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.

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End date: 30-04-2024

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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

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.

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

1. Ethics Approval

Does this project require animal or human ethics approval?

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

2. Data Collection and Analysis

How will you ensure your research is reproducible?

All methodological aspects of this project will be described in its research protocol. The detailed procedure of the research will be described in the thesis. The summary of the procedure will appear in research articles derived from this project.

3. Data Storage - Digital Data

Describe the volume of digital data that is expected to be generated in MB, GB, TB etc.

As the MP3 audio files from the interviews will not be permanently stored, we estimate we will need less than 1 TB for storage.

Storage type, location and backup

We will store backups at the University of Melbourne-provided REDCap, MediaFlux, and Onedrive.

Access, confidentiality and security

Only researchers involved in this project will have access to the data.

Storage of pre-existing data

Not applicable.

4. Data Storage - Non-Digital Data

Non-digital data types

Paper-based materials including forms, questionnaires, and diaries.

Storage location

During the study, non-digital data will be stored in a locked cabinet in a locked office under the responsibility of Mr Napak Pakdeesatitwara.
The participants will take custody of their own diaries as they have to complete them whenever they use music in daily life. Then, the diaries will be collected at week 8 and at 3-month follow-up (intervention group only) for digitization. After that, the diaries will be stored in a locked cabinet in a locked office under the responsibility of Mr Napak Pakdeesatitwara.

Safeguards and requirements

The non-digital data will be securely stored in a locked cabinet in a locked office under the responsibility of Mr Napak Pakdeesatitwara during the study. Only researchers involved in this study will have access to the non-digital data. The non-digital data will then be destroyed after the end of the project.

Other requirements

Non-digital data will be digitized for storage in REDCap. De-identified data will be stored in MediaFlux at the end of the project.

5. Intellectual Property, Copyright and Ownership

Contracts and agreements

TBC

Ownership

The University of Melbourne asserts ownership of intellectual property created by its staff and students.

Pre-existing data

Not applicable.

6. Data documentation and management

Naming conventions and filing structures

Backup versions will contain the study name and the date as in the example:
/ESTEEM_pilot_backup_DDMMYYYY

De-identified datasets will be labelled with the study name, as in the example below:
/ESTEEM-pilot
.../ESTEEM_pilot_dataset.cvs
.../ESTEEM_pilot_dictionary.xlsx
.../ESTEEM_pilot_methodology.pdf
.../ESTEEM_pilot_READme.txt

Version control

Backup versions will be indexed by date DDMMYYYY.

7. Post-project data retention, sharing and destruction

Data to retain

De-identified electronic data will not be destroyed, as per the National Statement on Ethical Conduct in Human Research, and will be made publicly accessible where possible and we will share data and other research outputs.
Usable de-identified data will be exported from REDCap. Then, the REDCap project will be deleted after all ESTEEM Project data are collected and analyzed and all foreseen articles are published. 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.
The audio files in Onedrive will be deleted after data analysis.
The original paper-based materials will be destroyed at the end of the project.

Pre-existing data

Not applicable.

Duration

The summary record of research data will be permanently retained as University archives. Datasets created from clinical trials will be temporarily retained for 15 years after completion of research activity, then destroyed.

Non-digital data

Not applicable.

Digital data

Storage type	Repository name	Location
Online	MediaFlux	The University of Melbourne

Licencing

TBC