has a special interest in improving the lives of people with atrial fibrillation.

Who should I contact if I have a complaint?
If you have or experience any concerns during the recruitment or duration of the study please contact the principal investigator Professor Lis Neubeck on 0131 455 2768 or email l.neubeck@napier.ac.uk. If you wish to raise a complaint in regards to the study please contact the elected independent person for this study Anne Rowat (details below).

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion for this study has been obtained from the South East Scotland REC 01.

If you have further questions about the study please contact:
Alice Pearsons on 0131 455 3392 or email a.pearsons@napier.ac.uk

If you would like to discuss this study with an independent person please contact:
Anne Rowat, Lecturer in the School of Health and Social Care on 0131 455 5670 or email a.rowat@napier.ac.uk