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University Hospital
SISTERS OF MERCY

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Not for prescription purposes

Version 2

Patient Informed Consent

DUBLIN CITY UNIVERSITY PATHway (Physical Activity Towards Health): Pilot Randomised Controlled Trial

Principal Investigator: Dr. Catherine Woods, School of Health and Human Performance,

Other Investigators: Dr. Deirdre Walsh, School of Health and Human Performance, Prof. Niall Moyna, School of Health and Human Performance, Ms. Clare McDermott, School of Health and Human Performance, Anne Gallagher, Cardiac Rehabilitation Coordinator, Mater Hospital, Dr. Ivan Casserly, Consultant Cardiologist, Mater Hospital, Helen Newton, Cardiac Rehabilitation Coordinator, Beaumont Hospital. Dr. Brendan McAdam, Consultant Cardiologist, Beaumont Hospital.

The purpose of this study is to assess the acceptability, short-term effectiveness on lifestyle and health related physical fitness and cost-effectiveness of the PATHway intervention in patients with cardio-vascular disease.

Involvement in this study will require you to take part in a 6-month technology-enabled remote randomised control trial. As part of this trial, you will be randomly assigned into groups that will either i) receive 'usual care' or ii) take part in an intervention that will receive the PATHway system which will allow you to engage with a tailored exercise and health behaviour change programme.

All participants will be asked to complete physiological tests and questionnaires when they begin, 3 months and finally at 6 months regardless of group.

As part of these tests and the start and at the end of the study you will have your blood taken. These bloods will then be analysed and stored in the Mater Hospital under the supervision of Dr. Maria FitzGibbons. We will ensure that any incidental findings are reported to the Cardiac Rehabilitation Unit. The cardiac rehabilitation coordinator will then ensure to inform you of any issues that may have been identified and will advise you on the usual care next steps.

Participant – please complete the following (Circle Yes or No for each question)

I have read the Patient information sheet (or had it read to me)

Yes/No

I understand the information provided

Yes/No

I have had an opportunity to ask questions and discuss this study

Yes/No

I have received satisfactory answers to all my questions

Yes/No

If at any point during your participation in the study you feel as if you wish to withdraw this is not a problem. You are under no obligation to stay involved if you do not wish too. However, you will be asked to arrange a convenient time to have the PATHway equipment collected/returned to the research team.

Please make sure to contact the investigators if you are unable or unwilling to continue in the project so as we can address any issues within the project.

Dublin City University will protect all the information about you, and your part in this study. All your personal data will be anonymized and assigned a unique code which will protect your identity. All your information will be stored securely and saved in accordance with EU law and best conduct guidelines.

Your identity or personal information will not be revealed or published.

The study findings may be presented at scientific meetings and published in a scientific journal but your identity will not be divulged and only presented as part of a group. Please be aware that the confidentiality of information provided can only be protected within the limitations of the law.

If you have questions about the research project, please feel free to call Dr. Deirdre Walsh at 01-7007653.

I have read and understood the information in this form. My questions and concerns have been answered by the researchers, and I have a copy of this consent form. Therefore, I consent to take part in this research project:

Participants Signature:_____

Name in Block Capitals:_____

Date:_____

Name of researcher taking Consent: Dr. Deirdre Walsh

Signature:


