PARTICIPANT INFORMATION SHEET/ CONSENT TO TAKE PART IN A RESEARCH STUDY

Detection of Atrial Fibrillation Recurrence Post-Ablation Using Photoplethysmography-Based Smartphone App (FibriCheck)

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Associate Investigators: Dr Suraya Hani Kamsani, Dr Melissa E. Middeldorp

Invitation to participate

You are invited to take part in this research project, which is called: Monitoring Atrial Fibrillation Recurrence Post-Ablation Using Photoplethysmography-Based Smartphone App (FibriCheck).

You have been invited because you have been diagnosed with atrial fibrillation (AF) and are about to undergo or have just undergone an AF ablation procedure. We are investigating whether a simple smartphone application, FibriCheck, can detect AF recurrence with good accuracy after an ablation procedure.

Your participation is voluntary

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved in taking part. Knowing what is involved will help you decide if you want to take part in this research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary and there will be no cost to you. If you don't wish to take part, you don't have to. Choosing not to take part in this study will not affect your current and future medical care in any way. Also, you may withdraw from the project at any time after you have commenced.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read
• Consent to take part in the research project
• Consent to be involved in the research described
• Consent to the use of your personal and health information, including linked data, as described.

You will be given a copy of this Participant Information and Consent Form to keep.

Your withdrawal from the study

You are under no obligation to continue with the research study. You may change your mind at any time about participating in the research. People withdraw from studies for various reasons and you do not need to provide a reason.

You can withdraw from the study at any time by completing and signing the ***'Participant Withdrawal of Consent Form'***. This form is provided at the end of this document and is to be completed by you and supplied to the research team if you choose to withdraw at a later date.

If you withdraw from the study, you will be able to choose whether the study will destroy or retain the information it has collected about you. You should only choose **one** of

these options, Where both boxes are ticked in error or neither box is ticked, the study will destroy all information it has collected about you.

What is the purpose of this research?

Background

Atrial fibrillation (AF) is the most common heart rhythm abnormality in the world. It affects almost 59.7million globally and approximately 2% of the general Australian population, equivalent to more than 500,000 people in 2020. Apart from increased risk of stroke, heart failure, hospital admissions and death, AF can also affect your quality of life due to its symptoms. AF ablation will help to alleviate your symptoms and improve your overall health. After an ablation procedure, it is crucial to determine whether you remain in normal heart rhythm or whether your AF recurs. Traditionally, this has been done with a Holter monitor that can be difficult to access.

What will this study aim to do?

This study will investigate whether a simple smartphone application, FibriCheck, can detect AF recurrence with good accuracy in patients after their AF ablation procedures.

What does participation in this research involve?

You will be participating in an observational research project. This study will not affect or change your standard care and treatment. Besides receiving your usual care for AF, as a participant in this study, you will receive an additional smartphone application (FibriCheck) to monitor your heart rhythm. This will be for two times a day over 1 month each time you wear your post ablation Holter. This monitoring period will start when you attend your first Holter appointment after your ablation procedure. You can also send extra transmissions should you feel any irregularities between appointments. Each measurement takes one minute, and it is purely done using your smartphone.

What will I have to do?

If you consent to participate:

- The FibriCheck app will be installed on your smartphone for free and detailed instructions will be given to you on how to use the app.

- You will be asked to take measurements (assessment of your heart rhythm) with the FibriCheck app two times per day over 1 month each time you wear your post ablation Holter. Each measurement will take only 60 seconds.

Assessment of your heart rhythm with the FibriCheck app

- Before its use, the FibriCheck application needs the following permissions from the user:
    - Access to smartphone camera (to scan QR code and record PPG signal)
    - Access to internet
    - Access to send notifications (optional)
- The FibriCheck app uses the smartphone's built-in camera to measure heart rate and assess your heart rhythm (PPG).
- During the measurement, you should be in a seated position with your arms resting on a table, holding your smartphone with your right hand. You should not speak or move during the measurement to avoid poor quality readings.
- For the measurement, you should cover the flashlight and the rear camera with your left index finger, and wait for 60 seconds.
- After completing the FibriCheck measurement, a context screen will appear where more information can be added to the measurement. You will be asked to indicate what you were doing immediately before taking the measurement (sleeping, sitting, standing, walking, exercising, others) and whether you were experiencing any symptom (palpitation, chest pain, shortness of breath, light-headedness, confusion, fatigue, or no symptom).
- After completion of the study, the FibriCheck app will not be uninstalled from the phone by the study team unless you or the owner of the phone removes the app. However, the free access to the app will be removed as the subscription granted to the research team is only for the duration of the study. Given this is a product which is commercially available, should you wish to continue, you may do so at your own cost and convenience. Further recordings outside of the study subscription will not be accessible or managed by the study team.

Questionnaires

You will also be asked to complete two questionnaires:

- At enrolment, you will be asked to complete a questionnaire on your perception and familiarity with smartphone technology.
- At the end of the study, you will also be asked to complete another questionnaire about your experience in using the FibriCheck app.

How long will my participation in the study last?

Participation in this study will be for 12 months.

Will there be any additional costs?

There is no additional cost associated with participating in this research project, nor will you be paid. The FibriCheck app will be provided to you free of charge for the duration of the study.

Who has sponsored this research study?

This study is sponsored by the Centre for Heart Rhythm Disorders at the University of Adelaide.

What are the alternatives to participation?

If you decide not to participate, your usual medical care will not be affected.

What are the possible benefits of participating?

We cannot guarantee or promise that you will receive any direct benefit from this research. One possible benefit is monitoring for AF recurrence outside your usual Holter monitor after your ablation. Most importantly, we hope that the findings of this research may be crucial in improving the clinical care of patients with AF.

What are the possible risks and disadvantages of participating?

There is no risk involved for the participants as a direct result of this study. The study involves only the use of a smartphone application.

Confidentiality and data security

By signing the consent form, you consent to the study doctor and relevant research staff collecting and using your personal information for the research project. This includes your

medical history, medication history, results of blood tests and other investigations, details of any hospital admissions, measurements from your FibriCheck app and any of your questionnaire responses.

Storage, retention and destruction of your information

Any information obtained in connection with this research project that can identify you will remain confidential and access will be limited to authorised research staff. Your information will only be used for the purpose of this research project and will only be disclosed with your permission, except as required by law.

Information we collect from you will be identifiable so that we can currently pair your results to your patient profile. This is important to ensure all data is analysed correctly and reported accurately. Heart rhythm monitoring data from FibriCheck app will be stored in a secured and certified (ISO27001 and ISO27701) cloud-based server in Germany used by FibriCheck owner company (Qompium). The data collected for this study will be stored in a study account that will be accessible only by the study team. All printed copies, forms and other project information will be kept in secure offices at the University of Adelaide where it will be swipe card and password protected. Electronic data collected will be stored in the internationally recognised Research Electronic Data Capture (REDCap) database format on local university secure servers, with internet connection, but only accessible through secure approved institutional access for project investigators and the database manager. This database logs all episodes of user access, design and data changes made.

Once the study is completed, this information will be de-identified and stored in secure archiving facilities at the University of Adelaide for 15 years, after which it will be securely destroyed in accordance with local approved procedures. Only authorised research staff will be able to re-identify the data if required prior to data destruction.

In addition to the processes described above, data may otherwise be discoverable through processes of law or for assessing compliance with research procedures.

In accordance with relevant Australian and/ or South Australian privacy and other relevant laws, you have a right to access the information collected and stored by researchers about you. You also have a right to request that information with which you disagree to be corrected.

Will the study affect my medical care

The study will not interfere with your usual medical care. Importantly, in case you feel unwell, you should seek emergent medical care and not rely on the FibriCheck app to guide you. Your participation in this study shall not affect any other right to compensation you may have under common law.

What happens when the research project ends

Once the research project is completed, all the information we collect will be published in scientific journals and presented at scientific meetings. All published/ presented information will not include any personal information or any individual results but instead will be the average result across every participant. If you interested in accessing the journal papers once published, please inform the research team.

Complaints and compensation

This study presents no risk for the participants. Therefore, no compensation is expected.

Who has reviewed this research project?

All research in Australia involving humans is reviewed by an independent group of people called Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the appropriate local HREC.

The research will be conducted according to NHMRC National Statement on Ethical Conduct in Human Research, 2007.

Further information and who to contact

If you need further information or have concerns about the study, you may contact the study team member below:

Name	Dr Suraya Hani Kamsani
Address	Centre for Heart Rhythm Disorders University of Adelaide, Royal Adelaide Hospital and South Australian Health & Medical Research Institute, Adelaide SA 5000

Email	surayahani.kamsani@adelaide.edu.au
Telephone	08 8128 4488

Reviewing HREC approving this research, HREC Executive Officer details and Complaints Contact Details

You may also contact the Human Research Ethic Committee at:

HREC Name	Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC)
Contact	Executive Officer
Telephone	(08) 7117 2229
Email	Health.CALHNResearchEthics@sa.gov.au

PARTICIPANT CONSENT FORM

Study name: Monitoring Atrial Fibrillation Recurrence Post-Ablation Using Photoplethysmography-Based Smartphone App (FibriCheck)

Principle Investigator:	**Associate Investigators:**
Prof Prashanthan Sanders	Dr Suraya Hani Kamsani, Dr Melissa Middeldorp

1. The nature, purpose and risks of the research project have been explained to me. I understand them and agree to take part.
2. I understand that I may not benefit from taking part in the trial.
3. I understand that, while information gained during the study may be published, I will not be identified and my personal results will remain confidential.
4. I understand that I can withdraw from the study at any stage and that this will not affect my medical care, now or in the future.
5. I understand that no reimbursement of expenses is provided as part of the study.
6. I agree to undergo the tests as indicated on page 3 of the participant information sheet.
7. I provide consent for access to my hospital records. In addition, I provide consent that copies of my admission discharge summary, ECG and relevant information may be taken by the research team.
8. I provide consent for approved data-linkage as part of this project.
9. I have had the opportunity to discuss taking part in this investigation with a family member or friend.

I (participant) verify that I understand the abovementioned terms and conditions and am willing/volunteering to participate in this trial:

Print Full Name: ----------

Signature: ---------- Date: ----------

Investigators details/signature:

I certify that I have explained the study to the participant/volunteer and consider that he/she understands what is involved.

Print Full Name: ----------

Signature: ---------- Date: ----------

PARTICIPANT WITHDRAWAL OF CONSENT FORM

Monitoring Atrial Fibrillation Recurrence Post-Ablation Using Photoplethysmography-Based Smartphone App (FibriCheck)

I wish to WITHDRAW my participation in the study effective from the date below. I request that the study handles the information they have collected about me in the following way (choose one option):

☐ DESTROY all information collected about me so it can no longer be used for research

☐ RETAIN all information collected about me so it can continue to be used for research

After my withdrawal from the study, I give permission for follow-up data to be collected about me from my medical record, or via data linkage, but not through direct contact with me, so it can continue to be used for research (choose one option):

Yes: ☐ No: ☐

I understand that:

1. no further information about me will be collected for the study from the withdrawal date, unless I have given my permission above;
2. information about me that has already been analysed and/or included in a publication by the study, may not be able to be destroyed; and
3. choosing to withdraw from the study will not affect my access to Health Services or Government benefits.

…… ……

Signature **Date**

……..……

Please print full name

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Date:
Time:
Comments (if applicable):

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/

Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.

This form should be forwarded by email to: surayahani.kamsani@adelaide.edu.au.

Alternatively, forms can be posted to:

Dr Suraya Hani Kamsani
Centre for Heart Rhythm Disorders, University of Adelaide,
Royal Adelaide Hospital and South Australian Health & Medical Research Institute, Adelaide SA 5000