Mater Misericordiae University Hospital
Sisters of Mercy
Ospidéal Ollscoile Mater Misericordiae
Siúracha na Trócaire

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Version 2

Plain Language Statement

Project Title: 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.

1.What is Cardiovascular disease (CVD) and the PATHway system?

Cardiovascular disease generally refers to conditions that involve narrowed or blocked blood vessels that can lead to issues in heart functioning.

The PATHway system is designed to help people who have CVD remain physically active and learn more about living a heart healthy lifestyle.

There are several parts to the PATHway system

-a laptop (which use WiFi or the internet)

- a Microsoft Kinect (like an xbox-often used to play video games)

-a Microsoft band 2 (which is a physical activity sensor that you wear on your wrist.

These pieces of equipment work together to enable you to exercise in your own home as you did during your cardiac rehab classes. You can

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use the laptop and Kinect to take part in virtual exercise classes or you can simply use the band to count your steps when you walk-all options are available to you.

PATHway can also provide healthy lifestyle guidance (e.g., managing exercise, quitting smoking, healthy eating etc.) to enable you to both better understand and deal with your own condition and to lead a healthier lifestyle in general.

You can turn on the PATHway and select to begin the exercises on the laptop, to read up on healthy lifestyle tips and recommendation or to check up on their progress with your own PATHway physical activity profile. An example of the PATHway system can be seen online here:

Below are images of the three pieces of equipment:

2.Details of what involvement in the Research Study will require

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 make a visit to the Vascular research unit in DCU. A pre-paid taxi service will be provided for all participants and a research team member will meet all participants at the taxi drop-off point to escort everyone to the Vascular research unit for physiological tests and questionnaires at baseline, 3months and finally at 6months regardless of group. During the visit to DCU, i) a blood sample

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will be drawn, ii) your height, weight, waist and hip circumference, and the amount of muscle and fat will be measured, iii) a picture will be taken of a blood vessel in your neck, iv) the health of a blood vessel in the arm will be assessed, v) your blood Pressure will be measured, vi) you will undergo a fitness level on a treadmill vii) your muscle strength and endurance will be measured and viii) you will complete questionnaires. You will be asked to fast for from 10pm the night before the visit to the VRU and will not be allowed to exercise for at least 24 hours before the visit to DCU.

- Two tablespoons of blood will be taken to measure a variety of biomarkers in the blood that are used to predict the risk of CVD. A bioelectrical impedance scale will be used to measure amount of muscle and fat. Your waist and hip circumference will be measured with a measuring tape. The blood samples, body fat and waist and hip measurements will be taken in a private room. A female researcher will measure height and weight and take the skinfold measurements in female participants.
- A special machine called an ultrasound will take a picture of a blood vessel in your neck. (figure A). The health of a blood vessel in your arm will be also measured using the ultrasound machine and involves two steps. The first step will involve blocking the blood flow to your lower arm for 5 minutes by inflating a blood pressure cuff, and then taking a picture when the blood pressure cuff in released. The second step involves spraying a medicine called glyceryl trinitrate under your tongue in order to widen the artery and then taking a picture 3 minutes later (figure B).

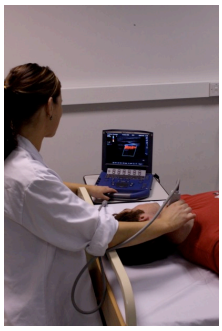

Figure A

Figure B

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- Your fitness will be assessed by having running on a treadmill while wearing a special headgear that is attached to a mouthpiece and connected to and ECG machine which looks at the activity of your heart.
- Your strength will be measured using three different ways. You will complete a hand grip test, a sit to stand test where you will sit and rise from a chair in a given time frame and finally using an isokinetic machine which will require you to sit in a chair while your leg is strapped in and you will push against a fixed force.

3. Potential risks from involvement in the Research Study

- You may experience some muscle soreness in his/her legs or nausea following exercise.
- Exercise carries with it a very small risk of abnormal heart rhythms, heart attack, or death in less than one in 30,000 patients. . In patients with established chronic illness the risk is higher. In cardiac rehabilitation programs the occurrence of major cardiovascular events ranges from 1/50,000 to 1/120,000 patient- hours of exercise, with only 2 fatalities reported per 1.5 million patient-hours of exercise. The School of health and Human performance in DCU have the facilities and personnel to deal with any emergencies that arise and an emergency plan is in place. A GP will provide medical supervision on site during testing. An emergency room and automated external defibrillator (AED) are available onsite. The research team are appropriately qualified and experienced in working with clinical populations in a safe and professional manner.
- Drawing blood may cause a slight pain where the needle is inserted and can leave a bruise. A person trained to take blood will be used to decrease these risks. The amount of blood drawn is not harmful.
- Stopping the flow of blood for a period of 5 minutes may induce slight discomfort in your arm which will go away when the blood pressure cuff is deflated.
- Glyceryl trinitrate, is a type of medicine called a nitrate that works by being converted in the body to a chemical called nitric oxide. This chemical (nitric oxide) is also made naturally by the body and has the effect of making the veins and arteries relax and widen (dilate).

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This makes it easier for the heart to pump blood around the body. There is a very small chance that you may get a headache that may last 5-10 minutes after glyceryl trinitrate is sprayed under your tongue.

4. Benefits from involvement in the Research Study

You will receive a report summarizing the results of the tests undertaken during the study. No other benefits have been promised.

5. Arrangements to protect confidentiality of data

Your identity and other personal information will not be revealed, published or used in further studies. You will be assigned an ID number under which all personal information will be stored and saved in a password protected file in a computer at DCU. The person is charge of the study and the other researchers listed on this ethics application will have access to the data. You need to be aware that confidentiality of information provided can only be protected within the limitations of the law. It is possible for data to be subject to subpoena, freedom of information claim or mandated reporting by some professions.

6. Advice as to whether or not data is to be destroyed after a minimum period

The original documentation will be stored for a maximum of 5 years. Thereafter the documentation will be shredded.

7. Involvement in the Research Study is voluntary

Involvement in this study is completely voluntary. You may withdraw from the Research Study at any point. There will be no penalty for withdrawing before all stages of the Research Study have been completed. If you withdraw from the study before all stages of the project are complete, all your data will be destroyed and all related data deleted irrevocably. Dr. Deirdre Walsh and Ms. Anne Gallagher are responsible for the coordination of this and can be contacted at any time if you have any concerns.

If participants have concerns about this study and wish to contact an independent person, please contact: The Secretary, Dublin City University Research Ethics Committee, c/o Office of the

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