



PUSAT PERUBATAN
Medical Centre

RESEARCH PROTOCOL

1. Particulars of Researcher

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Research expertise (List up to 5 fields of expertise):

Traumatic brain injury, Stroke, Neuromodulation, Cognitive rehabilitation

2. List of Co-researchers (Include all who have participated in the drafting of this proposal)

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3. Research Proposal

TITLE OF RESEARCH PROPOSAL
Enhancing Attention and Processing Speed Through Home-Based Music Therapy Rehabilitation Program After Stroke: A Feasibility Study in Malaysia
KEY WORDS
Music therapy; randomised controlled trial; rehabilitation; stroke; cognition; attention

BACKGROUND/ JUSTIFICATION

Stroke is a leading cause of long-term disability worldwide, often resulting in cognitive impairments, particularly in attention, which can significantly affect patients' quality of life and daily functioning. Evidence suggests that music therapy can enhance cognitive recovery during neurorehabilitation by engaging multiple brain networks and promoting neuroplasticity. While home-based rehabilitation has demonstrated effectiveness post stroke, there is limited evidence regarding the feasibility and impact of music therapy delivered at home for stable stroke patients. Furthermore, no studies have examined the efficacy of structured music therapy as part of a cognitive rehabilitation program in Malaysia, despite efforts over the past decade to promote music for therapeutic purposes. Unlike in other countries where music therapy is an established neurorehabilitation modality, it has not been formally incorporated into most local neurorehabilitation programs. This study proposes to investigate the effects of home-based music therapy on cognitive functions in stroke patients in Malaysian setting. If successful, this approach could support the integration of music therapy into clinical neurorehabilitation home-based settings, promoting its wider use for cognitive recovery post-stroke.

OBJECTIVES/OUTCOMES**Objectives:**

1. To determine the feasibility and acceptability of a structured home-based music therapy rehabilitation programme for improving attention and processing speed among stable stroke survivors in Malaysia, as measured by recruitment rate, adherence, retention, and participant satisfaction.
2. To explore the preliminary effects of the home-based music therapy rehabilitation programme on attention and processing speed in post-stroke patients using standardized cognitive outcome measures.
3. To assess the safety and practicality of implementing a home-based music therapy rehabilitation intervention, including monitoring adverse events, caregiver involvement, and compliance with the prescribed programme.

Expected outcomes:**1. Feasibility and Acceptability**

It is expected that the home-based music therapy rehabilitation programme will demonstrate acceptable feasibility among stable stroke survivors in Malaysia. This includes achieving satisfactory recruitment and retention rates, good adherence to the prescribed intervention, and positive participant-reported satisfaction. These outcomes will indicate that the programme is acceptable and practicable for implementation in a home setting within the local context.

2. Preliminary Cognitive Outcomes

The study is expected to show trends toward improvement in attention and processing speed following participation in the home-based music therapy rehabilitation programme, as measured by standardized cognitive assessment tools. While the study is not powered to determine definitive efficacy, the findings will provide preliminary data on potential cognitive benefits and inform the selection of outcome measures and effect size estimates for future larger-scale trials.

3. Safety and Practicality

The intervention is expected to be safe, with minimal or no adverse events related to participation. It is anticipated that participants and caregivers will be able to implement the programme with minimal difficulty, demonstrating adequate compliance with the prescribed activities. These findings will support the practicality of delivering a structured music therapy rehabilitation intervention in a home-based setting.

METHODOLOGY

Study design

This study will adopt a prospective, single-centre, randomized controlled feasibility study design with two parallel groups: an intervention group receiving music therapy in addition to standard neurorehabilitation, and a control group receiving only standard neurorehabilitation. The primary focus is to evaluate the feasibility, acceptability, and safety of a structured home-based musical rehabilitation programme for cognitive rehabilitation after stroke. Secondary objectives include exploration of preliminary effects on attention and processing speed.

Patients with a history of stroke who are admitted to, or attending follow-up at, University Malaya Medical Centre (UMMC) during the study period will be screened for eligibility. Eligible patients will be approached and provided with detailed information about the study and invited to participate. In addition, public advertisements (posters and flyers within UMMC) will be used to increase awareness of the study and facilitate recruitment. Patients who meet the inclusion criteria and agree to participate will be enrolled only after providing written informed consent.

Following enrolment, all participants will be allocated to either an intervention group or a control group in a 1:1 ratio. To ensure that there are exactly 20 patients in both the control and intervention groups, block randomization will be used using a random number generator. After randomization, the group assignments will be kept in a password-protected file that only the study coordinator can access. The assessor will not have access to this information because the patients will be labelled with anonymous codes that do not reveal whether they are in the control or intervention group. The assessor will only know the code, not the group assignment, ensuring unbiased evaluation.

A certified music therapist will prescribe the intervention and train the patients and caregivers before the start of the home-based music therapy. A trained assessor will evaluate the cognition at baseline, and also the outcome. The assessor is blinded to the patients' allocation group and will evaluate the cognitive outcomes at baseline, immediately after completion of the intervention period at four weeks and at 3 months post intervention.

Intervention group

The music therapy session described follows a structured and engaging approach, aimed at enhancing the patient's cognitive skills. Here's a summary of the session components:

Intervention Group: Home-Based Music Therapy Rehabilitation Program

1. Song Materials and Levels

The song materials selected for this research will be sourced from copyrighted compositions under UM Centre of Innovation and Enterprise (UMCIE). This maximizes the utilization of readily available resources and serves as a platform for promoting the original works of UM lecturers. The songs are organised into three difficulty levels, with approximately five songs per level. Songs within each level have equivalent rhythmic and cognitive demands, allowing variation without altering task difficulty.

2. Baseline Assessment for Music Therapy

Participants will undergo an initial level assessment conducted at the hospital by the trained music therapist. If travel is not feasible, level assessment is conducted at the participant's home. The songs will be presented to the participants and they will choose one song to start.

To ensure the safety of the research therapist conducting home-based assessments, a multi-layered safety protocol will be implemented for all home visits:

- a) a designated co-investigator will act as a safety contact. Before any home visit, the therapist will provide this contact with a full schedule, including the participant's address and the expected duration of the visit.
- b) the therapist will then follow a mandatory check-in procedure via text message:
 - Pre-departure: A message before leaving for the visit
 - Arrival: A message upon safely arriving at the participant's home
 - Departure: A message upon leaving the participant's home
 - Safe Return: A final message upon returning to a safe location.

Escalation Protocol:

If the safety contact does not receive the final "safe return" message within an agreed-upon time, they will first attempt to contact the therapist directly. If unsuccessful, they will then call the participant/caregiver. If contact cannot be established with either party, the safety contact will be authorised to contact the relevant local authorities to conduct a wellness check.

Confidentiality Protocol for Unofficial Recordings by Family Members

To protect participant confidentiality and the integrity of the research data, the following protocol will be implemented to address the possibility of family members or caregivers making personal recordings during home-based sessions:

1. Enhanced Informed Consent:

The Participant Information Sheet (PIS) and Consent Form will include a specific clause addressing this issue. During the consent process, the investigator will explicitly discuss the following with both the participant and the caregiver(s):

Purpose of Official Recordings: A clear explanation that the researcher's video recordings are for official data collection and analysis purposes only and will be stored securely according to the university's data protection policies.

Prohibition of Unofficial Recordings: A verbal and written request that family members and caregivers refrain from taking any personal photos, videos, or audio recordings during the structured assessment and intervention sessions.

Rationale: An explanation that this is to protect the participant's privacy and the integrity of the research data, as unofficial recordings are not covered by the study's ethical approval or data security protocols.

The following statement will be added to the consent form, requiring a separate signature or initials from the participant and/or legally authorised representative:

"I understand that the research team will video record the sessions for assessment and data analysis purposes only. I agree that I, and any family members or caregivers present, will not take any personal photographs, video recordings, or audio recordings during these sessions. I understand that any unauthorized recording would be a breach of the participant's confidentiality."

Pre-Session Reminder:

At the beginning of each home visit, the research therapist will provide a friendly, verbal reminder to everyone present (participant, family members, caregiver) about the confidentiality agreement and the request to refrain from using personal mobile phones or other devices to record the session.

3. Participant and Caregiver Training

At the beginning of the intervention, both participants and caregivers will undergo a structured training conducted by the music therapist to ensure they can independently carry out the program at home. The song chosen for the training will be different than the songs they will use during the home-based therapy rehabilitation program.

4. Caregiver Guidelines and Checklist

Caregivers are provided with written guidelines and a structured monitoring checklist to support adherence, safety monitoring, and documentation throughout the intervention.

5. Attentional Priming

Each session begins with 3–5 minutes of focused listening, during which participants will be instructed to observe and listen attentively to the musical compositions generated by the Finale music software. The software's user-friendly interface will display a tempo line adorned with pertinent remarks and symbols, providing clear guidance for the patients to follow.

An Eight-Tone Desk Bell (Figure 1) will be integrated with the Finale music software (Figure 2), enabling stroke patients to observe and listen to musical compositions generated.

6. Rhythm–Action Training

Participants will actively engage with the music and synchronise tapping on an Eight-Tone Desk Bell. The rhythmic and visual cues will be displayed on the Finale software interface, targeting processing speed, sustained attention, and sensorimotor integration.

7. Session Dosage and Frequency

Each session lasts 40 minutes and is conducted daily for five days per week, in accordance with rehabilitation literature. Session duration and frequency are recorded in the caregiver checklist.

8. Progress Monitoring and Adjustment

Progression is guided by bi-weekly level assessments by the music therapist at their homes. Adjustments made based on participant performance and endurance on the songs chosen earlier. The adjustments will include either changing the song within the same difficulty level or change to the songs in the next level of difficulty.

9. Adherence Monitoring

Caregivers will complete the checklist after each session, documenting completion, duration, participant alertness, and signs of fatigue. Weekly therapist phone call follow-ups support adherence and address concerns.

Control Group: Standard Care

Participants in the control group continue with usual standard neurorehabilitation program as prescribed by the rehabilitation team, without exposure to the music-based intervention.

This will provide a baseline to compare outcomes with the intervention group and evaluate the feasibility and preliminary effects of the music therapy intervention. The usual cognitive rehabilitation program during the subacute stroke period focuses on restoring cognitive abilities

such as attention, memory, executive functions, and communication. The key components typically include:

1. **Attention Training:** Exercises that improve sustained, selective, and divided attention, crucial for regaining concentration in daily activities.
2. **Memory Aids:** Tools like mnemonic strategies, repetition tasks, and external memory aids (e.g., calendars, notes) help rebuild short-term and working memory.
3. **Executive Function Training:** Targeting skills such as problem-solving, planning, and organizing tasks through structured exercises, gradually improving independent thinking.
4. **Communication and Language Therapy:** Speech-language pathologists work with patients to improve verbal and non-verbal communication, focusing on both comprehension and expression.
5. **Problem-Solving Exercises:** These help patients break down real-life problems into smaller, manageable steps, encouraging better decision-making skills.

Both the intervention and control groups will continue receiving the standard care



Figure 1. Eight-Tone Desk Bell

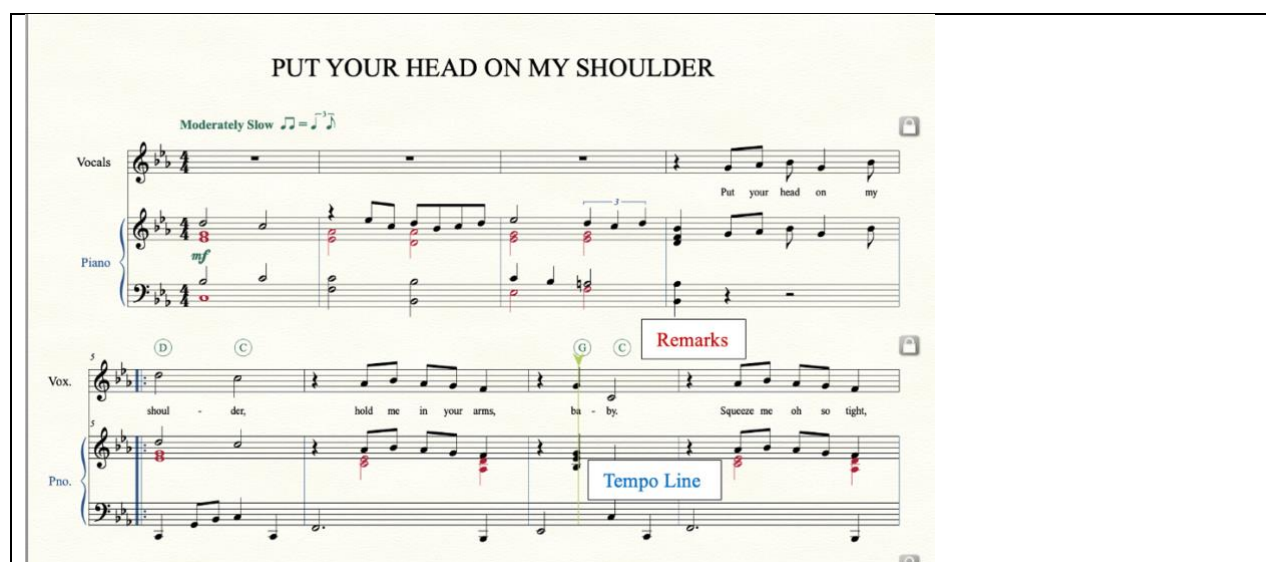


Figure 2: Finale Music Software User Interface

Inclusion Criteria:

1. Diagnosed with ischemic or haemorrhagic stroke confirmed by CT scan
2. Duration of stroke within the first one year
3. Age 18 – 70 years old
4. Ability to provide informed consent
5. Understands Bahasa Melayu or English with basic communication abilities to follow instructions during therapy sessions
6. Mild to moderate cognitive impairments with MoCA score of 10-25, with incomplete score for the attention sections
7. Availability of caregiver (formal or informal) who can assist in the music therapy, monitor and give feedback during the music therapy sessions at home
8. Have one normal functioning hand to perform the movements during the music therapy rehabilitation program
9. Have good balance and able to sit upright

Exclusion Criteria:

1. Severe aphasia
2. Significant uncorrected hearing or visual impairments preventing engagement in music therapy.
3. Severe or unstable medical conditions (e.g., uncontrolled hypertension or diabetes).
4. Medications that significantly impair cognition or motor function (e.g., high-dose sedatives).
5. History of neurological diseases other than stroke (eg, Parkinson's disease).

Outcome measures

This will be assessed at baseline, after completion of 4-week sessions and also at 3 months after completion. Primary outcome measures are Montreal Cognitive Assessment (MoCA), Trail Making Test (TMT A and B), Digit Span (Forward and Backward) and Clock Drawing Test (CDT). The secondary outcome measure is computer-based Cogniplus software for Reaction Time and Attention tests

Sample size calculation:

A sample of 40 subacute stroke patients (18 control and 18 intervention) within the first one year post-stroke, will be recruited from UMMC. This number is chosen based on practical considerations to evaluate feasibility metrics and exploratory analysis as in the objectives. For these purposes, a sample size of 36 is typically adequate to gather enough information about the practical aspects of the trial. This number could also ensure that the feasibility objectives are met even with at least 20% dropouts. This total number of 36 will be sufficient within the study period and the grant duration.

Statistical Analysis:

Descriptive Statistics and Exploratory Inferential Statistics will be used in this study.

The means, standard deviations, and 95% confidence intervals (CIs) for cognitive outcome measures (e.g., memory, attention, executive function scores) at baseline, post-intervention, and follow-up will be used. This will provide a preliminary understanding of the data distribution and effect sizes.

For the exploratory Inferential Statistics, independent t-test (or Mann-Whitney U Test) will be used to compare the mean changes in cognitive scores between the intervention and control groups. The independent t-test if the data are normally distributed. If not, we will use the Mann-Whitney U test as a non-parametric alternative.

Within each group, we will compare the baseline and post-intervention scores using the paired t-test for normally distributed data or the Wilcoxon signed-rank test for non-parametric data. Cohen's d will be used for independent t-tests (between groups) or r for non-parametric tests.

A repeated measures ANOVA (if the data is normally distributed) or a mixed-effects model will be used to explore changes over time (baseline, post-intervention, and follow-up). Given the small sample size, these analyses will likely be underpowered but can provide estimates of variability and preliminary trends.

RESEARCH DATA

Where will the data be kept?

The demographic data of the patients, and data on cognitive performance and other relevant data will be kept in a dedicated research file and hard drive. The files are in the laptop will be secured with password and the notes will be kept in a locker in the Department of Rehabilitation Medicine, Faculty of Medicine with one of the co-researchers.

Anonymity of data

All patients will be identified with a code number and not real names in the research files. The data entry into the excel sheet and into the research thumb drive will follow the similar process.

Who will have access to the research data?

All the co-researchers & research assistant

How long will the data be kept?

7 years

BUDGET / FINANCIAL SUPPORT (IF APPLICABLE):

Grant: BKP-ECRG of RM50,000

GANTT CHART

	Feb – April 2026	April – August 2026	Sept 2026	Oct – Feb 2026/27	March –June 2027	July – Oct 2027
1. Development of the project and trial registry						
2. Recruitment and randomisation phase						
3. Data entry & analysis						
4. Manuscript writing						
5. Submission for publication						
6. Promote research outcomes						

REFERENCES (up to 10 references)

1. Thaut, M. H., Gardiner, J. C., Holmberg, D., Horwitz, J., Kent, L., Andrews, G., Donelan, B., & McIntosh, G. R. (2009). Neurologic Music Therapy improves executive function and emotional adjustment in traumatic brain injury rehabilitation. *Annals of New York Academy Sciences*, 1169, 406-416.
2. Thaut, M. H. (2010). Neurologic Music Therapy in cognitive rehabilitation. *Music Perception*, 27(4), 281-285.
3. Yoo, G. E., & Kim, S. J. (2016). Rhythmic auditory cueing in motor rehabilitation for stroke patients: Systematic review and meta-analysis. *Journal of Music Therapy*, 53(2), 149-177
4. Alluri, V., Toivainen, P., Jääskeläinen, I. P., Glerean, E., Sams, M., & Brattico, E. (2012). Large-scale brain networks emerge from dynamic processing of musical timbre, key and rhythm. *NeuroImage*, 59(4), 3677-3689.
5. Antić, S., Morović, S., Kes, V. B., Zavoreo, I., Jurašić, M. J., & Demarin, V. (2012). Enhancement of stroke recovery by music. *Periodicum Biologorum*, 114(3), 397-401.
6. Cha, Y., Kim, Y., & Chung, Y. (2014). Immediate effects of rhythmic auditory stimulation with tempo changes on gait in stroke patients. *Journal of Physical Therapy Science*, 26(4), 479-482.
7. Magee, W. L., Clark, I. N., Tamplin, J., & Bradt, J. (2017). Music interventions for acquired brain injury: Reviews. *Cochrane Database of Systematic Reviews*, 2017(1), 1-130, doi: 10.1002/14651858.CD006787.pub3.
8. Stegemöller, E. L. (2014). Exploring a neuroplasticity model of music therapy. *Journal of Music Therapy*, 51(3), 211-227.
9. Magee WL, Clark I, Tamplin J, Bradt J. Music interventions for acquired brain injury. *Cochrane Database of Systematic Reviews* 2017, Issue 1. Art. No.: CD006787. DOI: 10.1002/14651858.CD006787.pub3.

10. Laver KE, Adey-Wakeling Z, Crotty M, Lannin NA, George S, Sherrington C. Telerehabilitation services for stroke. Cochrane Database of Systematic Reviews 2020, Issue 1. Art. No.: CD010255. DOI: 10.1002/14651858.CD010255.pub3.
11. Ke Wu, Chenxi Li and Sike Zhu et al. Application of Music Therapy in Stroke Rehabilitation: A Research Review. BIOR. 2025. Vol. 6(1). DOI: 10.15212/bioi-2025-0074

POTENTIAL IMPACT

This study could provide evidence supporting the integration of music therapy into neurorehabilitation programs for cognitive recovery post-stroke. It also has the potential to inform the development of accessible, low-cost, and culturally appropriate cognitive rehabilitation strategies for stroke survivors in Malaysia. By evaluating the feasibility and safety of a home-based musical rehabilitation programme, the findings may support wider adoption of community-based cognitive interventions that complement existing rehabilitation services. Preliminary evidence generated from this study will guide future larger-scale clinical trials and contribute to the integration of music-based therapies into neurorehabilitation practice. Ultimately, this approach may improve cognitive outcomes, promote patient engagement, and reduce long-term disability following stroke.

4. Please state whether you have submitted this research proposal for funding, now or before
 - Yes, a brief research proposal was submitted to the grant funder (BKP-ECRG) with the grant PI from the Faculty of Arts. The proposed study was approved and grant has been offered.

This proposal will be kept strictly private and confidential. It will not be shared with anyone without your prior approval.

Name of Researcher (CAPITAL): PROFESSOR DR MAZLINA BINTI MAZLAN

Signature of Researcher:



Date: 11-2-2026