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Original Article

The effect of music therapy on cognition in neurorehabilitation: A pilot crossover randomized controlled trial

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ABSTRACT

Objectives: This study aims to assess the feasibility of this pilot study's design and implementation and to compare the effect of active and passive music therapy interventions and standard care on cognition in neurorehabilitation.

Patients and methods: Participants aged 30 to 60 years with Mini-Mental State Examination scores between 10 and 22 and with no hearing impairment were included in this pilot crossover randomized controlled trial between October 2018 and August 2020. Each participant received one session of each of the following: active music therapy intervention consisting of instrument playing and singing, passive music therapy intervention consisting of relaxation and music imagery, and standard care, in a randomized sequence. Mini-Cog tests were conducted before and after each session, and the scores were collected for data analysis.

Results: Thirty-eight participants (31 males and 7 females; mean age: 44.4±8.0 years; range, 30 to 60 years) were included in the final analyses. The Kendall's W values ranged from 0.011 to 0.25, indicating a small effect across different permutations. The results showed no significant difference in pre- and postintervention Mini-Cog test scores between the experimental and control conditions [χ^2=3.047, p=0.218].

Conclusion: This pilot study is feasible in its design, procedures, and interventions. The maximum observed effect of 0.25 was used to calculate the sample size for a full-scale study, proposing 88 participants. Despite the nonsignificant results, this study served as a valuable resource for future research in cognitive rehabilitation and music therapy.

Keywords: Active, cognition, music therapy, neurorehabilitation needs, passive.

In a rehabilitation setting, patients who survived a stroke or traumatic brain injury, or have been diagnosed with dementia often face cognitive deficits.[1] The multifaceted impact of the aforementioned illnesses and injuries cause different levels of cognitive impairments, most commonly affecting memory, orientation, decision making, information processing, language, and attention.[2] Studies showed that middle-aged patients with stroke demonstrated difficulties in processing speed, working, and immediate memory, attention, executive function, completing tasks, engaging in discussions, and multitasking.[3,4]

It has been documented that music activates diffused areas of the brain; hence, even in the injured brain, there are still areas that can respond to music.[5] The neural mechanisms and systems of cognition and perception shared by both music and nonmusical cognition function in parallel. Hence, this shared system allows music to affect nonmusical functions such as memory, attention, and executive function.[6] Notably, the neuroplasticity model explains how music promotes brain plasticity, bridging the gap between the body of evidence and the application of music as therapy.[7]

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Music therapy research focusing on cognitive rehabilitation in individuals with acquired brain injury is lacking.[8] While music therapy was found to be superior to nonmusic conditions in some studies, a review about the effect of music therapy on cognition, with focus on dementia, updated that this is an area that has been barely explored, with inconsistent results.[9]

In terms of active music therapy interventions, several studies demonstrated significant results. Active music therapy was described as patients actively participating in making music.[10] Interactive sessions involving singing, rhythm accompaniment, movement to background music, and song guessing significantly improved memory and orientation in a group of patients with Alzheimer's disease (n=42), regardless of the severity of the disease.[11] A review supported that active music therapy interventions such as exercises with music, instrument playing, singing, and improvisation yielded promising results on global cognition in individuals with dementia.[9] In contrast, fewer studies have examined how passive music listening enhances cognition and performance. Listening to self-selected music or familiar music resulted in significant improvements in cognitive functioning.[12,13] Familiar and preferred music is the most effective for relaxation, particularly when self-chosen.[14]

There are limited studies comparing the outcome of active versus passive music therapy approaches in the rehabilitation literature. For patients with dementia (n=45), singing yielded higher Mini-Mental State Examination (MMSE) scores than music listening.[15] Similarly, interactive interventions, including singing, and music listening reduced stress and induced relaxation, while the interactive group showed significantly greater reductions in behavioral and psychological symptoms in dementia.[16] Lastly, a music improvisation-based study reported positive though nonsignificant effects on communication and relationships between the music therapists and subjects with dementia.[17]

Research about guided imagery on cognitive performance remains largely unexplored despite recognition that it enhances sports performance, reduces psychological stress, and facilitates improved health behaviors. Guided imagery involves the visualization of pleasant images, which potentially influences the alpha power, a brain wave frequency found to be positively correlated with information processing speeds. Guided imagery also has the potential to enhance attentional control[18] and working memory.[19]

A review of the literature in both Malaysia and Singapore revealed that the research in cognitive rehabilitation and music or music therapy is scarce.[20] In recent years, interest in cognitive rehabilitation has emerged, but research in Singapore has yet to include music therapy or music-based interventions.[20] More recent updates detailing advances in rehabilitation medicine, including dementia care, tend to focus on robotics and virtual reality.[21] There have been only three Singapore studies on music therapy in dementia care, specifically behavioral and psychological symptoms,[22] mood and engagement,[23] and an assessment scale to measure music therapy engagement for persons with dementia.[24] A review of the stroke research in Malaysia from 2000 to 2014 did not show any record of music or music therapy.[25] However, there appears to be some interest in the arts, as a recent study conducted in Malaysia explored the effect of dance and relaxation interventions on global cognition, anxiety, depression, and the quality of life among cognitively impaired elderly.[26]

In summary, clinical evidence lends substantial support for the benefits of music on physical rehabilitation of the injured brain,[27] while the evidence in cognitive rehabilitation is emerging. Although the effectiveness of music therapy in neurorehabilitation has been well established overseas, the state of local evidence is in its infancy in both Singapore and Malaysia, where services were started in 2011 and 2016, respectively.

Therefore, the primary focus of this study was to assess the feasibility of its design and procedures, and interventions and to determine the sample size of a full-scale study. The secondary focus was to investigate the effect of both active and passive music therapy interventions compared to the standard care condition on the cognition of individuals requiring neurorehabilitation in a Malaysian rehabilitation setting. Furthermore, the study hypothesized that music therapy interventions would significantly improve the cognition of participants with acquired brain injuries with cognitive needs.

PATIENTS AND METHODS

This pilot crossover randomized controlled trial was conducted with participants aged 30 to 60 years, as this age bracket represented a significant portion of the population at the facility, at the SOCSO Rehabilitation Centre between October 2018 and August 2020. Inclusion criteria required participants to score between 10 and 22 on the MMSE[28] to ensure a baseline level of cognitive function. The cut-off score is suggested by Shim et al.[29] to screen for cognitive impairment. In order to include participants with mild to moderate cognitive impairment, the lower cut-off is suggested to be 10, as those with scores lower than 10 are severe and likely to be untestable.[28] Participants were excluded if they met any of the exclusion criteria: scored above 22 or below 10 on the MMSE, had any documented current/active episodes of hallucinations or delusions, had hearing impairment, or had a language barrier, which meant they did not understand neither of English, Mandarin, or Malay. All instructions were standardized in the three main languages most commonly spoken at the facility: English, Mandarin, and Malay. The research participant selected their preferred language before the informed consent was obtained. Two key personnel at the site as the main referral sources screened new admissions for eligibility for the study, per inclusion criteria. One of the researchers, who was the music therapist providing interventions, obtained written informed consent from the research participant or their next-of-kin/guardian. The study protocol was approved by the SOCSO Rehabilitation Centre Ethics Committee (Date: 11.04.2018, No: PKS/PRPTAR/208/18/197[04]). The study was conducted in accordance with the principles of the Declaration of Helsinki.

To compare two contrasting music therapy interventions, active and passive interventions were selected. For active music therapy intervention, the researchers preselected a set list of song repertoire to keep more variables constant. Songs were categorized under three languages: English, Mandarin, and Malay. For each language, eight to 10 songs from varied genres were chosen based on the popularity and familiarity for each age range: 30-39, 40-49, and 50-59. The tonality of each song was preset and kept consistent. Sitting next to the research participant with the lyrics projected on the wall, the therapist sang with guitar accompaniment selected songs based on the participant's preferred language and age range from the prepared song repertoire. Then, participants were asked to play the beat along with the songs by using a preferred instrument chosen from a standardized assortment of percussion instruments and were encouraged to sing.

During the passive music therapy intervention, the therapist read a standardized relaxation script, while improvising on a full-size Casio keyboard. The imagery process began with a three-time deep breathing exercise, followed by an improvisation using the C Major pentatonic scale with homophonic texture and ternary form while guiding the participant to imagine a favorite place of their choice, and ended with another round of three-time deep breathing exercise. Throughout the imagery process, the research participant was instructed to close their eyes. The music tempo was kept at 60 beats per minute most of the time, apart from the slight ritardando at the end, and the volume was maintained between 50 to 70 decibels. The participant was allowed to request to stop the intervention at any time (Appendix 1).

In the control condition, participants engaged in mundane activities such as resting, reading magazines, or chatting with the music therapist in the same therapy room used for the active and passive conditions. After the therapist provided instructions, participants chose their preferred activity. The same music therapist implemented all the conditions for each research participant. The music therapist was a board-certified music therapist with over 20 years of clinical experience.

Each research participant received one active music therapy condition, one passive music therapy condition, and one control condition, with randomized sequence. The duration of each condition lasted approximately 15 min. All the research participants served as their own controls. All the three conditions were conducted in a therapy room onsite.

In this study, the Mini-Cog test was utilized to assess the participants' cognitive functioning. The Mini-Cog test is a short and simple screening tool for detecting cognitive impairments. It comprises two components: a memory task involving the recall of three words, and an assessment of executive function through a clock drawing task. Administering the test typically takes only 3 min, and it is available in multiple languages.[30] For each of the three conditions, every participant completed a Mini-Cog test using their preferred language both before (pretest) and after (posttest) the intervention or activity.

The sequence of the three conditions to be implemented over three weeks was randomized for each research participant, namely active music therapy (A), passive music therapy (P), and standard care control condition (C), using an online randomization generator: https://www.randomizer.org. Six possible permutations resulted: APC, ACP, PAC, PCA, CAP, and CPA. This randomization was generated prior to the recruitment process, and participants were assigned their respective sequences based on their order of recruitment into the study, following the informed consent process (Figure 1). To minimize bias, a single-blinding approach was implemented, ensuring that participants were unaware of which treatment they were receiving at any given time.

Statistical analysis

The estimation of sample size with different effect sizes in a full-scale study was calculated using G*Power version 3.1 software (Heinrich-Heine University Düsseldorf, Düsseldorf, Germany). The statistical test employed was analysis of variance for repeated measures, with a significance criterion set at alpha=0.05 and a power of 0.80.

Data were analyzed using IBM SPSS version 29.0 software (IBM Corp., Armonk, NY, USA). The pre- and postintervention Mini-Cog scores across each condition, for each research participant, were compared to determine the best effect size. Before analysis, all variables were subjected to a normality test using the Shapiro-Wilk test to determine the appropriate statistical method. The results indicated a nonnormal distribution, leading to a nonparametric test using Friedman's two-way analysis. The Friedman's test was utilized to evaluate potential differences in Mini-Cog test scores among conditions A, P, and C.

RESULTS

A total of 227 individuals underwent screening for both inclusion and exclusion criteria, resulting in 66 (29.07%) individuals meeting the eligibility criteria. Among them, 45 (68.18%) participants provided consent and participated in the study. Seven participants were discharged before completing all

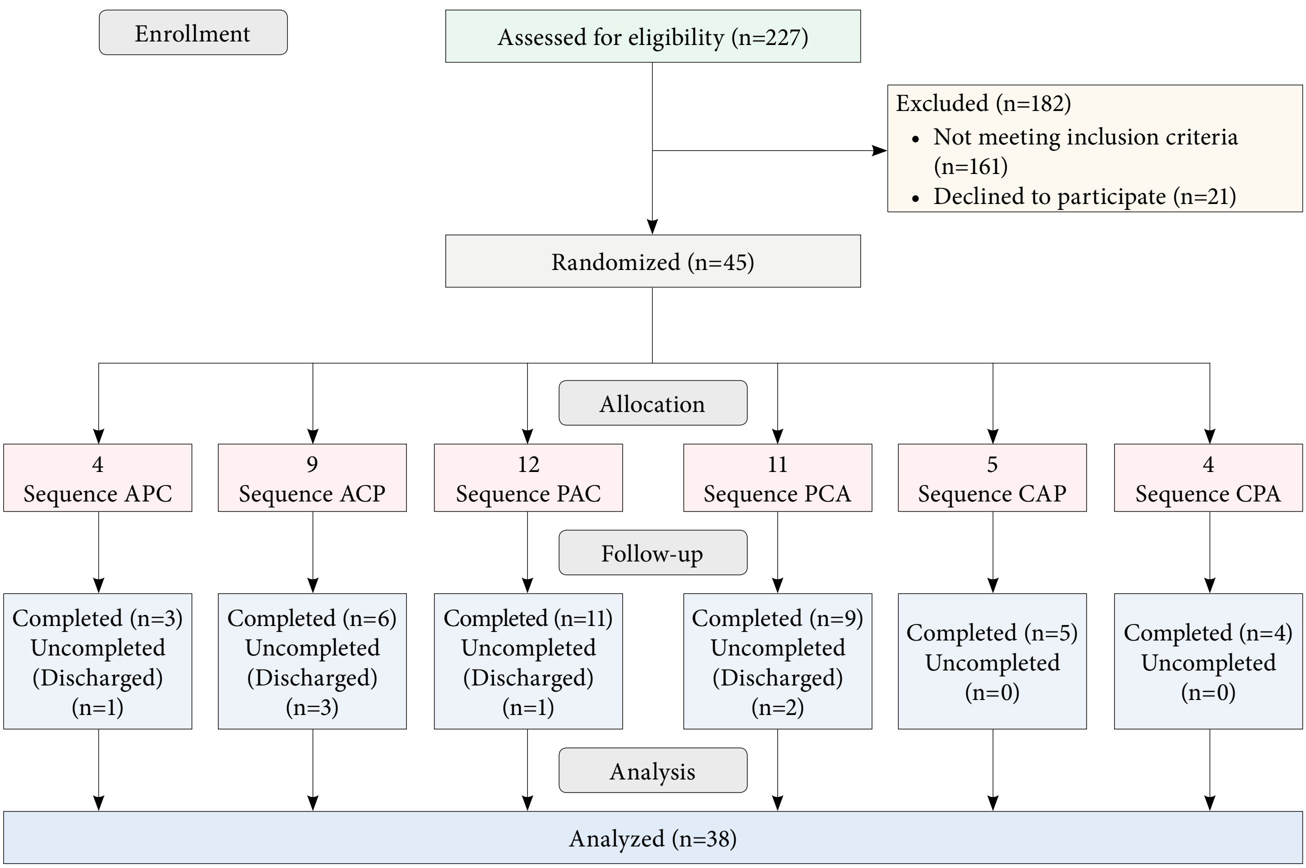

Figure 1. CONSORT flow diagram.

APC: Active passive control; ACP: Active control passive; PAC: Passive active control; PCA: Passive control active; CAP: Control active passive; CPA: Control passive active.

TABLE 1
Demographics of research participants

	n	%	Mean±SD	Median	IQR
Age			44.39±8.03	45.5	14
30-39	12	31.58			
40-49	13	34.21			
50-59	13	34.21			
Sex					
Female	7	18.42			
Male	31	81.58			
Diagnosis					
CVA	27	71.05			
Recurrent CVA	5	13.16			
Traumatic brain injury	5	13.16			
Dementia	1	2.63			

SD: Standard deviation; IQR: Interquartile range; CVA: Cerebrovascular accident.

three conditions. Data collection spanned a period of 23 months, during which data was gathered from 38 (84.44%) participants (31 males and 7 females; mean age: 44.4±8.0 years; range, 30 to 60 years). This span of nearly two years included a suspension of the recruitment process for four months due to the nationwide lockdown caused by the COVID-19 (coronavirus disease 2019) pandemic. The average rate of recruitment was 2.37 participants per month (45 participants/19 months). The feasibility of recruitment is shown in Figure 1. The majority of the participants were diagnosed with cerebrovascular accident (n=27, 71.05%). The demographic details of the research participants are shown in Table 1.

One of the important objectives of a pilot study is to estimate the sample size in a full-scale study.[31] Based on the findings of this study and different permutations with varying effect sizes (Table 2), the Kendall's W values ranged from 0.011 to 0.25, indicating a small effect according to Tomczak.[32] The results of the sample size analysis indicated a minimum sample size of 42, and with 95% power, the required sample size increased to 65 (Figure 2). Taking into account a 20% dropout rate, the recommended sample size was calculated to be n=88.

Table 3 shows the mean results of the pre- and posttests of Mini-Cog for six permutations. It is evident that in almost all posttest results across the three conditions, there was an increase in the Mini-Cog score, except for the active condition in the ACP sequence and the control condition in the CPA sequence, both the pre- and posttest results were identical.

Table 4 displays the result of the analysis comparing cognitive functioning among participants in active music therapy, passive music therapy, and standard care control condition using related samples of Friedman's two-way analysis. Results showed a nonsignificant difference (χ^2=3.047, p=0.218). Thus, there were no significant differences in the pre- and posttests of the Mini-Cog scores among conditions A, P, and C.

DISCUSSION

This study found that the differences in cognition scores between the active and passive music therapy conditions were not statistically significant compared to the control condition. These findings of this study aligned with previous studies that similarly found a lack of significant impact of music therapy on cognitive outcomes, although there was an improvement in MMSE scores in the experimental group.[33] Additionally,

TABLE 2
Effect size for different permutations

Permutation		Kendall's W
1	APC	0.167
2	ACP	0.246
3	PAC	0.011
4	PCA	0.141
5	CAP	0.018
6	CPA	0.250

APC: Active passive control; ACP: Active control passive; PAC: Passive active control; PCA: Passive control active; CAP: Control active passive; CPA: Control passive active.

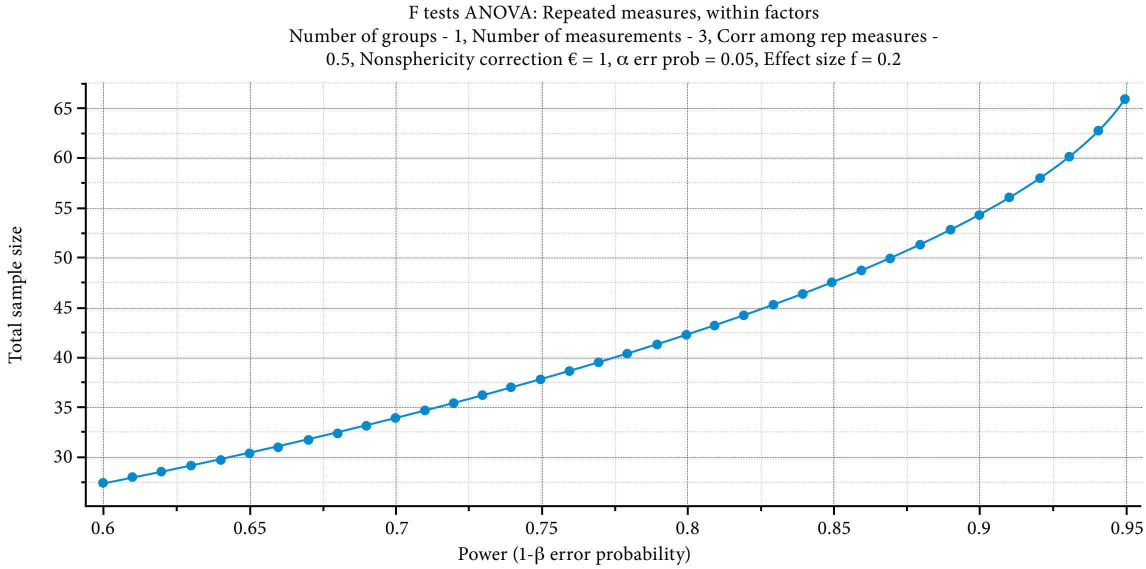

Figure 2. Power analysis.

TABLE 3
Mean results of Mini-Cog™ test scores across six permutations

Permutation			Active		Passive		Control	
			Preoperative	Postoperative	Preoperative	Postoperative	Preoperative	Postoperative
1	APC*	Mean±SD	4.00 (1.73)	4.00 (1.70)	3.00 (1.00)	3.33 (1.16)	2.67 (2.52)	3.33 (1.53)
		Median (IQR)	5.00 (-)	5.00 (-)	3.00 (-)	4.00 (-)	3.00 (-)	3.00 (-)
2	ACP	Mean±SD	1.50 (1.98)	3.17 (1.80)	1.67 (1.86)	2.17 (2.32)	2.67 (2.07)	2.83 (1.47)
		Median (IQR)	1.00 (3.00)	4.00 (3.00)	1.00 (4.00)	1.50 (5.00)	2.50 (4.00)	2.50 (3.00)
3	PAC	Mean±SD	2.55 (1.60)	3.18 (2.04)	2.45 (1.51)	3.45 (1.64)	2.36 (1.80)	3.18 (1.78)
		Median (IQR)	3.00 (3.00)	4.00 (4.00)	3.00 (3.00)	3.00 (3.00)	2.00 (3.00)	3.00 (3.00)
4	PCA	Mean±SD	3.44 (1.50)	3.78 (1.79)	3.56 (1.24)	4.00 (1.32)	3.22 (1.48)	3.33 (1.23)
		Median (IQR)	4.00 (3.00)	5.00 (3.00)	3.00 (3.00)	5.00 (3.00)	4.00 (2.00)	3.00 (3.00)
5	CAP	Mean±SD	2.80 (1.92)	3.40 (2.00)	2.60 (2.07)	3.20 (1.64)	2.60 (1.82)	3.00 (1.58)
		Median (IQR)	3.00 (4.00)	4.00 (4.00)	3.00 (4.00)	2.00 (3.00)	3.00 (3.00)	3.00 (3.00)
6	CPA	Mean±SD	2.00 (1.41)	3.00 (1.41)	3.50 (1.73)	3.75 (1.26)	2.00 (2.31)	2.00 (2.31)
		Median (IQR)	1.50 (3.00)	3.50 (3.00)	4.00 (3.00)	3.00 (3.00)	2.00 (4.00)	2.00 (4.00)

SD: Standard deviation; IQR: Interquartile range; APC: Active passive control; ACP: Active control passive; PAC: Passive active control; PCA: Passive control active; CAP: Control active passive; CPA: Control passive active. * For APC permutation IQR was not calculated due to low number of sample (n=3)

TABLE 4
The analysis comparing cognitive functioning among participants in active music therapy, passive music therapy, and standard care control condition

Group	Median	IQR	Q1-Q3	Z value	*p*
Active	0	1.25	0 - 1		
Passive	1	1	0 - 1	3.05	0.22
Standard	0	1	0 - 1		

IQR: Interquartile range; Q: Quartile.

a meta-analysis on cognitive functions in patients with dementia reported no significant effects of music therapy on cognitive outcomes.[9] A Cochrane review further supported these findings, noting a lack of strong evidence for the impact of music interventions on cognitive functioning in adults with acquired brain injury.[34] It is important to note that the authors of these reviews emphasized that the small sample sizes in the included trials were insufficient to detect any significant changes.[9,11,34] Similarly, in this study, although the effect size ($W=0.011\leq0.25$) was not statistically significant, likely due to the small sample size (n=38), the slight changes observed among groups suggested that there may be some effect of the interventions, even if it was not large enough to reach statistical significance.

Enhancing the recruitment process requires careful and strategic planning to effectively increase the sample size for more conclusive results. Since this pilot study was conducted at a rehabilitation institution for working adults, it had a limited age range of 30 to 60. This age bracket made up the greater proportion of this study population at the facility. By limiting the age range, the standard deviation of age was reduced. However, removing the age restriction and conducting the study across multiple facilities in the full-scale study could aid in expanding the sample size and expediting recruitment. With a recommended sample size of 88 participants, and a current recruitment rate of 2.37 participants per month, expanding recruitment across three different facilities is projected to yield an average of 7.11 participants enrolled each month. This would allow for the successful recruitment of the required 88 participants over a 12-month period while maintaining a retention rate of 80%. Additionally, by removing the age limitation and including individuals aged 18 and above who have neurorehabilitation needs, the recruitment process is expected to accelerate, potentially shortening the overall data collection timeline. Nevertheless, ensuring standardization of experimental and control conditions is crucial when recruiting from various facilities.

The feasibility of an intervention is primarily concerned with the researcher's ability to provide the intervention and complete the study procedures, while acceptability of an intervention is concerned with the suitability of the intervention from the recipients' perspective.[31] Any credentialed music therapist is undoubtedly equipped to provide both the active and passive music therapy interventions outlined in this pilot study. Another indicator of intervention feasibility and the acceptability of the intervention is the percentage of sessions participants completed.[31] Notably, in this study, 84.44% of participants successfully completed all three conditions, demonstrating the feasibility of both active and passive interventions. The participants who did not complete all three conditions were discharged earlier, which accounted for their incomplete participation. Importantly, none of the participants withdrew from the study prior to completion.

In this study, the researchers aimed to differentiate the selected interventions from other music-based interventions. Music therapy involves the systematic use of tailored music experiences within a therapeutic relationship to promote health while other music-based interventions such as passive listening to prerecorded music or music activities that involve mainly recreational goals. The researchers selected both playing instruments and singing as the active music therapy intervention based on the findings from the previous studies.[9,11] The therapist, with experience working with this population and an understanding of the cultural context, noted that participants tend to be more receptive to playing instruments than singing. Consequently, the instruction for active intervention emphasized on playing an instrument rather than singing. For the passive music therapy intervention, relaxation with music imagery was chosen, using a familiar pentatonic scale to align with the participants' ethnic and cultural backgrounds. Supporting this approach, previous research indicated that familiar and preferred music is most effective for relaxation.[14] To ensure the reliability of the study, the instructions for the participants, songs and the tonalities used in the active music therapy intervention, relaxation script, improvisation style, tonality and tempo, the flow of the session, and the venue were standardized (Appendix 2). This careful consideration was essential to ensure alignment with the diverse characteristics of the Malaysian community (multicultural, multireligious, multiethnic, and multilingual contexts).

Despite efforts to standardize instructions across languages, the therapist's interactions with each research participant was dynamic and still aimed at supporting the research participant's success during each study condition. Music therapy, whether active or passive, is a dynamic, relationship- and time-based phenomenon. Efforts aimed at standardizing the protocol can reduce some confounders, but it was not possible to remove them completely.

Notably, there were some limitations to this study. First, the small sample size may have reduced statistical power and increased the likelihood of type 2 errors, potentially leaving true effects undetected. This raises concerns about the reliability of the findings. Consequently, one of the primary focuses of this feasibility study was to determine an appropriate sample size for future research. Second, the initial plan of the study aimed for each participant to complete all three conditions over approximately three weeks; however, adherence to the session schedule was affected by several challenges. Participants missed sessions due to forgetfulness, and sessions were postponed because of public holidays, or personal emergencies and illnesses. Additionally, some participants were discharged earlier than anticipated. These inconsistencies in the timing between interventions may impact the generalizability of the study's findings. To minimize bias in future studies, it is important to establish standardized time frames and specify reasonable intervals between the three conditions. Third, in this study, the therapist also served as the administrator for the Mini-Cog test, which was necessary due to limited manpower. This dual role raises concerns about potential detection bias, as the therapist conducted the intervention and then immediately administered the test. Such bias may affect the objectivity of the results, as the therapist's prior knowledge of the intervention could unconsciously impact the scoring. In future research, it would be beneficial to separate the roles of the therapist and the test administrator or to implement additional measures to ensure objective assessment of cognitive outcomes. Apart from the abovementioned potential bias, the Mini-Cog test and the Montreal Cognitive Assessment (MoCA) were found to be relevant for screening adults with mild cognitive impairment. Considering the time required to administer these tests (approximately 10 min for the MoCA[35] and 3 min for Mini-Cog), the Mini-Cog was selected as it is quick, easy, and convenient to administer. Fusar-Poli et al.[9] noted that tedious assessment tools could affect results and recommended using a quick and easy assessment battery. However, it is important to note that MoCA measures various cognitive domains, including executive function, attention, memory, visuospatial skills, language, and orientation while Mini-Cog primarily focuses on memory and executive function. Future researchers should consider both test durations and participants' attention levels, as well as the different cognitive domains when designing similar studies. Fourth, the data collection phase, initially planned for one year, was extended to nearly two years due to unforeseen challenges such as participant recruitment issues, early participant discharge, and the COVID-19 outbreak. The COVID-19 pandemic disrupted session schedules and impacted participants' mental health. Nationwide lockdowns resulted in an unprecedented deleterious impact on mental health of the general population, particularly for people with dementia and their caregivers.[36] It is plausible that the research participants of this study, already experiencing cognitive deficits, were at least similarly impacted. Hence, it was not only the mere inconsistency of the number of gap-days between sessions, but what happened during those gaps that could have resulted in deterioration of mental well-being, including cognition. Lastly, given limited resources, as well as the time required for assessments and intervention, the researchers decided to use 15 min as the intervention duration. This 15-min duration was recommended to promote personal health and well-being.[37] While this intervention duration may appear short, it is important to acknowledge that significant impacts on cognition can still occur within this timeframe. Considering factors such as mental fatigue and concentration levels, the researchers used the 15-min intervention duration to optimize participant engagement and efficacy. Future studies may maintain this 15-min duration while expanding the sample size to further examine the intervention's impacts, allowing for a more comprehensive understanding of its effects on cognition in neurorehabilitation.

In conclusion, this pilot study represents pioneering research in Malaysia and the Southeast Asia region, examining the effect of music therapy on cognition in neurorehabilitation. It assessed the feasibility of conducting active and passive music therapy interventions compared to a control condition. The study design, procedures, and interventions were found to be feasible, and a sample size for a full-scale study was recommended. Insights gained from the study, including participant recruitment, evaluation tools, and potential challenges, provide valuable recommendations to future research. Attention to these insights can lead to more definitive results regarding the effects of active versus passive music therapy interventions on adults with neurorehabilitation needs.

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