**Participant Information Sheet (PIS)**

**Study title: What impact does a diagnosis of cardiomyopathy have on attitude to physical activity in adults?**

**REC Reference Number: \_\_\_\_\_\_\_\_\_**

**Participants will be given a copy of this information sheet**

We are BSc physiotherapy students at St George’s University of London*.* We would like to invite you to participate in this research project which forms part of our BSc physiotherapy Degree research. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please feel free to contact the research group if there is anything that is not clear or if you would like more information.

This study has been given a favourable ethical opinion by the St George`s Research Ethics Committee.

***What is the purpose of the study?***

The aim of this study is to explore how being diagnosed with cardiomyopathy and the information provided at diagnosis may have changed your attitude towards physical activity. The purpose of this research is to help understand and potentially improve current health care practices and aid future research in this area.

We are specifically interested in gaining an understanding of your perception and participation in physical activity before diagnosis and whether anything has changed since your diagnosis.

***Why have I been invited to take part?***

We are looking to invite 8 individuals to take part in this research who;

 ● Are over 18 years old

 ● Have a diagnosis of cardiomyopathy

 ● Have access to Microsoft Teams

* Consent to participate in this research

***Do I have to take part?***

No, participation is voluntary. You do not have to take part. You should read this information sheet and if you have any questions you should ask the research team.

***What will happen to me if I take part?***

You will be required to take part in a one-off interview on Microsoft Teams (MS Teams) with two members of our research team. One member of the research group will be conducting the interview while the other will be taking notes and will provide support if needed.

The interview will last approximately 1 hour. We will be taking an audio recording of the interview for transcription, therefore camera use is optional.

The interview will be recorded directly on MS Teams. The interviewer will also record the audio of the interview on a mobile device (on airplane mode). The conversation will be transcribed and sent to you via e-mail. We request you to read through the transcription carefully to ensure it is an accurate representation of the discussion. Following this, please e-mail the research team with your approval/request for amendments within 10 working days from the interview date.

The 2 recordings will be kept on a password protected OneDrive for 10 working days, at which point the recordings will be deleted.

You can withdraw from the study anytime up until 10 working days following the interview without providing a reason for this. In this case, all your personal details will be deleted immediately. After 10 working days withdrawal is not possible as the data will be anonymised, therefore we will be unable to identify your data for removal.

In order for you to participate, we require your written consent. You can find the consent form at the end of this document. Please read this carefully, sign each section if you agree and return via email to m2007356@sgul.ac.uk.

We will also ask for your verbal consent at the beginning of the interview.

Once we receive your signed consent form we will contact you via e-mail to schedule an interview date and time that suits you.

You will not be contacted for future research, however the anonymised data will potentially be used in future studies.

***What are the possible benefits and risks of taking part?***

There are no direct benefits for you, however the information we get from this study, can help shape future research into cardiomyopathy and improve health care practices for future generations.

The risk for taking part in this study is potentially becoming distressed as discussing this topic may be emotionally difficult for some. We will be ready to provide emotional support in a breakout room if needed.

***What if something goes wrong?***

If you wish to make a complaint about the conduct of the study you can contact our research supervisor using the details below for further advice and information:

Dimitra Nikoletou -

Address: 6th floor Hunter wing, St George’s University, Cranmer Terrace, Tooting, SW17 ORE, London.

Email: dinikole@sgul.ac.uk

Tel: 0208 725 2277.

The University has in force the relevant insurance policies which apply to this study. If you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should follow the instructions given above.

If at any point you become distressed during the interview and feel you need further support, please contact your GP or you can contact MIND on;

Phone number: 0300 123 3393

Email: info@mind.org.uk

***Who should I contact for further information?***

If you have any questions or require more information about this study, please contact us via email:

m2007356@sgul.ac.uk

***What data will be collected? How and where data will be stored? How long data will be kept?***

As a publicly-funded organisation, we have to ensure when we use identifiable personal information from people who have agreed to take part in research, this data is processed fairly and lawfully and is done so on the basis of **public interest**. This means that when you agree to take part in this research study, we will use your data in the ways needed to conduct and analyse the research study.

Personal data (age, gender) and special category data (date of diagnosis and physical activity habits before and after diagnosis) will be collected by BSc Physiotherapy students using MS Teams interview recordings. A separate audio recording will be conducted using a mobile phone on airplane mode.

Conversation will be transcribed and emailed to you for verification as discussed above.

Once you have verified the transcript and notified the research team, your data will be anonymised and the recordings will be deleted (within 10 working days from the interview date).

The anonymised transcripts and consent forms will be kept on a password protected One Drive linked to St George's University for 5 years. Following this, all data will be destroyed. The password will only be known to the researchers involved.

***Who is Handling My Data?***

St George’s University of London as the sponsor, will act as the ‘Data Controller’ for this study. We will process your personal data on behalf of the controller and are responsible for looking after your information and using it properly. This information will include your name, age, and gender, which is regarded as ‘personal data’ and your diagnosis, the date of your diagnosis and your physical activity habits which is regarded as a ‘special category personal data’ (defined above). We will use this information as explained in the ‘What is the purpose of the study’ section above.

***What happens if I change my mind?***

You have the right to change your mind and withdraw any time up until 10 working days after the interview. After this time your data will be anonymised and cannot be withdrawn or changed. We will use no personally identifiable information to safeguard your rights.

You can find out more about how we use your information:

[**https://www.sgul.ac.uk/privacy**](https://www.sgul.ac.uk/privacy)

Or contact our university Data Protection Officer at:

**Email:** **dataprotection@sgul.ac.uk**

**Tel: 020 8725 0668**

***What will happen to the results of the study?***

The information you provide will be analysed to produce our research project dissertation. These will be used to help to potentially shape future research in this area. A copy of the final report summarising the main findings of the research can be provided upon request.

***Will my data be used for future research?***

All data will be anonymised which means that all personal data will be removed and no longer accessible, therefore the research data cannot be traced back to an individual. The anonymised data will only be used for the purpose of research and cannot be used to contact you or affect you directly. Our research supervisor Dimitra Nikoletou will have continued access to the anonymised data, which may be used in future studies.

***What if I want to complain about the way data is handled?***

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner’s Office (ICO) (<https://ico.org.uk/>).

***Data Protection Privacy Notice***

St George`s University London conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. The University’s data protection policy governing the use of personal data by the University can be found on its website (<https://www.sgul.ac.uk/about/our-professional-services/information-services/information-governance/data-protection/data-protection-policy>).

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University’s policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the St George London University is required by law to disclose it.

For the purposes of data protection law, the University is the ‘Data Controller’ for this study, which means that we are responsible for looking after your information and using it properly. It will keep identifiable information about you for 5 years after the study has finished after which time any link between you and your information will be removed.

**Thank you for taking the time to read this information sheet and for considering taking part in this research!**

**If you would like to participate in this study, please complete the consent form below and return it via email to:**

m2007356@sgul.ac.uk

**For further information, please contact the research group via the above email or our research supervisor; Dimitra Nikoleou:**

dinikole@sgul.ac.uk