L-Università ta' Malta

Faculty of Medicine and Surgery

Coronary Risk Reduction Intervention for Siblings and Offspring of patients with premature Coronary heart disease: The CRISO pilot intervention study.

Information letter for participants

I would like to invite you to join a research study.

Before you decide it is important for you to understand 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.

What is the purpose of this research?

I am carrying out a University Project to understand ways in which I can help people to improve their lifestyle and heart health.

Smoking, poor diet, and lack of exercise are associated with obesity, inadequate blood pressure, glucose and cholesterol control, all being risk factors that lead to coronary heart disease.

However, if lifestyle factors such as cigarette smoking, physical inactivity and unhealthy diet are modified, there might be substantial decrease in coronary heart disease risk. If you are screened and identified, this will give the opportunity for prevention to take place before establishment of the disease, hence preventing or delaying the disease.

Do you have a brother or a sister or parents who had a heart attack before the age of 55 for men or the age of 65 for women?

If the answer is yes, you might be the right candidate to take part in this programme.

Do I have to take part?

No. It is entirely up to you.

What will happen to me if I take part?

At a convenient time, you will be invited to come at Mater Dei Hospital. (Cardiac Rehabilitation Unit, Yellow wards, -1 floor), where I will discuss the project programme

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with you and answer any questions you might have. If you are happy to take part, I will ask you to sign a consent form. Even after you have signed this consent form and agreed to join the project, you are free to withdraw from the programme at any time, without giving any reasons and this will not compromise your medical management. However any results that have been already produced from anonymised data will not be destroyed and will be included in the study.

In order to collect information, you will be asked basic information (e.g. date of birth, body height, body weight) and answer some questionnaires about diet, exercise and smoking. I will investigate parameters such as blood cholesterol, glucose, heart rate, blood pressure and global cardiovascular risk. This evaluation will take place 3 times (baseline assessment, 6 month follow-up, 12 month follow-up). Biomedical results (cholesterol, glucose and thyroid function results) will become part of your medical record. An MDH employee (Dr Carina Debattista/Ms Josette Desira/Prof Joseph Galea) will provide the researcher (Mr Justin Lee Mifsud) with the results. Calculation and explanation of risk will be provided. A plan towards a healthier lifestyle will be discussed. The program will include lifestyle interventions to help you plan and manage your own risk. You will be assigned to one of prevention programs that is available. Depending on your risk profile I may ask you for a second blood sample for DNA testing of genes that control the lipids. This will be performed solely for this research (CRISO). DNA testing in this study is not of a diagnostic nature. Thus, results of genetic testing will not be forwarded to you. The genetic data and blood samples are to be kept until completion of the study and then destroyed by myself.

This will support in developing an individualised programme to examine the usefulness of it by understanding ways in which help can be provided to improve your lifestyle and your heart health.

In total, you will have 4 separate visits of around 1 hour each (baseline assessment, CRISO lifestyle intervention programme/verbal lifestyle advice only, 6-month follow-up, 12-month follow-up). Apart from this, you may have 12 telephone support calls in the first three months. You can also be asked to be interviewed and with your consent audio recorded at month 12.

What is the procedure that is being tested?

This study is simply looking at preventative intervention to support you to improve your lifestyle and your heart health.

What are the side effects of any treatment received when taking part?

There are no treatments given as part of this testing.

What are the possible disadvantages and risks of taking part?

The assessment techniques are safe and potential risks are very minimal if having these assessments performed correctly. Some bruising is possible after withdrawing of blood.

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What are the possible benefits of taking part?

These could be health benefits, such as weight, blood pressure and blood glucose improvement. However, I am hoping to gain understanding about preventive behavioural interventions; this research may also lead to knowledge into which elements of behavioural interventions are likely to be feasible. DNA testing in this study is not of a diagnostic nature and no immediate benefits will be gained.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements, but you would be treated freely at Mater Dei hospital. If you are harmed due to negligence, then you may have grounds for a legal action.

Will taking part in this study be kept confidential?

The information that you give will be entirely confidential and your identity will not be known to anyone else outside this research. All the data collected will be coded and stored in a secure encrypted computer and only the researcher and the supervisor will have access to it. The interviews will be audio recorded and will be destroyed once the information has been transcribed. The transcriptions will not include any personal information that will identify the participant. Data will be placed in a secured place within the Faculty of Health Sciences after which they will be destroyed once the study is completed. If the study is published in a scientific journal, no individual will be identified in any way.

What will happen to the results of the research study?

The results of the study will be analysed by the researcher and presented at behavioural science, cardiology and other health care conferences and published in scientific journals. Please note that confidentiality will be maintained and it will not be possible to identify you from any publications.

Who is organising and funding the research?

The study has been organised by Justin Lee Mifsud, a researcher based at University of Malta. This research is funded by University of Malta.

Who has reviewed the study?

This study is approved by the University of Malta Ethics Committee and the Health Ethics Committee.

You may ask for further information by telephoning 23401109/ 79433879, or 254555488/ 99823852 which has a 24-hour answer phone. The persons to speak to, who are responsible for the study, are Justin Lee Mifsud and Joseph Galea.

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Criteria for inclusion: You are eligible to participate in this study if you

1) Are a healthy person age 30 and over.

2) Have a brother or sister or a parent who had a heart attack before the age of 55 for males and 65 for females.

Criteria for exclusion:

You CANNOT take part in this study if you:

1) Are pregnant,

2) Had episodes of angina or had a heart attack,

3) Not able to climb a flight of stairs comfortably without the need to stop halfway

4) Have diabetes

5) Have rheumatoid arthritis

6) Have chronic kidney disease

7) Have atrial fibrillation

'Under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said Regulation, you have the right to obtain access to, rectify, and where applicable ask for the data concerning you to be erased'

Thank you for taking time to read this information sheet. You can keep this information sheet and please do not hesitate to ask if you need any further information. You should contact Justin Lee Mifsud on the contact details below.

Signature of the researcher:

Date: _____

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