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## Plan Overview

*A Data Management Plan created using DMPMelbourne*

**Title:** Empowering Sustainable Therapeutic Engagement with Music (ESTEEM): A Pilot Study of a Self-administered Music Therapy Program for Cardiac Rehabilitation Participants in Thailand

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**Template:** University of Melbourne DMP Template

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### Project abstract:

Cardiovascular diseases (CVDs) are life-threatening chronic health conditions. The relationship between CVDs and mental health is bidirectional. Music can be beneficial to mental health of those living with CVDs. However, research that involves the process of music therapy in cardiac rehabilitation, facilitated by a music therapist, is largely absent. Moreover, little research has been done on the effects of continuous engagement with music for long-term health benefits, despite the chronic nature of CVDs and the fact that self-management is a major focus in cardiac rehabilitation. Therefore, the ESTEEM music therapy program will enable people with CVDs in cardiac rehabilitation to develop capacity in self-administering music interventions to address their psychological wellbeing. This pilot mixed-method two-arm parallel randomized controlled trial aims to 1) determine the feasibility of the ESTEEM program and the research protocol, 2) collect pilot data necessary for determining the sample size for a larger trial in the future (i.e., depression, anxiety, and stress using DASS-21), and 3) gather information about the participants' experience via diaries and interviews.

**ID:** 1918

**Start date:** 05-08-2022

**End date:** 30-04-2024

**Last modified:** 26-12-2023

### Copyright information:

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# Empowering Sustainable Therapeutic Engagement with Music (ESTEEM): A Pilot Study of a Self-administered Music Therapy Program for Cardiac Rehabilitation Participants in Thailand - Managing Data @Melbourne

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## 1. Getting Started

### Faculty / Department

- Faculty of VCA and MCM

Music Therapy, Creative Arts and Music Therapy Research Unit (CAMTRU).

### Project Start Date

05/08/2022

### Project End Date

30/04/2024

## 2. Developing your DMP (about your data)

### What kinds of data will you collect, create or reuse?

To address the research aims, this project involves the use of both digital and non-digital data.

Firstly, participants' characteristics, demographics, and consent will be collected at the registration and uploaded digitally into REDCap. De-identified data will be stored in MediaFlux at the end of the project.

To address the feasibility aim, participation rate and incident (e.g., adverse events, encountered challenges) will be recorded in REDCap. De-identified data will be stored in MediaFlux at the end of the project.

To address the quantitative aim, the participants will complete paper-based Depression Anxiety and Stress Scale 21 (DASS-21) questionnaires. Data from the completed DASS-21 will be entered into REDCap. De-identified data will be stored in MediaFlux at the end of the project.

To address the qualitative aim, data from paper-based diaries will be entered into REDCap. De-identified data will be stored in MediaFlux at the end of the project. MP3 audio-recorded interviews of the participants' experience will be transcribed and entered into REDCap. The audio files will be stored in Onedrive, then deleted after data analysis. De-identified transcriptions will be stored in MediaFlux at the end of the project.

The original paper-based materials will be securely stored in a locked cabinet in a locked office until the end of the project, and then destroyed.

After all ESTEEM Project data are collected and analyzed and all foreseen articles are published, the REDCap project will be deleted. All de-identified data will be stored in MediaFlux with the corresponding dictionaries and a README document with instruction on using the data.

Original participant codes and identifier variables will be stored in a separate digital password-protected file.

### What file formats will the data be in?

In REDCap, data can be exported in several formats (e.g., .csv, Stata, SPSS, R, etc.). The participants will complete their paper-based forms, questionnaires, and diaries. Data from the interviews will be recorded in .mp3. Other formats of data in this project include .xlsx, .docx, .csv, .txt, and .pdf.

## 3. Ethics and Legal Issues

### How will you manage any ethical issues?

This project is a pilot two-arm randomized controlled trial involving 12 participants per arm (24 participants in total). The participants in this project will be Phase 2-3 cardiac rehabilitation participants who are clinically stable and showing evidence of expected physical recovery.

This project received ethics approvals from the University of Melbourne and the Faculty of Medicine, Chulalongkorn University.

All data will be collected with consent from the participants. The collected data will be de-identified, and any identifiable data will be kept securely and separately. Only researchers involved in the study will have access to the data.

### How will you manage copyright and Intellectual Property Right (IPR) issues?

No copyrighted material will be collected in this study.

## 4. Organising, Storing and Backing-up your Data

### How will you store and backup your data during the project?

Data will be digitized and stored electronically at the University of Melbourne-provided REDCap (for identifiable data), MediaFlux (for de-identified data), and Onedrive (for audio recordings during the analysis) which is backed up by University IT.

The paper-based materials will be securely stored in a locked cabinet in a locked office until the end of the study, then destroyed.

#### **How will you manage access and security?**

REDCap, MediaFlux, and Onedrive are secure online data management platforms provided by the University of Melbourne. They will be used for the storage and management of digital data. The digital data will be stored with the corresponding dictionaries and a README.txt document with instructions on using the dataset.

The original paper-based materials will be securely stored in a locked cabinet in a locked office until the end of the study, then destroyed.

Only researchers involved in the study will have access to the data.

## **5. Documenting and Describing your Data**

#### **What documentation and metadata will accompany the data?**

A README.txt file will be present that describes the file organization, directly structure, naming convention and data standards used. A separate data dictionary will explain the fields and column types and format for tabular data.

#### **How will the consistency and quality of the data be controlled?**

The PhD Candidate will be responsible for entering data into REDCap, MediaFlux, and Onedrive. The PhD Candidate will also review the data for consistency, missing, and errors during data collection and after completion.

## **6. Sharing and Preserving your Data**

#### **How will you share your data?**

De-identified electronic data will not be destroyed, as per the National Statement on Ethical Conduct in Human Research. They will be made publicly accessible where possible and we will share data and other research outputs. Future research may benefit from access to our de-identified data, and several journals now require publication of de-identified raw data sets. Furthermore, data collection imposes a burden on participants, and not making it available/accessible may trigger requests for new or further data collection that imposes a potential future burden. Therefore, we have included a section in the Plain Language Statement (PLS) to explain that de-identified data may be published and shared with other researchers. In addition, Dr Jeanette Tamplin, the Responsible Researcher and Primary Supervisor, will maintain responsibility for the custody of the data and research outputs and securely store these at The University of Melbourne until they are made publicly accessible in de-identified format or destroyed.

#### **Are there any restrictions on data sharing required?**

Data will be made available upon request to Dr Jeanette Tamplin, the responsible researcher, following the publication of the project.