Stage 3. Patient 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. This study involves no interventions and is entirely exploratory.
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?

Corona virus disease 2019 (COVID-19) is a viral infection that has a direct effect on respiratory system and other organs including the heart. Recent studies suggested that patients who recovered from COVID-19 may continue to experience symptoms including fatigue, shortness of breath and irregular heartbeats. But this is not true for everyone. Evidences have shown that physical rehabilitation programmes have a positive effect in improving patients condition and reduce disease related symptoms such as shortness of breath, cough, palpitation and severe fatigue. However, the effect of rehabilitation programme on reversing abnormal heart rhythm in patients with COVID-19 has not yet been studied.
In this project we will collect information about your heart activity before and after rehabilitation to evaluate the benefits of the programme on reversing any cardiac rhythm disturbance that we may or may not detect.

Why have I been chosen?

We are inviting patients who have recovered from COVID-19 and have been enrolled into a post hospitalization rehabilitation programme 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. If you agree to take part in the research, you will sign a consent form.

At the start of the study, we will collect some information about you using questionnaires about your quality of life, disease symptoms , anxiety and mental health. We will also assess your usual exercise routine. We will connect a monitor called "Actigraph" which will be used to record your physical activity and a " Holter " device to record your heart activity at the start of the study, and again at the end of your rehabilitation programme.

Then, you will start your rehabilitation programme which includes a twice weekly sessions of disease education and exercise training including physical mobility and muscle strength training which will last for six weeks supervised by health care professionals.

What do I have to do?

After consent, you will be asked to complete the following assessments. These will be conducted when you first start the study and after 6 weeks of rehabilitation programme. Some of these details may be obtained from your medical notes if they have recently been collected from you.

Routine measures that will be collected:-

***Basic Details**

We will take your basic details (age, gender, current medication, height & weight etc). We will also discuss your previous medical history.

***Exercise Capacity**

You will be asked to walk between two cones at a set pace (recorded bleeps on a CD) until you need to stop. Depending on your walking ability this test takes between 5 and 15 minutes. For the initial assessment, you will be required to do 2 of these tests. The first will be practice, to allow you to become familiar with the test.

***Questionnaires**

You will be asked to complete some questionnaires about your disease symptoms, quality of life, anxiety and mental health . These Questionnaires will give us a guide to how your condition affects your daily life. There are some other questionnaires to complete, each taking around 5 minutes.

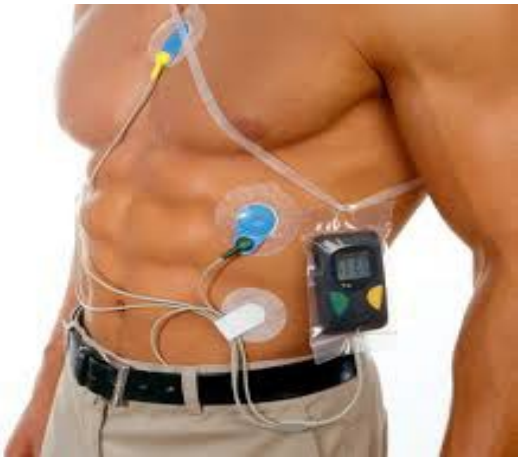
Study measures

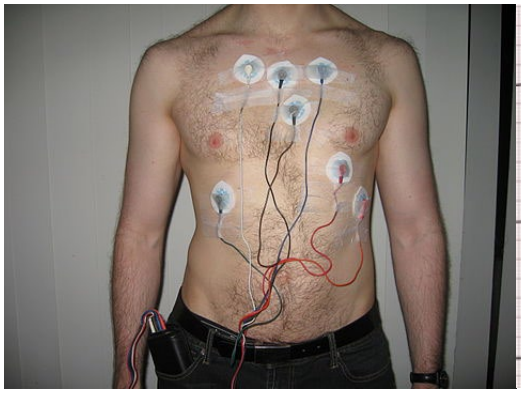
*** Heart activity**

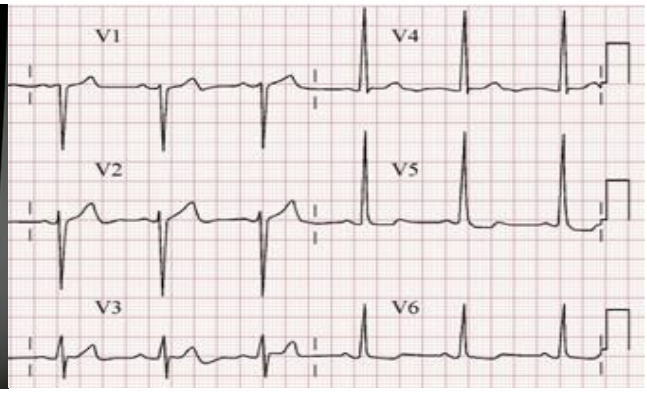
Before starting the study, we will connect a small monitor to record your heart activity, for 10 minutes and for 24 hours. **We will repeat this procedure another time upon completion of the study.**

You will have a 12 small sticky patches called "Electrodes" attached on your chest, these are connected by wires to a small recording machine called "Holter" which picks up your heart electrical activities for 10 minute period.

For the 24 hours monitoring: We will connect the monitor again and it will be placed on a belt around your waist. While you're wearing the recorder, you can do everything you would normally do except having a bath or shower. When completed 24 hours, the research team will contact you to collect the monitor from you. so the results can be analysed.







*** Physical Activity**

Before starting the study, you will receive a monitor which will record your activity levels. You will be wearing the Activity Monitor **every day during waking hours for the next 7 days and another 7 days at week 6 of rehabilitation programme.** You do not need to do anything with the monitor - just wear it.

You will put the activity monitor on every morning as soon as you get up and take it off just before you go to bed. The Activity Monitor is worn on an elastic belt around your waist on your right hip and can be worn either underneath or on top of your clothing just as long as the belt is 'snug' around your waist.

This monitor is **not waterproof** so you will take it off if you are bathing, showering or doing watersports activities (e.g., swimming). However, it is fine to wear the activity monitor if it is raining.

You will make a note if you take off your device in your daily log that we will give to you. This will help us to interpret your data more accurately.

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 understanding the effect of rehabilitation on your heart function therefore benefiting other patients.

What are the possible risks and disadvantages of taking part?

There are minimal identified risks to taking part in this research. You may experience some muscle aching and general tiredness after performing the walking tests and this is usually mild and wears off after a couple of days.

Will all information taken about me during this study be kept confidential?

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. 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.