Date: 4th April 2025

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

You are being invited to participate in a research study. Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Please read carefully the information provided here. If you agree to participate, please sign the consent form. You will be given a copy of this document to take home with you.

STUDY INFORMATION

Protocol Title: The Effects of Music Therapy Interventions on Cognition among Adults with Neuro-rehabilitation Needs

Principal Investigator: Lim Kar Gee, MA, MT-BC (Board Certified Music Therapist)
Socso Tun Razak Rehabilitation Centre, Malacca, Malaysia
+6012–2340689

OVERVIEW OF THE RESEARCH STUDY

You are being invited to participate in a research study of the effects of music therapy interventions on cognition. We hope to learn how both active and passive music therapy interventions may affect cognition. You were selected as a possible participant in this study because you are in the age range of 30 to 60 and you score between 10 to 22 on Mini-Mental State Examination (MMSE).

This study will recruit at least 30 participants from Socso Tun Razak Rehabilitation Centre at Malacca in Malaysia over a period of 5 months. When your participation in the study ends, you will no longer have access to the specific interventions as detailed in the study, unless special additional arrangements are made by the Principal Investigator.

PURPOSE OF THE STUDY

The study is being conducted because passive or active music therapy interventions are not yet established as a standard intervention in participants with cognitive neuro-rehabilitation needs. We hope that your participation will help us to determine the effect of passive or active music therapy interventions as compared to other study conditions.

YOUR RESPONSIBILITIES IN THIS STUDY

If you agree to participate in this study, you should*:*

- Keep your study appointments. If it is necessary to miss an appointment, please contact the Principal Investigator (PI) to reschedule as soon as you know you will miss the appointment.
- Complete all three sessions to the best of your ability.

WITHDRAWAL FROM STUDY

You are free to withdraw your consent and discontinue your participation at any time without prejudice to you or effect on your therapy regime. If you decide to stop taking part in this study, you should inform the PI immediately.

If you withdraw from the study, or the study is stopped for any reason,

- be assured that there are no known risks or consequences of discontinuing the sessions.
- if you would like continued music therapy sessions (outside of the study), please inform the PI.

However, the data that have been collected until the time of your withdrawal will be kept and analysed, so as to complete, as much as possible, a comprehensive evaluation of the data.
The PI of this study may stop your participation in the study at any time for one or more of the following reasons*:*

- Failure to follow the instructions of the PI.
- The study is cancelled.

POSSIBLE RISKS AND DISCOMFORTS

The PI does not foresee any additional risks if you participate in the study, compared to the day-to-day standard therapy protocol, as the interventions will be implemented in the same physical environments, with same equipment and personnel. There could also be potential risk of breach of confidentiality and anonymity. There are existing measures in place to manage this risk. Please speak with the PI if you have concerns.

POTENTIAL BENEFITS

You may benefit from improved cognition as a result of the music therapy interventions

PARTICIPANT'S RIGHTS

Your participation in this study is entirely voluntary. Your questions will be answered clearly and to your satisfaction.

In the event of any new information becoming available that may affect your decision to continue to participate in this study, you or your legal representative will be informed in a timely manner by the PI.

By signing and participating in the study, you do not waive any of your legal rights to revoke your consent and withdraw from the study at any time.

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

Information collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. Only the PI will have access to the confidential information being collected.

However, Socso Tun Razak Rehabilitation Centre will be granted direct access to your original medical records to check study procedures and data, without making any of your information public.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by Socso Tun Razak Rehabilitation Centre, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties for the purpose of future research studies ("Future Studies").

Where required, such Future Studies will be submitted for review and necessary approval by the relevant institutional review board.

"Personal Data" means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. Examples of personal data include medical conditions, medications, investigations and treatment history.

By signing the Consent Form, you also confirm that you have read, understood and consented to the Malaysia Personal Data Protection Act 2010, the full version of which is available at http://www.pdp.gov.my/index.php/en/.

Data collected and entered into the data collection forms are the property of Socso Tun Razak Rehabilitation Centre. In the event of any publication regarding this study, your identity will remain confidential.

COSTS OF PARTICIPATION

There are no foreseen costs for participation in this study.

WHO TO CONTACT IF YOU HAVE QUESTIONS REGARDING THE STUDY

If you have questions about this research study, you may contact the PI, Lim Kar Gee, at +6012-2340689.

WHO HAS REVIEWED THE STUDY

This study has been reviewed by the Research Committee, Research and Development Department, Socso Rehabilitation Centre for ethics approval.

CONSENT FORM

Details of Research Study

Protocol Title:

The Effects of Music Therapy Interventions on Cognition among Adults with Neuro-rehabilitation Needs

Principal Investigator:

Lim Kar Gee, MA, MT-BC

Socso Tun Razak Rehabilitation Centre, Malacca, Malaysia

+6012-2340689

Particulars

Name: NRIC No.:

Sex: Date of birth _____
dd/mm/yyyy

Race: Chinese/ Malay/ Indian /Others (please specify) _____

I agree to participate in the research study as described and on the terms set out in the Participant Information Sheet.

I have fully discussed and understood the purpose and procedures of this study. I have been given the Participant Information Sheet and the opportunity to ask questions about this study and have received satisfactory answers and information.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons and without my medical care being affected.

By participating in this research study, I confirm that I have understood and consent to the Malaysia Personal Data Protection Act 2010. I also consent to the use of my Personal Data for Future Research.

All of the above has been explained to me in a language that I understand.

_____	_____	_____
Name of participant	Signature/Thumbprint (Right / Left)	Date of signing

To be filled by participant's next-of-kin, where applicable

I hereby give consent for the above participant to participate in the proposed research study. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

I confirm that I have understood and consent to the Malaysia Personal Data Protection Act 2010. I also consent to the use of the participant's Personal Data for Future Research.

All of the above has been explained to me in a language that I understand.

_____	_____	_____
Name of participant's next-of-kin (relationship to participant)	Signature	Date of signing

To be filled by witness, where applicable

An impartial witness should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read. After the written consent form and any written information to be provided to participant, is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form.

Witnessed by: _____ _____

Name of witness Designation of witness

_____ _____

Signature of witness Date of signing

Primary Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/participant's next-of-kin signing this consent form had the study fully explained and clearly understands the nature, risks and benefits of their / their next-of-kin's participation in the study.

_____	_____	_____
Name of PI	Signature	Date