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Patient Information Sheet

A Web-Based Cardiac REhabilitatioN Alternative for Those Declining or Dropping Out Of Conventional Rehabilitation: The WREN Feasibility Study.

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Invitation

You are being invited to take part in a research study being conducted by the cardiac rehabilitation team. Before you decide whether to participate it is important to know why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the study?

Evidence has shown that cardiac rehabilitation for patients with coronary heart disease (CHD) benefits the patient through improved physical, psychological and social functioning. Cardiac rehabilitation is usually delivered in hospital-based group sessions and, according to national guidelines should be offered to all patients leaving hospital following an acute myocardial infarction (MI/ "heart attack") or cardiac surgery. However, only 45% of eligible individuals with CHD are accessing this service. This lack of uptake may be for several reasons such as work commitments and difficulties with transport to the hospital. So having access to a web-based rehabilitation programme which covers topics such as medication and symptom management, exercise and nutrition, and which could be accessed at home and even on the move, could well be a more suitable solution for many patients with CHD. This would enable patients to have access to help and advice and a full cardiac rehab programme without having to travel to hospital.

'Activate***your***Heart®' is a web-based cardiac rehabilitation programme which was developed at Glenfield Hospital, Leicester over a number of years. Early results from pilot studies indicate that 'Activate***your***Heart® is successful in improving anxiety and depression, exercise capacity and quality of life in patients with CHD.

This is a feasibility study that has been designed to test whether a web-based rehabilitation programme is a feasible and acceptable alternative for patients who decline or drop out from conventional rehabilitation classes. This study is needed in order to inform the current delivery of the rehabilitation service and to optimise patient care.

Why have I been chosen?

We are inviting people with CHD who have *either* recently declined an invitation to take part in conventional rehabilitation classes *or* who have recently dropped out of these classes to take part in the study. To be eligible to take part you should have access to the internet via a computer, tablet or smartphone. It is important for us to see how people progress using the web-based rehabilitation programme. This knowledge will help us develop and improve future services.

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. 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. The data collected to the point of withdrawal may still be used.

What will happen if I take part?

If you decline to take part in, or do not wish to continue with, conventional rehabilitation classes, you may be contacted about the study by telephone or letter. If you are interested in the study, a member of the cardiac rehabilitation team will discuss the study with you and provide you with this information sheet. If you provisionally agree to take part in the research we will arrange a convenient date and time for you to come back to discuss the project in more detail. The cardiac rehabilitation specialists who assess you will ensure that it is safe for you to exercise unsupervised at home. If you agree to take part in the research, you will sign a consent form and then you will be placed at random into either the **web-based** rehabilitation group (intervention) or **usual care** group (control). Making comparisons between these two groups will show us how

effective the web-based programme could be for people who do not want to take part in conventional rehabilitation classes**.** We put people into groups and give each group a different treatment; the results are then compared to see if one approach is better than the other. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly) using a computer. There will be a 60% chance of being allocated to web-based programme.

We will collect some information from you using questionnaires and walking tests at the start of the study, after 8 weeks and again at 6 months. Overall your involvement will last up to 6-months, although the study will go on for much longer. We would like, with your permission, to inform your General Practitioner (GP) that you have agreed to take part in this study.

If during the study you decide you would prefer to take up the cardiac rehabilitation classes instead, that will be possible but we would need to withdraw you from the study.

What do I have to do?

After consent, you will be asked to complete the following assessments, regardless of which group you are allocated to. These will happen when you first start the study, after 8 weeks and again at 6 months. Each assessment visit lasts for approximately one hour. Some of these details may be obtained from your medical notes if they have recently been collected from you.

All participants

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 quality of life, anxiety & depression levels and confidence. This will give us a guide to how your condition affects your daily life. There are 5 questionnaires to complete, each taking around 5 minutes.

Symptoms

We will ask you to complete a symptom diary to monitor any cardiac symptoms, every day for one week. This will only take a couple of minutes to complete.

Interview

After your final appointment, you may be invited to take part in a semi structured interview. This will involve a discussion about declining or dropping out of the conventional classes and, if you used the web-based programme, this will be an opportunity to feedback what was useful about the website and any suggestions for improvement. This should not last longer than an hour and can take place in your own home, at the hospital or over the telephone. With your consent we would

like to record the interview. You do not have to do this interview to still be part of this research study.

Control group

After randomisation, if you are assigned to the **usual care** (control) group, you will continue to be followed up in the community by your GP and given standard advice on your heart condition. This represents 'best usual care' for this area. At 6 months, you will be offered the opportunity to go onto the 'Activate your Heart' web-based programme.

Intervention group

If you are assigned to the **web-based** (intervention) group, you will receive an introductory session to help you use and navigate your way around the website.

This session may take up to 1 hour. You will also be expected to enter some information about your current condition and previous medical history on to the web-based programme. This will produce an individual plan. You will probably use the website most days. The web programme will outline how to manage your condition including information on drug and symptom management, exercise and nutrition. Included will be some home-based exercises you can carry out in your own time. The website has 4 stages with tasks and goals to achieve to progress to the next stage. You will have access to a patients' discussion forum and an 'ask the expert' feature, where you can chat to your fellow patients or a cardiac rehabilitation specialist. You can also contact one of the team by telephone if you have any queries.

What are the possible disadvantages and risks 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 if you are randomised to the web-based exercise programme. This is usually mild and wears off after a couple of days.

If you are randomised to the control group, you will not receive any form of rehabilitation. This would be standard care if you declined rehabilitation classes or dropped out during a conventional cardiac rehabilitation programme. However you will be offered the opportunity to go onto the 'Activate***your***Heart®' web-based programme at your 6 month assessment.

You will be asked to make additional visits to hospital over the 6 month study period. This is a potential inconvenience but, in our experience, most patients are happy to attend. Travel expenses will be reimbursed or a taxi provided for these assessment visits.

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 your understanding of exercise and rehabilitation and inform both present and future cardiac rehabilitation programmes, therefore benefiting other CHD patients.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (0116 250 2758). There are no special

compensation arrangements in the unlikely event that you are harmed through taking part in the research project. If you are harmed due to someone's negligence you may have grounds for legal action but may also have to pay costs for such action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms would be available to you. Advice can be sought from the Patient Information and Liaison Service (PILS). Their telephone number is: 08081 788337 and their email address is: pils.complaints.compliments@uhl-tr.nhs.uk.

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

All information that is collected about you during the course of the research will be kept strictly confidential. With your permission, we will inform your GP that you are taking part in the study and that they may be contacted for relevant reports. Information about you will be initially stored on paper and then transferred to a secure web-based database. Full access to this database will be restricted to the study coordinator. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. Participants will not be identified in any subsequent written material; for example, numbers will be used to refer to participants' names. Results will be reported in such a way that completely preserves confidentiality.

What will happen to the results of the research study?

The results of the study will be disseminated in peer and lay journals, professional publications and presentations made at relevant conferences. Results will be reported in such a way that preserves confidentiality. All participants will also receive a summary letter of the results.

Who is organising and funding the research?

The study is sponsored by the University Hospitals of Leicester. The study is being funded by the Research for Patient Benefit (RFPB) programme which is part of the funding body National Institute for Health Research (NIHR). The Cardiac Rehabilitation team at your local hospital will be recruiting participants to the study. The study is also supported by the NIHR Leicester Respiratory Biomedical Research Unit (BRU).

Who has reviewed the study?

All research that involves NHS patients or staff, information from NHS medical records or uses NHS premises or facilities must be given a favourable opinion by an NHS Research Ethics Committee before it goes ahead. A favourable opinion 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. This study has been reviewed and given favourable opinion by the NHS Health Research Authority (NRES) Committee NRES Committee East Midlands – Leicester**.**

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

Contact for further information

For further information please **contact**:

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Thank you for reading this information leaflet.

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