

Patient Interview Information Sheet

Rehabilitation for Cardiac Arrhythmia

You are being invited to take a part in a research study. Please take the time to read the following information carefully and discuss it with others. Please ask us if there is anything that you don't understand or if you would like more information.

Thank you for reading this.

What is the purpose of the study?

Atrial fibrillation (AF) is a heart condition that causes irregular and often fast heartbeat.

The common symptoms associated with AF are palpitations, chest pain, shortness of breath, tiredness, dizziness, sweating, sleep disturbance, exercise intolerance, anxiety and depression which effect patients quality of life (QoL).

Evidence has shown that hospital based cardiac rehabilitation benefits AF patient through improving their physical activities, mental health, ability to perform social activities and overall quality of life.

In this interview, we are trying to understand the impact of the symptoms of AF upon you, and how we might be able to help you manage these symptoms. We would also like to seek your views toward enrolling into a rehabilitation programme.

Why have I been chosen?

We are inviting people with AF who are on the waiting list for ablation procedure to take part in the study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. Please remember if you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. If you withdraw from the study, we will keep the information about you

that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information

<http://www.leicestershospitals.nhs.uk/aboutus/our-news/general-data-protection-regulations-gdpr/>

What will happen if I take part?

If you are interested in the study, the researcher will discuss the study with you and provide you with this information sheet.

After consent, you will be invited to take a part in a private interview between you and the researcher. This will involve a discussion about the impact of the symptoms of AF upon you, and how we might be able to help you manage these symptoms. Your activity level and your views toward enrolling into a rehabilitation programme.

This should not last longer than an hour and will be through the phone . With your consent, we would like to record this interview.

What are the possible benefits of taking part?

There may not be any direct benefit to participants who decide to take part. However we would hope that taking part in the research may help us to understand your views toward rehabilitation programme and inform both present and future cardiac rehabilitation programmes, therefore benefiting other AF patients.

What are the possible risks of taking part?

There are no identified risks to taking part in this research.

How will we use information about you?

University Hospitals of Leicester is the sponsor for this study. Any information which allows identification of you as an individual is kept strictly confidential and where possible a unique identifier will be used instead. We will store all your information on a password protected database on secure computers. Only certain members of University Hospitals of Leicester staff will access this database. Procedures for handling, processing, storage and destruction of your data are compliant with GDPR. GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act 2018. All

research using patient data must follow UK laws and rules. The paper records are retained and filed in your medical notes.

Regulating authorities will have access to anonymous data only for the purpose of monitoring the quality of the research and clinical service and ensuring patient safety. Anonymous data will be retained for 5 years within University Hospitals of Leicester NHS Trust.

Where can you find out more about how your information is used?

You can find out more about how we use your information by contacting UHLsponsor@uhl-tr.nhs.uk or

- At www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to ma880@leicester.ac.uk, or
- by ringing us on 01162502671.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

What will happen to the results of the research study?

Results from this research study that use will be disseminated in peer and lay journals, professional publications and in presentations at conferences and within the results section of the PhD researcher's thesis. Results will be reported to respect confidentiality. No identifiable information will be published. You are entitled to see any results or information about you under the Data Protection Act 2018.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the lead researcher, Professor Sally Singh, who will do her best to answer your questions. Professor Singh can be contacted on (01162502671).

If you remain unhappy and wish to complain formally, you can contact the Research and Innovation Office at the University Hospitals of Leicester via email UHLsponsor@uhl-tr.nhs.uk

If you are not happy with their response or believe we are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

Who is organising and funding the research?

University Hospitals of Leicester NHS Trust is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this research and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

The study is being funded by the Saudi Ministry of Higher Education as part of a PhD award to Ms. Alhotye to study at University of Leicester.

Who has reviewed the study?

This study has been reviewed by the South Central – Oxford C Research Ethics Committee. This review does not guarantee that you will not come to any harm if you take part. However, it means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information upon which to make an informed decision on whether to participate or not.

If you decide to participate in this study you will be given a copy of the participant information sheet and a copy of the signed consent form to keep.

Thank you for taking time to consider this study. Please ask any questions and let us know if there are things that you do not understand, or would like more information about.

Please address any further questions to:

Chief Investigator: Prof. Sally Singh, Head of cardiac and pulmonary rehabilitation, Glenfield Hospital. sally.singh@uhl-tr.nhs.uk

Student Researcher: Ms. Munyra Alhotye, PhD student at University of Leicester.

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Thank you for taking the time to read this information sheet.