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EFFECTS OF STRUCTURED EXERCISES AND MUSIC THERAPY ON THE FUNCTIONAL INDEPENDENCE OF STROKE SURVIVORS: A RANDOMIZED CONTROLLED CLINICAL TRIAL

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ABSTRACT

Background: Stroke is a leading cause of disability worldwide. It is a condition of public health importance and often leaves survivors with functional impairments that significantly impact their daily lives. Improving the functional independence of stroke survivors is a critical public health concern. **Aim:** This study aimed at determining if structured exercises combined with music therapy improves the functional independence of stroke survivors as compared to structured exercises alone. **Methods:** The study design was a randomized controlled clinical trial (RCT) in which 86 strokes. survivors who were purposively recruited from two tertiary hospitals in Rivers State (University of Port Harcourt Teaching Hospital and River State University Teaching Hospital) were randomized into two groups – experimental and control groups in a parallel ratio of 1:1. The intervention was given for a period of 6 months. All ethical procedures were followed in line with the declaration of Helsinki. Baseline values were measured and compared within groups using Paired t-test and between the groups using Independent t-test. Post-intervention value of the variables was measured and within group comparison was made using Paired t-test while Independent t-test was used for comparism between the groups. **Results:** There was a statistically significant mean difference within the groups for the functional independence and its two subscales – motor and cognition subscales (P=0.000). The mean difference between the groups for functional independence and motor subscale was not statistically significant (t= 1.39, P=0.167; t=1.82, P=0.073) while that of cognition subscale was statistically

significant (t=2.46, P=0.016). **Conclusion:** Structured exercises combined with music therapy do not significantly improve the functional independence of stroke survivors as compared to structured exercises alone. Physiotherapists and other rehabilitation experts should incorporate music therapy sessions prior to conventional treatments in order to boost cognitive functions of the stroke survivors.

KEYWORDS: Structured Exercises, Music Therapy, Stroke Survivors, Functional Independence, Rivers State.

INTRODUCTION

Stroke is the leading cause of long-term disability, functional impairment, and reduced quality of life [1-3]. It is a leading cause of disability worldwide, and the second leading cause of death and years of life lost after heart disease [4]. 79.5 million people were affected by stroke globally in 2016 [1]. Out of this 79.5 million, 13.6 million were new strokes [1]. Stroke is a major public health challenge in many low- and middle- income countries [5-7]. In Nigeria, stroke is a major cause of neurological admissions and its incidence has been on the increase due to rise in the incidence and prevalence of hypertension and diabetes [8-10].

Stroke rehabilitation is a crucial part of the recovery process for individuals who have experienced stroke [11]. The process of stroke recovery involves various therapeutic interventions aimed at improving functional independence and quality of life [12, 13]. Among these, structured exercises have gained recognition for their potential in facilitating recovery and rehabilitation [14-16]. Structured exercises have been used in rehabilitation disciplines such as physical therapy and occupational therapy etc. in enhancing the functional status of stroke survivors [17, 18]. Structured exercises play a significant role in helping stroke survivors regain lost abilities; improve their functional independence and overall quality of life [14, 19]. These exercises are designed to address various physical and cognitive impairments resulting from stroke. Here are different types of structured exercises used in stroke rehabilitation: Range of motion (ROM) exercises, strength training exercises, balance and coordination exercises, endurance training, functional mobility training, constraint-induced movement therapy (CIMT), task-specific training, aquatic therapy, mirror therapy etc. [19, 20-23].

Music therapy, on the other hand, is an innovative approach that has gained popularity in stroke rehabilitation [14, 24-27]. It utilizes music as a therapeutic tool to address physical, emotional, cognitive, and social goals [25, 28]. Studies examining the effects of music therapy on stroke survivors have reported promising outcomes [24-27, 29, 30]. Music therapy interventions include: improvisation, receptive music listening, song writing (composition), lyric discussion and music performance. According to Grau-Sánchez et al. [30], music-based interventions can be broadly divided into passive and active interventions. Passive music interventions usually refer to listening to music, which has been shown to be effective in different neurological conditions to enhance cognition and mood [31]. On the other hand, active music-based interventions require the production of music [32].

The functional independence of stroke survivors is not only a personal achievement but also a critical public health concern [33]. Maximizing independence through targeted interventions not only enhances the lives of survivors but also alleviates the burden on healthcare systems and society at large [33]. Emphasizing rehabilitation, assistive technologies, caregiver support, and community engagement can significantly contribute to the holistic recovery and integration of stroke survivors, ultimately advancing the goal of functional independence in public health [34].

METHODS

Study registration

This study was registered with the Pan African Clinical Trial Registry, South Africa Medical Research Council, Cochrane Centre, PO BOX 19070, Tygerberg 7505, South Africa. The registration was done before the commencement of the trial and in accordance with the World Health Organization (WHO) and International Committee of Medical Journal Editors (ICMJE) standards. The website is pactr.samrc.ac.za, and the unique identification number of the study is PACTR202308481941633.

Study Design

This study was a Randomized Controlled Clinical Trial (RCT). Simple randomization and parallel design with ratio of 1:1 was used to randomly assign the participants to two groups – A (experimental group) and B (control group) using table of random numbers created by a computer software program.

Study Area

The study area was tertiary hospitals in Rivers State which include University of Port Harcourt Teaching Hospital (UPTH) and Rivers State University Teaching Hospital (RSUTH), Port Harcourt.

Study Participants

The participants for the study were stroke survivors at the University of Port Harcourt Teaching Hospital (UPTH) and Rivers State University Teaching Hospital (RSUTH), Rivers State. They were recruited from the General Outpatient Department (GOPD), Medical Outpatient Clinic (MOPC), and Physiotherapy Department of both hospitals.

Inclusion Criteria:

1. Male and female adults 18 years and above.
2. Being a stroke survivor for at least six months.

Exclusion Criterion:

1. Individuals with significant underlying heart disease
2. Individuals with psychiatric co-morbidity
3. Individuals too ill to participate in the study.

Sampling method

This was a purposive sampling technique. Those who met the inclusion criteria and possessed the required characteristics were selected and recruited for the study.

Sample Size Determination

The sample size was determined using the formula for experimental studies:

$n= [Z\alpha/2+ Z1-\beta]2\ [P1(1-P1) + P2(1-P2)]\ /(P1-P2)2$ [35]

Where: n = size per group

P1= Proportion of outcome in control group = recovery rate by conventional treatment = 40%. With the outcome in the experimental group that is at least 30% better than the conventional treatment, we have P2= proportion of outcome in experimental group = (40%+30%) = 70%

Therefore, P1 = 0.4 while P2 = 0.7. Effect size = difference in P1 and P2 = 30% = 0.3

Zα/2= standard normal deviate for a two-sided test while Z1-β= power of the test.

P1= 0.4; P2=0.7; Zα/2=5%; Z1-β=80%.

At 5% level of significance, Zα/2 = 1.96

At statistical power of 80% and a β- error of 20%, Z1-β = 0.84

n = (1.96+0.84)2 [0.4 (1-0.4) + 0.7(1-0.7)] / (0.7-0.4)2

n = 7.84 × [(0.24 + 0.21)] / (0.3)2

n = (7.84 × 0.45) / 0.09

n = 3.528/0.09

n = 39.2 = 39 approx.

Considering 10% attrition rate, we have 39+3.9 = 42.9 = 43 approx.

Therefore, n = 43 = sample size per group. For both groups, we have a total of 43 × 2 = 86.

Study Instruments:

The major study instrument was ***a semi-structured questionnaire*** having part A and B. Part A includes the socio-demographic features of the participants while part B includes the functional Independence Measure (FIM). The FIM was used to measure the functional independence (primary outcome) of the stroke survivors

The Functional Independence Measure (FIM)

The FIM has become a widely adopted assessment tool used not only in rehabilitation settings but also in long-term care facilities and research studies [36]. Its standardized nature has made it an essential component in assessing patients' functional status, setting rehabilitation goals, and determining resource allocation in healthcare [37]. The FIM quantitatively assesses the level of independence for performing a series of motor and cognitive tasks of daily living, according to the following items: self-care, transfers, walking, sphincter control, communication and social cognition, memory, social interaction and troubleshooting. FIM scores provide a quantitative measure of an individual's functional independence. They can be used to track an individual's progress over time and compare their functional status to that of others. Higher scores indicate a greater level of independence, while lower scores suggest a greater degree of dependence on others or assistive devices. Each item receives a score ranging from 1 to 7. The complete score can vary from 18 to 126, indicating the functional status of the individual. 18 points correspond to total dependence - when the subject needs maximum or total help; 19 to 103 means moderate dependence - when the subject needs supervision or minimal help, while 104 to 126 means complete independence - absence of help from third parties. The FIM has demonstrated high levels of intra-rater (0.95) and inter-rater (0.95) reliability [38].

Trial Procedure

This clinical trial was carried out in line with the Consolidated Standards of Reporting Trials (CONSORT) guideline 86 eligible stroke survivors were recruited into the study. They were randomly allocated into any of the two groups - group A or group B using a table of random numbers created by a computer software program. All the participants underwent pre-intervention assessment for the level of functional independence. A statistician prepared the computer-generated random sequence which was made available to a member of the research team who did not take part in the enrollment, evaluation, or treatment sessions. This member of the team who was situated off site was the holder of the sequence and communicated directly to the principal investigator. A 2-arm parallel design with a ratio of 1:1 was utilized in assigning participants to the groups. Group A was the experimental group (receiving structured exercises combined with music therapy) while group B was the control group (receiving structured exercises alone). The participants were blinded in that only the principal investigator knew the participants that were assigned to each group. To achieve this, each group had their treatments on separate days.

In this study, structured exercises included free active exercises, resisted active exercises and other forms of strengthening exercises, proprioceptive neuro-muscular facilitation, auto-assisted exercises, weight bearing exercises, bridging exercises, balance training exercises, gait training, bicycle ergometer and treadmill exercises, standing and walking re-education. The structured exercises were given two times a week at alternate days for one hour per treatment session. It was the same for every participant. For the music therapy, it included 30 minutes of receptive and relaxed listening of classic music instrumentals via the headphone played on an android phone prior to the conventional treatment (structured exercises). It was the same for all the participants. Group A (experimental group) had their structured exercises plus music therapy on Mondays and Wednesdays while Group B (Control) had their structured exercises on Tuesdays and Thursdays. The intervention was given for a period of 6 months, and then the stroke survivors were re-assessed. To further minimize bias, the outcome of the intervention was measured by another set of trained research assistants who were not involved in the initial measurement and treatment.

The Consolidated Standards of Reporting Trials (CONSORT) Flowchart diagrams of the clinical trial (Figures 1 & 2) are as follows:

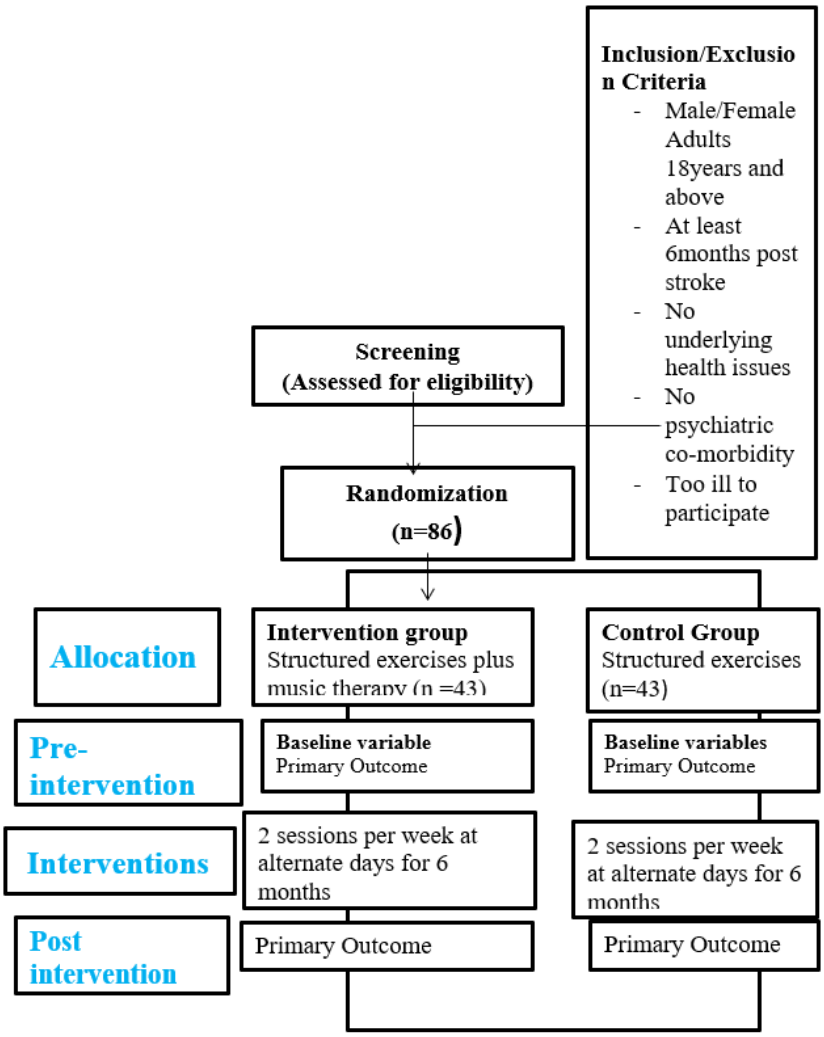

Figure 1 *(Study design (CONSORT diagram) before the commencement of the trial: A 2-arm parallel randomized controlled clinical trial with two treatment groups [(structured exercises combined with music therapy, n = 43), and Control group (Structured exercises, n = 43)])*

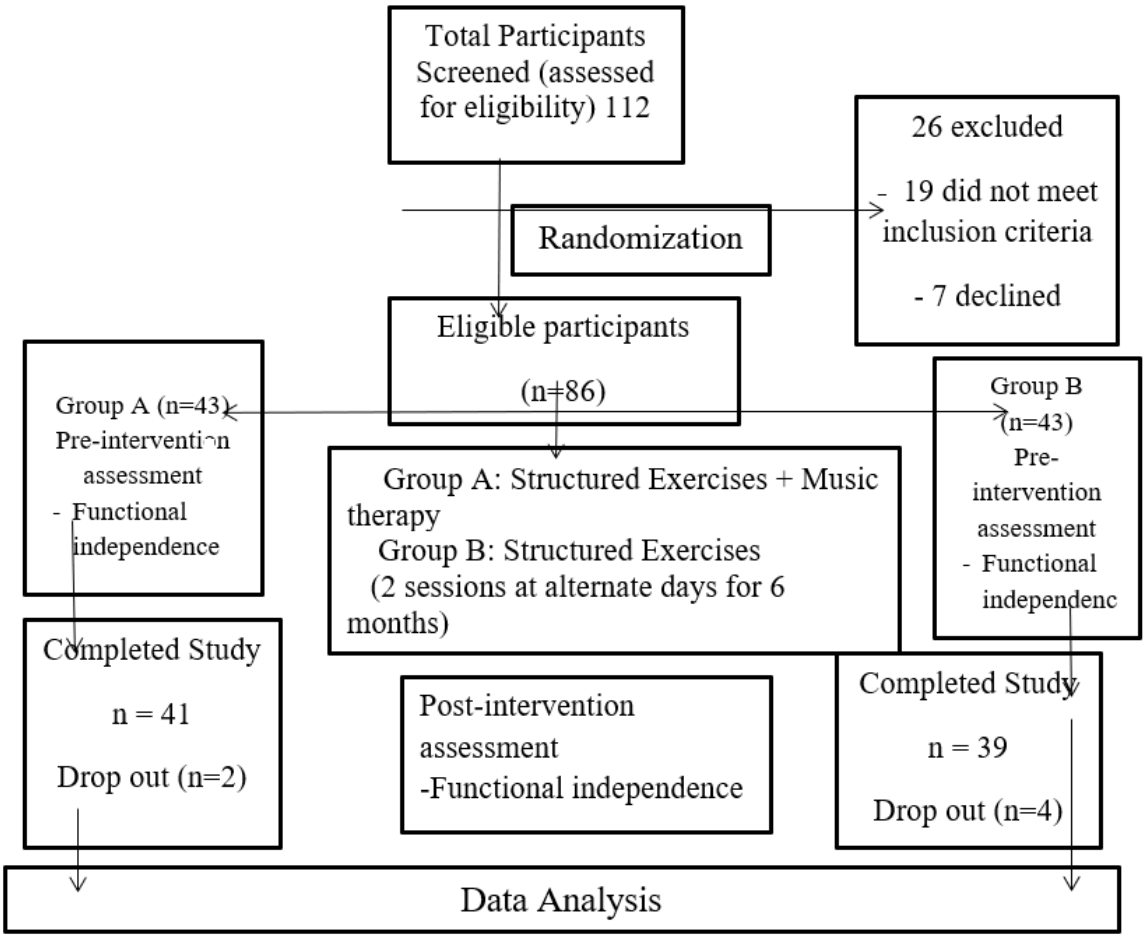

Figure 2 *(CONSORT diagram illustrating the flow of participants through the trial: A 2-arm RCT with groups A & B.)*

Data Analysis

Data was analyzed using IBM SPSS version 23. Descriptive statistics was calculated for all the variables and participant characteristics. Mean and standard deviations were calculated for the functional independence and its two subscales - motor and cognition subscales. Shapiro–Wilk test was used to determine the normality of data. Baseline values were measured and compared within groups using Paired t-test and between the groups using Independent t-test. Post-intervention value of the variables was measured and within group comparison was made using Paired t-test while Independent t-test was used for comparism between the groups.

Ethical Considerations

All ethical procedures were followed in line with the Declaration of Helsinki. Ethical approval for the study was gotten from three different institutions. These institutions are: University of Port Harcourt (UPH), University of Port Harcourt Teaching Hospital (UPTH), and Rivers State University Teaching Hospital (RSUTH). This approval was given after the research proposal was submitted to the ethics research committees of these institutions for critical review and approval. The reference number of the UPH ethical approval is UPH/CEREMAD/REC/MM89/092, while that of UPTH and RSUTH are UPTH/ADM/90/S.II/VOL.XI/1641 and RSUTH/REC/2023424 respectively.

All study participants fully gave their written informed consents before the commencement of the study. The researcher provided two consent forms. The first consent form was the introductory letter stating the research topic, name of the researcher and the purpose of the study. This was to acquaint the participants with the purpose of the study, enabling them to make up their mind whether or not to participate in the study. The purpose of the study was thoroughly explained to the participants. The second consent form included some basic agreement questions. It had boxes where the participants were asked to tick which showed that they agreed with the terms of the research study. Informed consent was given before the participants were admitted into the study.

The principle of confidentiality was adequately followed. The information received from the participants was treated with a high-level confidentiality and used for the purpose of this study only. Under no condition was it revealed to other parties or used for other purposes.

RESULTS

Table 1 *(Socio-Demographic Characteristics of the Participants.)*

Variable	Experimental Group (n=43) n (%)	Control Group (n=43) n (%)	Total (n=86) n (%)
Age			
21-30	1 (2.3)	0 (0)	1 (1.2)
31-40	2 (4.7)	0 (0)	2 (2.3)
41-50	6 (14.0)	3 (7.0)	9 (10.5)
51-60	18 (41.9)	25 (58.1)	43 (50.0)
61-70	13 (30.2)	13 (30.2)	26 (30.2)
71-80	3 (7.0)	2 (4.7)	5 (5.8)
Sex			
Male	22 (51.2)	24 (55.8)	46 (53.5)
Female	21 (48.8)	19 (44.2)	40 (46.5)
Marital Status			
Single	3 (7.0)	2 (4.7)	5 (5.8)
Married	31 (72.1)	30 (69.8)	61 (70.9)
Separated	3 (7.0)	3 (7.0)	6 (7.0)
Divorced	3 (7.0)	2 (4.7)	5 (5.8)
Widowed	3 (7.0)	6 (14.0)	9 (10.5)
Religion			
Christianity	35 (81.4)	33 (76.7)	68 (79.1)
Islam	4 (9.3)	4 (9.3)	8 (9.3)
African Trad.	3 (7.0)	4 (9.3)	7 (8.1)
Religion	1 (2.3)	2 (4.7)	3 (3.5)
Free Thinker			

Occupation			
Civil Service	15 (34.9)	14 (32.6)	29 (33.7)
Public Service	3 (7.0)	7 (16.3)	10 (11.6)
Trader	5 (11.6)	7 (16.3)	12 (14.0)
Farmer	4 (9.3)	2 (4.7)	6 (7.0)
Apprentice	1 (2.3)	0 (0)	1 (1.2)
Retired	15 (34.9)	13 (30.2)	28 (32.6)
Education			
Primary	2 (4.7)	2 (4.7)	4 (4.7)
Secondary	10 (23.3)	12 (27.9)	22 (25.6)
Tertiary	30 (69.8)	29 (67.4)	59 (68.6)
No Formal Education	1 (2.3)	0 (0)	1 (1.2)

Table 1 gives a description of the socio-demographic characteristics of the participants in terms of age, sex, marital status, religion, occupation, and educational level. In terms of age, majority of the participants in the experimental group were within 51-60 years (41.9%) followed by 61-70 age bracket (30.2%). Majority of the participants in the control group were also within 51-60 years (58.1%) followed by 61-70 age bracket (30.2%). In all, majority of all the participants were within the age bracket of 51-60 (50%). In terms of sex, majority of the participants in the experimental group were males 22 (51.2%) while a smaller percentage was female 21 (48.8%). Majority of the participants in the control group were also males 24 (55.8%) with a smaller percentage was female 19 (44.2%). Overall, the proportion of males and females in the study were 46 (53.5%) and 40 (46.5%) respectively. In terms of marital status, majority of the participants in the experimental group were married 31 (72.1%) while majority of the subjects in the control group were married as well 30 (69.8%). The overall proportion of married men and women in the study was 61 (70.9%). With regards to religion, majority of the participants in the experimental group were Christians 35 (81.4%). Majority of the participants in the control group were also Christians 33 (76.7%). Christianity was therefore the major religion of all the participants with a total proportion of 68 (79.1%). When it comes to occupation, majority of the participants in the experimental group were civil servants and retirees both having a proportion of 15 (34.9%) whereas in the control group, majority were civil servants 14 (32.6%) but followed closely by retirees 13 (30.2%). Civil service was therefore the major occupation of the participants with a total proportion of 29 (33.7%). In terms of educational level, majority of the participants in the experimental group had tertiary education 30 (69.8%). Majority of the participants in the control groups also had tertiary education 29 (67.4%). Tertiary education was therefore the major form among all the participants in the study 59 (68.6%).

Table 2 *(Comparism of Baseline and Post-Intervention Values of Functional Independence in the Experimental Group (n=43))*

Variable	Baseline Mean±SD	Post-Intervention Mean±SD	t-value	df	p-value
Motor Subscale	51.98±10.22	63.88±11.00	-20.91	40	0.000*
Cognition Subscale	30.10±2.40	32.71±1.62	-11.83	40	0.000*
Functional Independence Measure (FIM) Score	82.00±9.37	96.56±10.96	-25.15	40	0.000*

** Statistically significant* *P<0.05 = statistically significant*

Table 2 revealed that the mean motor subscale of functional independence of the participants in the experimental group pre and post-intervention were 51.98±10.22 and 63.88±11.00 respectively. The observed difference in mean was statistically significant (t-value = -20.91, p-value =0.000). For the cognition subscale, the mean scores were 30.10±2.40 and 32.71±1.62 pre and post intervention. The observed difference in mean was statistically significant (t-value = -11.83, p-value =0.000). For the Functional Independence (motor + cognition subscales), the mean scores were 82.00±9.37 and 96.56±10.96 pre and post intervention. The observed difference in mean was statistically significant (t-value = -25.15, p-value =0.000).

Table 3 *(Comparism of Baseline and Post-Intervention Values of Functional Independence in the Control Group (n=43))*

Variable	Baseline Mean±SD	Post-Intervention Mean±SD	t-value	df	p-value
Motor Subscale	53.10±9.85	60.69±9.33	-20.90	38	0.000*
Cognition Subscale	29.95±2.65	31.59±2.39	-11.35	38	0.000*
Functional Independence Measure (FIM) Score	83.05±10.43	92.28±10.01	-24.35	38	0.000*

** Statistically significant* *P<0.05 = statistically significant*

Table 3 revealed that the mean motor subscale of functional independence of the participants in the control group pre and post-intervention were 53.10±9.85 and 60.69±9.33 respectively. The observed difference in mean was statistically significant (t-value = -20.90, p-value =0.000). For the cognition subscale, the mean scores were 29.95±2.65 and 31.59±2.39 pre and post intervention. The observed difference in mean was statistically significant (t-value = -11.35, p-value =0.000). For the Functional Independence (motor + cognition subscales), the mean were 83.05±10.43 and 92.28±10.01 pre and post intervention. The observed difference in mean was statistically significant (t-value =-24.35, p-value =0.000).

Table 4 *(Comparism of Mean Difference in Baseline Values of Functional Independence between the Two Groups.)*

Variable	Experimental Group (n=43) Mean±SD	Control Group (n=43) Mean±SD	t-value	df	p-value
Motor Subscale	51.88±10.00	52.91±9.68	-0.482	84	0.631
Cognition Subscale	30.12±2.40	29.95±2.54	0.305	84	0.761
Functional Independence Measure (FIM) Score	82.00±9.37	82.86±10.31	-0.405	84	0.687

** Statistically significant* *P<0.05 = statistically significant*

Table 4. revealed that the mean motor subscale of functional independence of the participants in the experiment and control groups at baseline were 51.88±10.00 and 52.91±9.68 respectively. The mean difference was not statistically significant (t-value = -0.482, p-value = 0.631). For the cognition subscale, the mean scores were 30.12±2.40 and 29.95±2.54 respectively. The mean difference was not statistically significant (t-value = 0.305, p-value = 0.761). For the Functional Independence (motor + cognition subscales), the mean scores were 82.00±9.37 and 82.86±10.31 respectively. The observed difference in mean was not statistically significant (t-value = -0.405, p-value =0.687).

Table 5 *(Comparism of Mean Difference in Post-Intervention Values of Functional Independence between the Two Groups.)*

Variable	Experimental Group(n=43) Mean±SD	Control Group (n=43) Mean±SD	t-value	df	p-value
Motor Subscale	63.88±11.00	60.69±9.33	1.39	78	0.167
Cognition Subscale	32.71±1.62	31.59±2.39	2.459	78	0.016*
Functional Independence Measure (FIM) Score	96.56±10.96	92.28±10.01	1.821	78	0.073

** Statistically significant* *P<0.05 = statistically significant*

Table 5 revealed that the mean motor subscale of functional independence of the participants in the experiment and control groups post-intervention were 63.88±11.00 and 60.69±9.33 respectively. The mean difference was not statistically significant (t-value = 1.39, p-value = 0.167). For the cognition subscale, the mean scores were 32.71±1.62 and 31.59±2.39 respectively. The mean difference observed was statistically significant (t-value = 2.459, p-value = 0.016). For the Functional Independence (motor + cognition subscales), the mean scores were 96.56±10.96 and 92.28±10.01 respectively. The observed difference in mean was not statistically significant (t-value = 1.821, p-value = 0.073).

DISCUSSION

This randomized controlled clinical trial determined if structured exercises combined with music therapy improves the functional independence of stroke survivors as compared to structured exercises alone. The study revealed that majority of the participants were male, aged between 51- 60years. Also, majority of these stroke survivors were civil servants, Christians, married and had education up to tertiary level. The result of the socio-demographic information in this study is consistent with previous findings [6, 7, 39]. Although the study designs and focus of these studies are different, they all made use of stroke survivors as their study participants. Secondly, they were all carried out within the same region. Oti et al., [6] and Oti et al., [7] reported that majority of the stroke survivors in their studies were males,

Christians, married and between the age brackets of 51-60 years. However, contrary to the finding of this study, Oti et al., [7] reported that majority of the stroke survivors were into business, while Oti et al., [6] revealed that majority of the stroke survivors were traders. Onwuchekwa et al., [39], on the other hand, reported that majority of the stroke survivors in their study were males in mid-age to elderly population.

The result of this study revealed a statistically significant mean difference (P-value =0.000) for all the variables (motor subscale, cognitive subscale and FIM score) within both groups – experimental and control groups. In other words, the mean difference pre and post intervention of functional independence and its subscales (motor and cognition subscales) within the two group of the stroke survivors - those who received structured exercises combined with music therapy (experimental group) and those who received structured exercises alone (control group) was statistically significant. This result shows that both interventions produced significant effects within the two groups. Although there was a significant mean difference within both groups, the stroke survivors in the experimental group recorded more improvement as shown in the scores of motor subscale, cognitive subscale, and FIM. The result of this study shows that structured exercises alone and structured exercises combined with music therapy both improve the functional independence of stroke survivors. Secondly, this improvement is more in the group that received structured exercises combined with music therapy (experimental group). Thirdly, the difference in mean (baseline and post-intervention) values of functional independence of the stroke survivors and its subscales within the groups was statistically significant. This finding is in tandem with the findings of Basha [15], Jeba et al., [16], Jun et al., [40], Tong et al., [27], Yoon et al., [41], Scholz et al., [42], Raglio et al., [43], and Friedman et al., [29]. However, the finding of this present study in which participants in the experimental group had more improvement than the control group differs from the position of Van Vugt et al., [28]. Van Vugt et al., [28] posited that participants in the control group of their study recorded more improvement than those in the experimental group.

Furthermore, the result of this study revealed that there is no statistical mean difference ($P > 0.05$) in the baseline values of all the variables (motor subscale, cognition subscale, FIM scores) between the.two groups. In the same vein, the result revealed a significant mean difference in the post-intervention values of the cognition subscale ($P=0.016$) but an insignificant mean difference in the post-intervention values of the motor subscale and the functional independence ($P > 0.05$). This means that structured exercises combined with passive music therapy (receptive listening of classical music instrumentals) only have a significant effect on the cognition of the stroke survivors but not on their motor functions and overall functional independence as compared to structured exercise alone. This finding is similar to the position of Jeba et al., [16] who investigated the effects of music therapy on spasticity, functional independence and quality of life in hemiplegic stroke patients. Jeba et al., [16] however, did not report the values of the motor and cognition subscales, but reported only that of the functional independence of the stroke survivors.

CONCLUSION

Structured exercises combined with music therapy do not significantly improve the functional independence of stroke survivors as compared to structured exercises alone. Music therapy has significant effect on the cognition of stroke survivors. Therefore, Physiotherapists and other rehabilitation experts should incorporate music therapy sessions prior to conventional treatments in order to boost cognitive functions of the stroke survivors.

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DISCLOSURES

The authors declare no conflict of interest.

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