Research Report

EFFECT OF ADJUNCTIVE MUSIC LISTENING IN SCHIZOPHRENIA – A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Music-based interventions are currently being researched for their effectiveness in schizophrenia. Very few studies have been done in the acute phase. Further, there is a dearth of published Indian research in this context. **Methods:** A prospective, randomized, controlled, single-blind study was done in a tertiary psychiatric hospital in South India from October-2015 to March-2016. Immediately after admission, consenting adult patients with schizophrenia were randomly assigned to two groups. Over four weeks, Group-A(N=51) received 20 sessions of music-listening as an add-on to standard care, and Group-B(N=53) received standard care alone. Reduction in Positive and Negative Syndrome Scale (PANSS) scores and the drug dosage requirements for both groups were compared. Statistical analysis was done using two-way repeated-measures ANOVA for PANSS score reduction and Mann-Whitney U for drug dosage comparison. **Results:** We observed a greater decrease in PANSS scores in Group-A than Group B, but this difference did not reach significance ($p>0.05$ for all three subscales and total score). Group-A required lesser risperidone-equivalent doses than Group-B, but this was not significant ($p=0.27$). However, Group-A required significantly lesser diazepam equivalent ($p=0.003$) and trihexyphenidyl ($p=0.007$) doses than Group-B. **Conclusions**: The above findings suggest a possible additional benefit of adding music listening to standard care for the acute phase management of schizophrenia and reducing drug dosage requirements. Music-based interventions for schizophrenia warrant further research, especially in the Indian context and wider application in clinical practice.

Keywords: schizophrenia, music listening, acute phase, symptom reduction, drug dose requirements

INTRODUCTION

Schizophrenia is a severe mental disorder that affects one percent of the world population.[1] It comprises a complex array of symptoms that can be broadly classified as positive and negative symptoms.[2] Antipsychotics have an indispensable role in the management of schizophrenia.[3] In addition to pharmacotherapy, various non-pharmacological interventions have been used as adjunctive therapy for schizophrenia. Among them, four interventions have strong support – assertive community treatment, crisis intervention, psychoeducation and music therapy.[4]

Music-based interventions for schizophrenia are currently being researched for their effectiveness. Music

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therapy is defined as "a reflexive process wherein the therapist helps the client optimize the client's health, using various facets of music experience and the relationships formed through them as the impetus for change".[5] While music therapy requires a trained music therapist, music medicine can be offered as ancillary therapy by medical personnel not necessarily specialized in music therapy.[6] Hence music listening, which is part of music medicine, was used in this study.

When combined with music-based interventions, standard procedures have been found to be more effective in improving symptoms of schizophrenia.[7] However, very few studies have been carried out in the acute phase of the illness.[8–11] For a modality that can be heavily influenced by socio-cultural factors, there is a definite dearth of published Indian research in this context.[12] Therefore, we aimed to evaluate the effect of adjunctive music listening on the various symptoms of schizophrenia and the drug dosage requirements, in the acute phase, in a South Indian population.

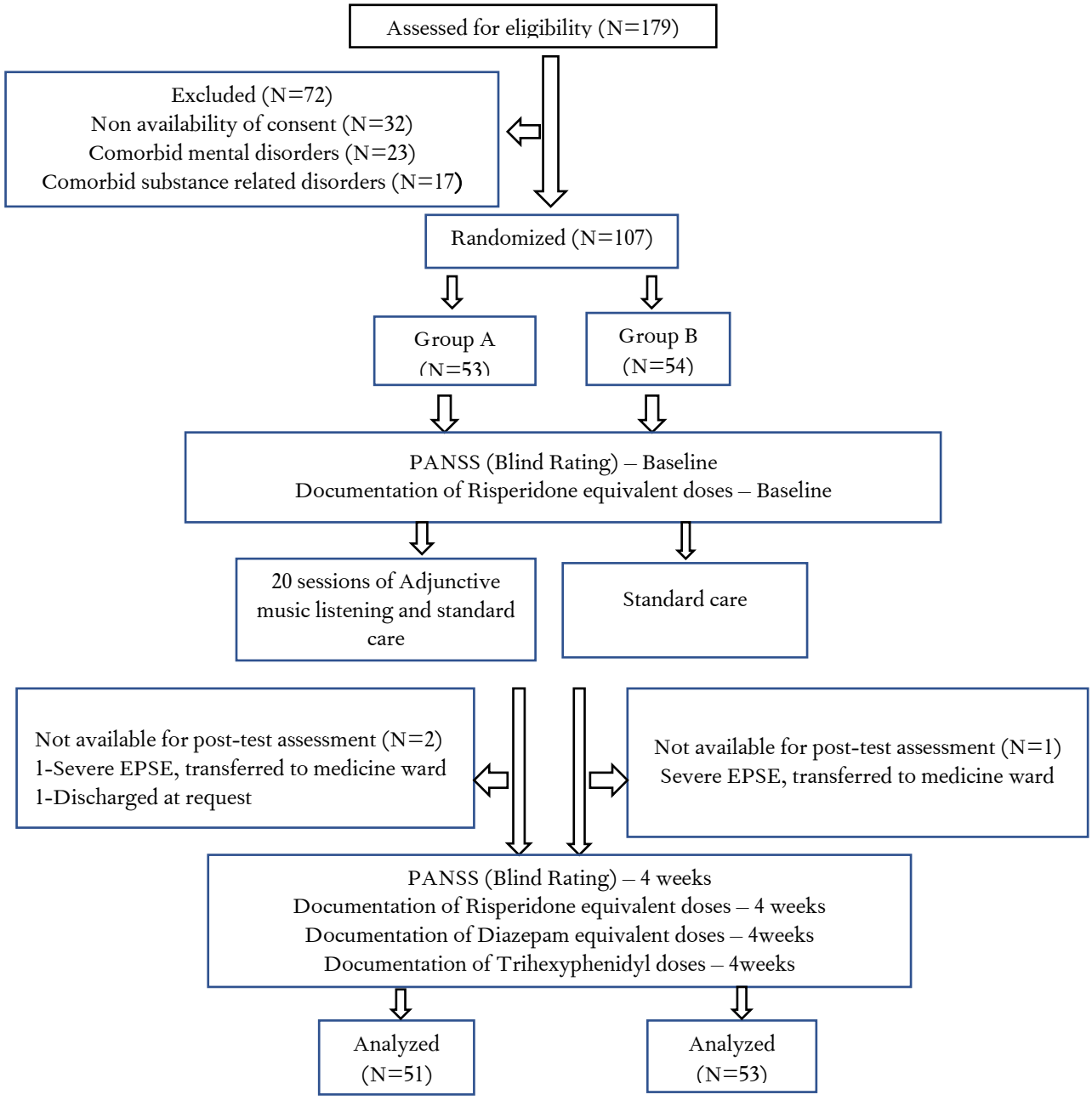


Figure1.Consort digram

MATERIALS AND METHODS

Subjects: The study was conducted in a tertiary Psychiatric facility in South India, with an in-patient strength of 530 beds. The study period was six months, between October 2015 and March 2016. A priori sample size was calculated using the online sample size calculator www.sample-size.net. Based on a two-tailed test, a conventional alpha set as 0.05, conventional power as 0.8 and effect size (Cohen d) assumed as 0.6, the minimum required sample size for both arms was 87. Over six months, 179 consecutive patients, aged 19 to 64 years, getting admitted with a DSM-5[13] diagnosis of schizophrenia were considered for inclusion into the study. Patients with substance dependence, co-morbid mental disorders, intellectual disability, hearing loss, cognitive impairment and who did not give consent were excluded. A total of 107 patients were randomized by online randomization software into two groups. Group A (N=53) received standard care plus 20 sessions of adjunctive music listening, and Group B (N=54) received standard care alone. Two patients from the former group and one from the latter group were not available for final assessment. Since the dropout rate was less than 5%, they were excluded, and final analysis was done on 104 patients (Group A – 51, Group B – 53).

Procedure: A randomized, controlled study design incorporating non-blinded treatment and blinded assessments were employed. Immediately after admission, patients in Group A were divided into groups of 5 to 10 participants per group and were administered five sessions of music listening per week for four weeks. Thus each patient received a total of 20 sessions. Each session lasted 30 minutes. A qualified music therapist was consulted, and appropriate tracks from Indian classical and Western classical musical genres were selected and compiled into twenty playlists, each playlist running for 30 minutes. All the tracks consisted of instrumental music, with even and consistent volume and velocity without any unpredictable and sudden changes in amplitude. Discordant notes or harmonies were not present in any of the tracks. Investigator chose a playlist for each session from the set of playlists. Since it was a group format, individual choices of patients could not be considered. The same sequence of playlists was used for all patients. Patients listened to the selected music playlist through speakers, with a comfortable volume level, while being seated in a quiet room in the evening. The investigator supervised the sessions. Patients in Group B did not experience any scheduled sessions of music listening. However, no effort was made to control the naturalistic music listening they may experience in various settings.

Outcome measurement: Structured data collection pro forma was used to record the socio-demographic variables (age, gender, marital status, educational status, occupational status, socioeconomic status and area of domicile) and clinical variables (duration of illness, number of previous hospitalizations and drug dosage levels) of the participants. The investigator recorded these. The primary outcome measurement was comparing the reduction in Positive and Negative Syndrome Scale (PANSS)[14] scores between the two groups. PANSS is a 30-item semi-structured clinical interview. It has three subscales – positive, negative and general psychopathology. Each item rates along a seven-point continuum (1-Absent, 7-Extreme). Scores for each subscale can be added to derive a PANSS total score. It evaluates the clinical profile of a patient with schizophrenia and provides an assessment of treatment response. The rating was done at baseline and four weeks. The raters were blind to the group assignment of the patients. The patient's treating psychiatrist, who was also blind to the group assignment, was in charge of adjusting antipsychotic doses or adding benzodiazepines or trihexyphenidyl based on clinical requirements.

Ethical considerations: Written, informed consent as per the ICMR guidelines was obtained for all participants. All patients received standard care, irrespective of the group. After obtaining approval from the Institutional Scientific and Ethical committees, the trial was registered on the Clinical Trials Registry – India (CTRI) website, number CTRI/2016/04/006841.

Statistical analysis: All data analysis was performed under the supervision of a biostatistician using Microsoft Excel software and IBM SPSS Version 22 © Copyright IBM Corporation and other(s) 1989, 2013. Percentages and ratios were used to present the data pertaining to the distribution of the socio-demographic and clinical variables in both groups. Numeric variables were represented as mean±SD and categorical variables

Table 1: Socio-demographic and Clinical characteristics of the patients

Characteristic	Group A (N=51)	Group B (N=53)	P value
Gender (%)			
Male	29 (56.86)	37 (69.81)	0.17
Female	22 (43.14)	16 (30.19)	
Marital status (%)			
Single	10 (19.61)	11 (20.76)	
Married	33 (64.71)	40 (75.47)	0.20
Widowed	2 (3.92)	0 (0)	
Divorced	6 (11.76)	2 (3.77)	
Socioeconomic class (%)			
Upper middle	8 (15.68)	4 (7.55)	
Lower middle	33 (64.71)	37 (69.81)	0.43
Upper lower	10 (19.61)	12 (22.64)	
Area of Domicile (%)			
Rural	39 (76.47)	42 (79.25)	0.73
Urban	12 (23.53)	11 (20.75)	
Mean age in years (SD)	37.41 (7.5)	35.02 (7.4)	0.11
Mean duration of Schizophrenia in years (SD)	9.45 (6.8)	8.66 (6.9)	0.50
Mean Number of Previous Hospitalizations (SD)	3.92 (4.0)	2.94 (3.3)	0.18
Mean Risperidone equivalent dose (SD)			
Baseline	3.39 (0.68)	3.38 (0.76)	0.96
Four weeks	4.98 (0.82)	5.51 (1.48)	0.27
Mean Diazepam equivalent dose –Four weeks (SD)	8.33 (3.27)	10.75 4.21)	0.003*
Mean rihexyphenidyl dose – Four weeks (SD)	1.61 (1.02)	2.21 (1.22)	0.007*

Group A – Music listening + Usual care group, Group B – Usual care group

were represented as percentages and proportions. Tests of Normality were conducted on all continuous variables using the Shapiro-Wilk test. Parametric tests were used for the variables with a normal distribution, and non-parametric tests were used for the skewed variables. Baseline comparisons of the two groups were carried out by independent samples t-test (continuous variables with a normal distribution), Mann-Whitney U test (continuous variables with non-normal distribution) and chi-square test (categorical variables). Two way Repeated measures ANOVA was used to check the significance of the change of PANSS scores within and between the two groups. Mann-Whitney U test was used to check whether the groups differed in terms of doses of drugs. Statistical significance was set at $p \leq 0.05$

RESULTS

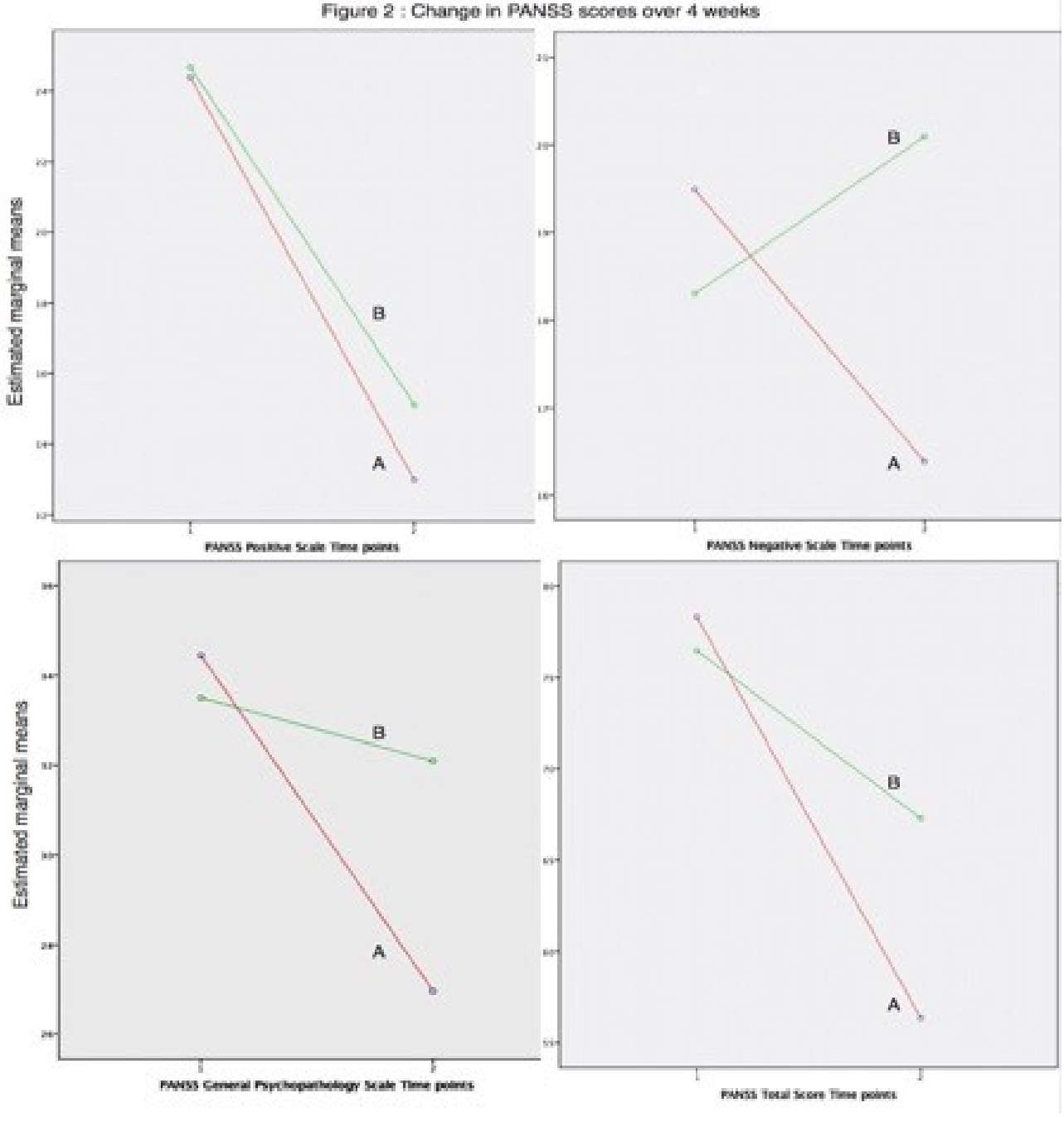
Figure 1 shows the CONSORT diagram following the patients through the randomized controlled trial. Baseline comparison of the socio-demographic and clinical variables showed that the two groups were similar. Table 1 shows the comparison of socio-demographic and clinical variables for both groups. Group A had a greater decrease in scores than Group B in the positive subscale scores, but this difference did not

Table 2. Comparison of PANSS scores at baseline and four weeks

Variable	Group A (N=51)	Group B (N=53)	P-value
PANSS-positive			
Baseline	24.39(3.99)	24.68(4.75)	0.08
Four weeks	12.98(3.20)	15.11(3.42)	
PANSS-negative			
Baseline	19.49(5.67)	18.30(5.94)	0.26
Four weeks	16.39(5.30)	20.09(6.35)	
PANSS-general			
Baseline	34.45(10.08)	33.51(10.98)	0.30
Four weeks	26.96(8.27)	32.09(9.84)	
PANSS-total			
Baseline	78.33(5.67)	76.49(15.50)	0.86
Four weeks	56.33(10.75)	67.30(14.58)	

Group A – Music listening + Usual care group, Group B – Usual care group. PANSS- Positive and Negative Symptoms Scale.

Figure 2 : Change in PANSS scores over 4 weeks



reach statistical significance (p=0.08). In the negative subscale score, Group A had a decrease in mean scores, whereas Group B had an increase in mean scores. However, this difference did not reach statistical significance (p=0.26). Group A had a greater decrease in the general psychopathology subscale scores than Group B, but this difference did not reach statistical significance (p=0.30). Similarly, Group A had a greater decrease in PANSS total scores than Group B, but this difference did not reach statistical significance (p=0.84).

A comparison of PANSS scores for both groups is presented in Table 2, and the change in PANSS scores over four weeks is shown in Figure 2.

Within each group, the change in PANSS (positive, negative, general psychopathology and total) scores over four weeks were significant ($p<0.05$ for all subscales and total score). But on comparing between groups, the difference in scores did not reach statistical significance.

Group A required lesser doses of risperidone than Group B, but this difference did not reach statistical significance (p=0.27). However, Group A required significantly lesser doses of Diazepam (p=0.003) and Trihexyphenidyl (p=0.007) than Group B.

DISCUSSION

This study suggests a possible additional benefit of adjunctive music listening for patients with schizophrenia in the acute phase. The results are comparable to some previous music-based research in schizophrenia, which has provided limited quantitative and qualitative evidence.[7,15] It was not surprising that statistically significant differences were not achieved between the two groups, owing to the brief nature of the intervention. Further, both groups received standard care. However, it was interesting to note the trend where a greater decrease in all the PANSS subscales and total scores was observed in the group that received music listening and standard care. It was also interesting that this group required lesser risperidone-equivalent doses, diazepam-equivalent doses, and trihexyphenidyl doses than the group that received standard care alone.

Variations in the methodology could have contributed to the differences observed in our results when compared with some previous studies. One feature that distinguishes our study from previous research was that we employed the music listening method while most other studies used music therapy (active and passive) methods.[8–10,16–19] The music listening method may be particularly useful in settings where resources might be limited.

In our study, we noticed a beneficial effect of music listening on all the symptom domains of schizophrenia, but none reached statistical significance. Similarly, another RCT, which employed music therapy method for a period of 3 months, also found a favourable effect of music listening on the symptoms of schizophrenia but did not achieve statistical significance.[8] We also did not notice a differential impact of music listening on the positive and negative symptoms of schizophrenia. However, a Cochrane review of RCTs done on music therapy in schizophrenia concluded that music therapy had an additional benefit on the negative symptoms more than on the positive symptoms.[7] The studies included in the Cochrane review had a longer duration of music intervention than our study, which might have contributed to this discrepancy. Further, a meta-analysis that included both RCTs and non-RCTs on music interventions in schizophrenia concluded that the treatment effect was significantly better in music intervention groups across all symptom domains (positive, negative and general psychopathology).[15] In a condition like schizophrenia, any additional benefit more than the usual can be presumed to be significant. Though statistical significance may not have been achieved, the clinical significance is obvious. When music listening is added to standard care, there seems to be an additional benefit across all symptom domains in schizophrenia.

Our study observed that when music listening was added to standard care, lower doses of antipsychotics, benzodiazepines, and trihexyphenidyl were needed. While the difference in antipsychotic dose requirements was not statistically significant, benzodiazepine and trihexyphenidyl doses were significantly lower in this group. Similar to our study, a previous RCT has found that lower antipsychotic drug doses were required for the group with music intervention.[19] However, one quasi-randomized controlled trial found no significant difference in drug dosage requirements.[11] But, we can infer that music listening, when added to standard care, lowers antipsychotic dose requirements. Further, patients may have a better sleep profile and lesser agitation, as evidenced by the significantly lower benzodiazepine dosage requirements. Since trihexyphenidyl doses were significantly lower in this group, it may indirectly mean that there were lesser extrapyramidal side effects when music listening was added to standard care. However, this was not objectively measured in our study.

Limitations

This trial was conducted on a hospital sample and in-patients - it was not assessed whether home-based music listening would show similar benefits. Patients were aware of the group assignment - they were not blinded. The trial duration was for one month - sustainability and long term effects were not assessed. Participant's previous knowledge, interest or expertise in music, which could have influenced the outcome, was not measured. Only music listening format was used - results may have been different if music therapy was used.

CONCLUSIONS

This study was a Randomized Controlled Trial to determine the effects of adjunctive music listening in schizophrenia. It was done in the acute phase of the illness immediately after admission, thus showing the feasibility of music based interventions in the acute phase of schizophrenia. Even though statistically significant effects were not observed in the symptom domains, there is an indication for a clinical benefit that warrants the use of adjunctive music listening in patients with schizophrenia. This trial showed a statistically significant difference in the drug dosage requirements of diazepam and trihexyphenidyl. Lower risperidone doses were needed, but this difference did not reach statistical significance. However, since lower doses of drugs are required when music listening is added, the cost of care is reduced, and the occurrence of adverse effects due to medications may be diminished. The observed trend shows promising results in favour of adjunctive music listening. The significance could have emerged with a larger sample and longer follow-up. Further, where resources may be limited, passive music listening may be used as a format for music therapy with equal benefits. Music listening is a cost-effective, well tolerated intervention that definitely warrants further research and wider application in clinical practice.

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Conflict of interest:
None declared.

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