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Does listening to music in acute stroke improve outcomes? A single-blinded quasi-randomized pilot study

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ABSTRACT

Evidence indicates that daily listening to music can improve outcomes in patients recovering from a recent stroke. This study investigated the feasibility and impact of music-listening in addition to standard stroke unit care. It was hypothesized that patients (N = 38) who listened to 70 hours of self-selected music via MP3 players in the first 12 weeks post stroke in addition to standard stroke unit care would experience improved outcomes compared with patients who received standard stroke care alone. Adherence was monitored via weekly diary entries with regular phone contact from researchers. This single-blinded, two armed quasi-randomized pilot study recruited adult participants diagnosed with a recent stroke (≤7 days). The primary outcomes were depression and cognition (memory and attention) at 3 month and the secondary outcomes were anxiety, language, disability and quality of life at 3 or 6 months. Of the 38 participants 11 had a prior history of stroke and 8 died during follow-up. There were no between-group differences in baseline characteristics and no between-group differences in any outcome over time. Adherence to the listening-to-music intervention was low (22.2%). This study demonstrates the feasibility of adding daily listening to music to standard stroke unit care. However, compliance was low. Although those in the intervention group reported that listening to music was a positive experience, it was not associated with any differences in outcomes of interest.

Keywords: Mood, Music, Rehabilitation, Stroke

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INTRODUCTION

Stroke is the greatest contributor to adult disability and one of the leading causes of death [1, 2]. For patients recovering from a recent stroke, evidence suggests that stroke unit care [3, 4], an enriched environment [5–7], intensive, repetitive task-specific training [8, 9] and a brain-based [10] and multi-modal approach [11] are important in maximizing recovery.

One method for enriching the stroke recovery environment would be to encourage patients to routinely listen to music that they enjoy [12]. Music therapy has been utilized within rehabilitation settings with the aim of stimulating brain centers involved in attention, emotion, cognition, behavior, and communication [13–15]. Music interventions include listening to live or recorded music and active participation in groups facilitated by a music therapist.

Music listening can stimulate a variety of cognitive, perceptual, sensorimotor and emotional processes in the brain which may in turn be transferable to other rehabilitation tasks [16, 17]. Studies using functional neuroimaging have indicated that limbic and para-limbic brain structures are stimulated by music listening [18, 19]. In an older cohort of normal adults, Lee et al. [20] demonstrated that significant improvements in quality of life in older people were associated with listening to music of choice on a daily basis. In studies of patients with stroke, listening to music was associated with improvements in mood, reduced depressive symptoms and increased participation in social activities [21, 22]. In a single-blind, randomized controlled trial, Sarkamo et al. [21] recruited 60 patients with a stroke in the middle cerebral artery territory. Participants were randomly allocated to a music group who listened to self-selected music daily for at least one hour (preferred music), a language group who listened to auditory narrative books at least one hour daily or a standard care (control) group. The music group experienced less depression and confusion, and experienced significant improvements in the domains of verbal memory and focused attention than the language and control groups. These results have not been replicated or applied in an English speaking cohort, or to patients with stroke in other brain locations or subsequent stroke.

In order to address this gap, the current study aimed to investigate the effect of listening to music in the first 12 weeks post stroke on depression and cognition, and the feasibility of adding a listening-to-music component to standard, Stroke Unit care. It was hypothesized that, when compared to patients who received standard, Stroke Unit care only, those who received standard care and also listened to 70 hours of self-selected music in the first 12 weeks post stroke would have improved outcomes in depression and cognition.

MATERIALS AND METHODS

The study received ethical approval from the Hunter New England Local Health District Human Research Ethics Committee (LNR/12/HNE/121; Clinical trial number: 365311). All participants or carers provided written consent to participate in the project.

Randomization: This study was a single-blinded, two armed quasi-randomized pilot study. Randomization was based on every 10 patients being alternatively allocated into either the intervention or control group during the 24 month recruiting period with primary investigators responsible for group allocation. This method was chosen to reduce treatment group contamination due to the close proximity of patients within the four bed stroke unit. The second intervention block was incomplete due to the study period ending. No stratification factors were used for randomization.

Blinding: The follow-up outcome measures (Table 1) were measured by assessors who were blinded to a participant's group allocation.

Participants

Participants were recruited from a regional four-bed stroke unit in New South Wales, Australia. Inclusion criteria included admission into the Stroke Unit, stroke (hemorrhagic or infarct) occurred ≤7 days ago, and age >18 years (stroke diagnosed via CT scan). Patients were excluded if they were unable to comprehend or comply with the consent process, were diagnosed with deafness and/or were identified as palliative.

Intervention

All participants received standard stroke unit care as guided by the Australian National Stroke Foundation guidelines [23]. All participants were asked about how much music they listened to prior to their stroke, and, if a participant was unable to respond, a family member was asked instead.

Participants randomized to the intervention group were encouraged to listen to their preferred music on an MP3 player for at least one hour a day, at least 6 days a week for the first 12 weeks post-stroke (≥70 hours of music listening). This protocol was established based on prior research results [21]. The music that a participant preferred and the frequency of music they listened to prior to admission, were established during an interview at baseline (Supplementary Material: Musical Taste Questionnaire). Patients and family members were trained in utilizing the MP3 players and written instructions were also provided. During their hospital admission, staff prompted participant's to listen to music, and assisted them in setting up the MP3 players. Staff were not able to assist patients with MP3 setup after discharge.

Those in the intervention group were asked to use a diary to record how many hours they listened to the music through the MP3 player, and to provide free text comments on their experiences of listening to music throughout the 12-week study period (Supplementary Material: Music Diary for Intervention Group). Families were able to assist patients to complete the diary entries. The diary entries were taken at face value and qualitative analysis of the diary comments was completed.

The intervention continued for twelve weeks irrespective of whether or not a patient was still in hospital or had been discharged home or transferred to another facility such as a nursing home. Patients were discharged with MP3 players, diaries and received weekly follow-up phone calls from the research team.

Patients randomized to the control group were not prevented or discouraged from listening to music.

Outcome Measures

Demographic data included age, length of stay, history of depression and stroke sub-type using the Oxfordshire Stroke Classification system [24].

A summary of the outcome measures used is included in Table 1. For the primary outcomes, depression was measured using the Hospital Anxiety Depression Scale (HADS) [25–27]. This is a validated post stroke screening measure designed to assess the presence of mood disorder. Memory and attention were measured using two subsets from the COGNISTAT (http://www.cognistat.com/) [28]. This is a validated cognitive screening assessment that is more sensitive to cognitive function than many other cognitive screening examinations. For the secondary outcomes, anxiety was measured using the HADS [25–27], aphasia was measured using spontaneous speech, naming, verbal fluency and sequential commands subtests of the Western Aphasia Battery (WAB) [29, 30]. The WAB is a standardized aphasia battery validated for use with stroke populations. The subsets will provide information on language skills. Health related quality of life was measured using the Stroke and Aphasia Quality of Life [31]. The latter is specifically designed to administer to stroke survivors with or without aphasia [32, 33]. In addition, the Modified Rankin Score (MRS) [34, 35] measured disability [36] and the Functional Independence Measure (FIMTM) (http://ahsri.uow.edu.au/aroc/whatisfim/index.html#fim) measured global function. Both are widely accepted measures in stroke rehabilitation to measure functional change.

Data Analysis

Baseline characteristics were described using the mean and standard deviation (SD) for continuous variables and the frequency (n) and percentage for categorical variables. Analyses followed the intention to treat principle. A small number of patients who died during follow-up (n = 8) or self-withdrew (n = 3) from the study had their last observation carried forward.

For continuous outcomes measured only once during follow-up, differences between mean follow-up scores in the intervention and control groups were assessed using linear regression, adjusting for baseline scores when measured (i.e. ANCOVA). Between-group differences in global function (MRS) at 3 and 6 month post stroke, were assessed using linear regression in a generalized estimating equation framework, adjusting for baseline. This model assumed fixed effects of treatment group and time, and included group×time interactions to assess between-group differences. An autoregressive correlation structure was assumed to account for correlation of repeated measures within patients.

For ordinal outcomes measured at 3 months only, group differences in the odds of being in sequentially higher categories were assessed using ordinal logistic regression, assuming proportionality of sequential odds. No models were adjusted for patient characteristics, reflecting the lack of stratification variables.

Results show estimated parameters, 95% confidence intervals and p-values for the main effect of treatment group. For continuous outcomes, parameters represent the predicted difference in the mean outcome between the treatment and control groups, adjusted for the baseline value if measured. For ordinal outcomes, parameters are expressed as odds ratios, reflecting the predicted ratio in mean odds of being in sequentially higher categories of severity.

For the primary outcomes of depression, memory and attention, associations reaching $p < 0.017$ (0.05/3) were considered significant, after incorporating Bonferroni adjustment for testing three primary outcomes. At a significance level of 0.017, our sample (N=38, see below) had 80% power to detect a between-group difference in means of 4.2 for the continuous depression measure, assuming a standard deviation of 4 [37] and correlation of 0.3 between baseline and third month outcomes. For the ordinal outcomes, the study had 80% power to detect an odds ratio of 0.24.

For the remaining outcomes, analyses were considered exploratory and significance was assessed at the 0.05 level for each outcome. All statistical analyses were programmed using SAS V9.4 (SAS Institute, Cary, North Carolina, USA).

RESULTS

Of the patients with stroke who were admitted to the stroke unit during the recruitment period (n = 82), 42 met the inclusion criteria and of these (Figure 1) 38 stroke patients consented to participate and were randomized. At three months one patient died in the control group. At sixth month three patients in the treatment group died, while in the control group, four patients died and one was

lost to follow-up. The mean age of all participants was 76 years (SD 11.8) and there was an equal number of males and females (n = 19).

Baseline characteristics showed relative balance across the two treatment groups (Table 2). Eleven participants had a prior history of stroke and 95% were right-handed. Around 30% had a moderate-to-mild stroke (MRS: 2–3) but the majority (71%) of participants had a moderate-to-severe stroke (MRS: 4–5). FIM scores were balanced across groups on admission and discharge. Length of stay was 19 days in the treatment group and 16 days in the control group.

Impact of Listening-to-Music

Primary Outcomes

Mood: At 3 months post-stroke, there was no significant treatment group difference in the mean depression scores (Table 3). The estimated mean depression score was 0.47 points lower in the intervention group than in the control group, but this difference was not significant (p = 0.62). As anticipated [38], a participant's baseline score significantly predicted the follow-up score for depression (p < 0.0001). Of interest mean depression scores for both groups were within normal range at baseline and three months post stroke.

Cognition: There was no significant difference between intervention and control groups in the odds of being in a more severe memory (OR=1.26, P=0.70) or attention category (OR=1.03, P=0.97) (Table 3).

Secondary Outcomes

Mood: At 3 months post stroke, there was no significant treatment group difference in anxiety scores (Table 4). The estimated mean anxiety score was 0.5 points higher in the intervention group, but again, this difference was non-significant (p = 0.54). As anticipated [38], a participant's baseline score significantly predicted the follow-up score for anxiety (p < 0.0001), with mean scores in the normal range for both groups at baseline and 3 months post stroke.

Language: There were no significant treatment group differences in the WAB spontaneous speech, sequential commands, naming or word fluency scores (Table 4) and across all four domains, as anticipated, a participant's baseline score significantly predicted the follow-up score (p < 0.0001). Compared to the control group, the estimated mean score in the intervention group was 0.07 points higher for spontaneous speech, 1.03 points lower for sequential commands, 3.34 points higher for naming and 0.61 points lower for word fluency.

Global Function: For global function, time was associated with significant reductions in the mean MRS functional score in the control group, with the mean reducing by 0.8 (p = 0.0087) points in the first three months. The group×time interaction in the intervention group was not significant (P = 0.74, Table 4) indicating that there was no significant difference in improvement in the first three months between intervention and control groups [39].

Time was significantly associated with recovery in global function at three months and at six months (1.42; p < 0.0001) in all participants and was not significantly different between intervention groups (p = 0.16 for the group×time interaction).

Quality of Life: The estimated mean SAQOL score was 0.06 points lower in the intervention group, but this difference was non-significant (p = 0.80; 95% CI -0.54 to 0.42). Both groups self-rated high quality of life scores at six months post stroke (Control mean score = 4.28, Intervention mean score = 4.21).

Feasibility of Adding Listening-to-Music to Standard, Stroke Unit Care

Of the participants in the intervention group, 17 of the 18 returned their music listening diaries. Only 22% achieved the target dose of music listening. The majority (78%) of participants in the intervention group did not achieve the target dose and two-thirds spent less than 50 hours listening to music during the 12-week intervention period (Table 5).

In the hospital phase, participants demonstrated increased music listening. Upon discharge home, and in particular, the last month of intervention, music listening reduced proportionality with eight participants listening to no music in the last week of intervention.

Experience of Listening to Music

Despite the low adherence rates, the qualitative data documented in the diary indicated that participants experienced positive benefits from listening to music, reporting it as relaxing, stimulating and a means of passing time as demonstrated below:

"I look forward to the music, best part of the day" (P1)

"I find I'm quite relaxed every time I listen to music whether it be 1 or 2 (hours)" (P2).

"Pleasant listening today" (P3).

DISCUSSION

Despite the fact that this study found no between-group differences, it has highlighted some important findings in relation to introducing prescribed doses of listening to music as an adjunct to standard care in patients recovering from a recent stroke. Evidence demonstrates that in patients with stroke, listening to self-selected music on a daily basis can improve health-related quality of life outcomes [20], reduce depressive symptoms, reduce confusion, improve memory and attention and increase participation [21, 22, 40]. However, in the first 12 weeks post stroke, we found that in clinical practice, it was difficult to implement 70 hours of music listening,

with findings indicating a 50-hour target may be more achievable over a shorter duration.

Interestingly, participants in both groups reported frequent or daily music listening prior to their stroke (Table 2), which may have produced treatment group contamination and thus influenced the study outcomes.

At the very least, time spent listening to music appeared to induce self-reported, positive outcomes as indicated in the diary responses, and is one potential strategy to enrich the recovery environment [6] and to increase the amount of time patients with stroke actively participate in everyday activities [10]. Mood scores were low at baseline and three month follow up in both groups, whilst quality of life ratings were higher than expected.

In contrast to previous studies [21] the current study included all patients with stroke, irrespective of stroke severity, stroke classification or prior history of stroke. Whether or not it is more effective in specific patient cohorts, for example less severe strokes or those with post stroke aphasia, is yet to be demonstrated [7].

Adding listening-to-music to standard, stroke unit care was feasible, but the participants in the intervention group were not able to adhere to the target of 70 hours of music listening in the first 12 weeks post stroke. A target of 50 hours in the first eight weeks may be more achievable with strategies to improve music listening adherence once discharged home from rehabilitation.

Study Limitations

This study may have been limited by the low participant numbers, the low adherence rates to the listening-to-music intervention and the high dropout rate (24%). Larger studies are needed to evaluate the effect of music therapy. Decreasing the duration and intensity of the intervention may improve adherence, however, this will need to be balanced against desired treatment efficacy. Perhaps adherence could be improved with an electronic recording or reminding method (e.g., reminder text or email message). Another study limitation is that participants in the control group did not record their music listening. In future, all participants should record their music listening. It may be noted that the control group tended to listen to music more regularly prior to the stroke than the intervention group (Table 2). This group, therefore, may have listened to more music than anticipated, as a result of their pre-morbid nature/ usual activities.

Table 1: Outcome measures across study timeline

Measure	Procedure	Domain	Description	Administered
Primary Outcomes				
Hospital Anxiety and Depression Score [25–26]	Questionnaire	Mood-Depression	Range=0–21 Normal<8	Baseline and 3 months
Cognistat [28]	Memory Subset Attention Subset	Cognition	Range=0–12 Normal ≥10 Range=0–8 Normal ≥6	Baseline and 3 months
Secondary Outcomes				
Hospital Anxiety and Depression Score [25–26]	Questionnaire	Mood-Anxiety	Range=0 to 21 Normal<8	Baseline and 3 months
Western Aphasia Battery [29–30]	 Spontaneous speech Naming Verbal Fluency Sequential commands	Language	Aphasia assessment Range=0–20 Range=0–60 Range=0–20 Range=0–80	Baseline and 3 months
Stroke and Aphasia Quality of Life Scale [31–33]	Questionnaire	Quality of Life	Aphasia-friendly Range=1–5 Higher Score = higher ratings of QOL	6 months
Modified Rankin Score [34, 35]	Disability	Disability	Range=0–6 Higher Score = Functional Independence	Baseline, 3 and 6 months
Functional Independence Measure (FIM)		Global Function	Range=18–126 Higher Score = Functional Independence	Baseline and discharge from hospital

Table 2: Baseline characteristics of participants

Variable	Category	Control~(n=20)	Treatment~(n=18)
Age	50–60	4 (20%)	0
	60–70	1 (5.0%)	2 (11%)
	70–80	5 (25%)	7 (39%)
	80+	10 (50%)	9 (50%)
Sex	Male	9 (45%)	10 (56%)
	Female	11 (55%)	8 (44%)
Stroke side	Unknown	1 (5.0%)	4 (22%)
	Left	8 (40%)	8 (44%)
	Right	11 (55%)	6 (33%)
Oxfordshire	TACI	5 (25%)	0
	PACI	3 (15%)	3 (17%)
	POCI	4 (20%)	6 (33%)
	LACI	5 (25%)	7 (39%)
	Hemorrhagic	3 (15%)	2 (11%)
Handedness	Right	19 (95%)	17 (94%)
	Left	1 (5.0%)	1 (5.6%)
Prior History of Depression	Yes	3 (15%)	5 (28%)
	No	17 (85%)	13 (72%)
Currently on Anti-depressants	Yes	3 (16%)	3 (17%)
	No	16 (84%)	15 (83%)
	Missing	1	0
Prior History of stroke	Yes	7 (35%)	4 (22%)
	No	13 (65%)	14 (78%)
Admission FIM (mean)	Maximal/total assistance	3 (15%)	4 (22%)
	Supervision/moderate assistance	12 (60%)	8 (44%)
	Modified/complete independence	5 (25%)	6 (33%)
Prior music listening	Rarely/never	2 (11%)	0
	Sometimes	3 (16%)	7 (41%)
	Frequently/daily	14 (74%)	10 (59%)
	Missing	1	1

FIM Functional Independence Measure

Table 3: Primary Outcomes: Linear regression results for depression and ordinal logistics regression results for cognition at 3 months post-stroke. The control group was used as a reference group.

Mood: Linear Regression		Baseline M (SD)	Follow up M (SD)	Beta Coefficient	95% LCL	95% UCL	p-value
Depression	Treatment	5.88 (4.15)	4.40 (4.05)	-0.4682	-2.3419	1.4055	0.6243
	Control	5.39 (3.47)	4.59 (2.65)				
Cognition: Logistic Regression				**Odds ratio**			
Memory	Treatment	2.78 (1.17)	2.33 (1.37)	1.2623	0.3837	4.1531	0.7015
	Control	2.40 (1.27)	2.15 (1.35)				
Attention	Treatment	1.61 (1.09)	1.56 (0.98)	1.0282	0.2472	4.2768	0.9695
	Control	1.45 (1.00)	1.60 (1.14)				

Note: LCL = lower confidence limit; UCL = upper confidence limit; Key: §= p<0.05

Table 4: Secondary outcomes: Linear regression results for anxiety and global function and ordinal logistics regression results for language at 3 months post-stroke. The control group was used as a reference group

Mood and Global Function: Linear Regression		Baseline M (SD)	Follow-up M (SD)	Follow-up 6th month M (SD)	Beta Coefficient	95% LCL	95% UCL	P-value
Anxiety	Treatment	5.88 (4.15)	4.40 (4.05)		0.5037	-1.1155	2.1230	0.5420
	Control	5.39 (3.47)	4.59 (2.65)					
MRS	Treatment	3.72 (1.02)	3.06 (1.59)	1.56 (1.26)	0.13 (3 months)	-0.65 (3 months)	0.92 (3 months)	0.74 (3 months)
	Control	3.90 (0.79)	3.10 (1.37)	2.41 (1.54)	-0.60 (6 months)	-1.45 (6 months)	0.24 (6 months)	0.16 (6 months)
Language: Logistic Regression					**Odds ratio**			
Spontaneous Speech	Treatment	15.83 (6.70)	16.78 (5.08)		0.0749	-1.2072	1.3571	0.9088
	Control	17.60 (4.88)	17.95 (4.08)					
Sequential Commands	Treatment	64.56 (28.83)	65.06 (28.32)		-1.0328	-6.1481	4.0826	0.6923
	Control	70.53 (19.67)	71.45 (19.44)					
Naming	Treatment	49.89 (19.68)	52.33 (13.99)		3.3389	-1.8371	8.5151	0.2061
	Control	54.05 (14.67)	52.15 (16.68)					
Verbal Fluency	Treatment	12.61 (6.24)	12.06 (6.36)		0.6057	-2.6555	1.4442	0.5625
	Control	12.20 (5.74)	12.30 (6.07)					

Note: LCL Lower Confidence Limit, UCL Upper Confidence Limit, MRS Modified Rankin Score,
Key: §= $p < 0.05$

Table 5: Listening-to-music "dose" of participants in the intervention group

Total hours	Frequency	Percent	Cumulative %
≥ 70	4	22.2	22.2
50–70	3	16.7	38.9
33–50	5	27.8	66.7
16–33	1	5.6	72.2
0–16	4	22.2	94.4
0	1	5.5	100

There are several reasons why between group differences were not found in the current study. First, the study was undertaken in the acute and sub-acute phases, and at a time when almost all patients with stroke are experiencing recovery as a result of the combined impact of natural history and rehabilitation. Second, the study's small sample size may not have had sufficient power to detect between-group differences in recovery outcomes. Third, the poor adherence rates to the intervention may have diluted the association between music-listening and positive recovery outcomes.

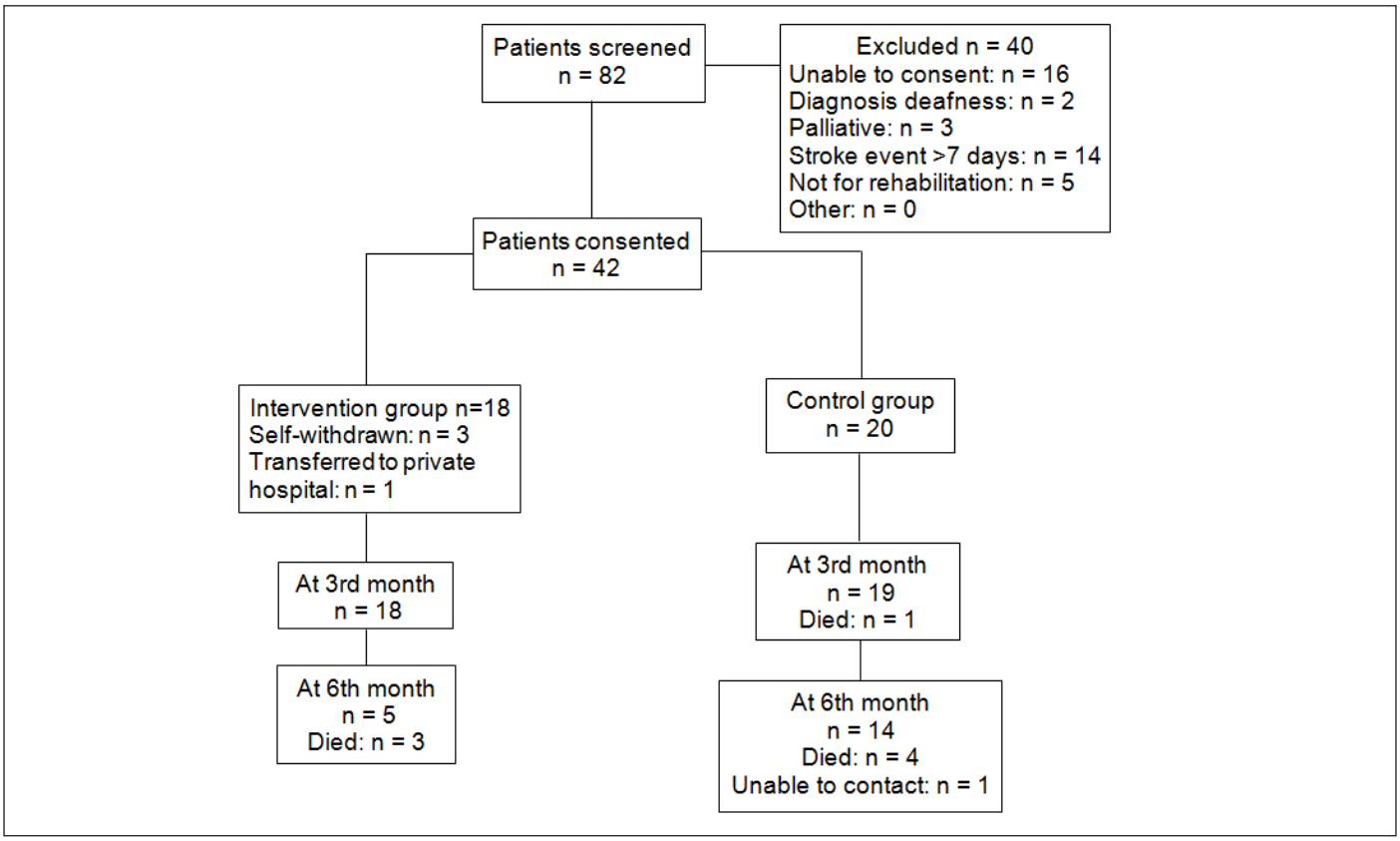

Figure 1: Consort Diagram

CONCLUSION

This study demonstrates that adding daily listening to music to standard stroke unit care is feasible, but was unable to demonstrate benefit to mood and cognition in patients diagnosed with a recent stroke. There were also challenges to this cohort of patients listening to 70 hours of self-selected music during the first three months post stroke.

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Colette Sanctuary – Acquisition of data, Analysis and interpretation of data, Drafting the article, Revising it critically for important intellectual content, Final approval of the version to be published
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Guarantor
The corresponding author is the guarantor of submission.

Conflict of Interest
Authors declare no conflict of interest.

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SUPPLEMENTARY MATERIAL

Musical Taste Questionnaire

'Stroke Sounds': Music Listening in Stroke Rehabilitation

Musical Taste Questionnaire

Do you enjoy listening to music?
□ Yes □ No □ Impartial

What type of music do you enjoy listening to?

_____
_____
_____

What is your favorite type of music? Choose one or more.

- ♫ Classical
- ♫ Jazz
- ♫ Blues
- ♫ Country and Western
- ♫ Pop
- ♫ Easy listening (Lounge/Swing)
- ♫ Reggae
- ♫ Folk
- ♫ Opera
- ♫ Gospel
- ♫ Latino
- ♫ Other

What are some of your favorite bands, singers or performers?

_____
_____
_____

Music Diary for Intervention Group

Name: _____
'Stroke Sounds'
Music Listening Diary
BOOKLET: Weeks 1–4

Start date: _____
Finish date: _____

Listening to your favorite music after having had a stroke has been shown to help your recovery.

For this program you will need to listen to 1 hour of music each day for 6 days a week through the MP3 music player we have supplied. Overall this will be for 12 weeks.

Please take the time to fill out this diary every day. It is very important that this information is accurate.

Each day fill out the date and tick whether you have completed listening to your 1 hour of music or not. The comments box can be filled in if you have listened to more or less than the hour we would like you to listen to on the MP3 music player.

When you have finished this booklet you will need to return it to us by mail in the postage paid envelope supplied.

A new booklet will be supplied to you by post for weeks 1–4
At the end of 12 weeks you will need to return your music player to Dr

_____when you have your appointment to see him. Your appointment is:

DATE:_____

A member from our team will call you to organize a home visit after you have completed the 12 weeks of music listening. This person will ask you some questions to look for your improvements since the stroke. Some participants we have tested have not listened to music, so it is very important that the person that visits does not know whether or not you have participated in listening to music daily.
This person will then contact you around 6 months after your stroke to ask you some further questions.

WEEK 1

Date	1 hour music listening with MP3	Comments
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	

WEEK 2

Date	1 hour music listening via MP3	Comments
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	