TWO GROUP PRETEST-POSTTEST RANDOMIZED FEASIBILITY TRIAL IN ESTIMATING EFFICACY OF THERAPEUTIC LISTENING PROGRAMME AND TRADITIONAL MUSIC THERAPY ON DEPRESSION AND QUALITY OF LIFE AMONG INSTITUTIONALIZED ADOLESCENTS

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ABSTRACT

PURPOSE: Depression has become the leading cause of disability worldwide. Therapeutic Listening and music therapy are the emerging nonpharmacological approaches for depression, which lacks evidence. To estimate the effects of TL on depression and quality of life (QoL) among institutionalized adolescents.

METHOD: A two group pretest-posttest randomized trial recruited 24 institutionalized adolescents with depression through the simple random sampling. Recruited institutionalized adolescents were randomized equally into, therapeutic listening programme (TLP) group and traditional music therapy (TMT) group through block randomization. Both the groups received their respective interventions for 30 minutes a day, 2 days a week for 8 weeks. Participants in TMT group received intervention using earphones with a duration of 2 sessions of 30 minutes each per day, 5 days a week for 8 weeks. The primary outcome measures were Children's Depression Inventory (CDI-2) and Youth Quality of Life Instrument – Short Form (YQOL-SF). Electroencephalogram (EEG) were also recorded in addition to CDI-2 and YQOL-SF. All the outcome measures were measured at baseline and 8 weeks post intervention.

RESULT: Statistically significant improvements (p<0.05), were observed in CDI-2, YQOL-SF and EEG parameters among the institutionalized individuals suffering from depression in TMT group when compared to TLP group.

CONCLUSION: Feasibility of TLP and TMT in treating institutionalized adolescents with depression were verified. TMT have demonstrated significant improvement in depression, QoL and brain activity among the institutionalized adolescent suffering from depression when compared to TL.

Keywords: Adolescents; depression; music therapy; quality of life; therapeutic listening programme.

I. INTRODUCTION

Depression is a common chronic recurrent debilitating diseases state, resulting in impairment in educational, occupational, and social functioning, 21–28% of youth encountering major depression by the age of 19 years.¹ World Health Organization evaluates that depression to be the first leading cause of worldwide illness by 2030.²,³ There is no single hypothesis that elucidates all attributes of the signs and symptoms of depression.⁴ The hazard components of depression in the youthful age incorporate family ancestry of depression, youth traumatic experience of parental misfortune, upsetting life occasions, educational, professional goals, and substance abuse, demographic features, and estrogen hormones in females.⁵,⁶

The evidence says that adolescent who has less fortunate wellbeing and poor associations with their friends has comorbidty of tension and depressive symptoms. Extreme nervousness manifestations are related to poor quality of life (QoL), which can increase the vulnerability for medical complications. There is also a rising consensus
that effective treatment of depression should not only focus on symptom severity but also the decreased functions and quality of life, and better health. Treatment decisions for depression are not equivalent in youths as in adults. Considered treatments include both pharmacological and non-pharmacological treatments.

Therapeutic Listening® is a type of non-pharmacological intervention based on traditional music therapy (TMT), utilizes electronically modified music using high-quality headphones. Arousal, self-control, and emotions are all improved by sensory input developed by Sheila Frick in 1990 [59].

There is a dearth of evidence supporting the use of Therapeutic Listening in people having depression. Therefore, the study aims to explore the effect of therapeutic listening programme (TLP) and TMT on the severity of depression and quality of life in institutionalized adolescents with an Alternative hypothesis TL may be effective in improving the severity of depression and Quality of Life of institutionalized adolescent with depression.

**Methodology:**

This assessor-blinded Randomized Controlled Trial was approved by the institutional ethics committee and the study was performed according to the principles laid by, declaration of Helsinki (Revised 2013), Council for International Organizations of Medical Sciences guidelines, International ethical guidelines for health-related research involving humans (2016) and National guidelines for biomedical and health research involving human participants by Indian Council of Medical Research, 2017. The ethical guidelines that followed the national ethical guidelines for biomedical and health research involving human participants by the Indian Council of Medical Research, 2017. The trial was registered under ClinicalTrials.gov, NCT 03445 on June 6, 2020. Consent for participation in the study was obtained from the participants and their parents/guardians before the start of the study. The selection criteria for the study participants were mentioned in

**Table 1.**

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutionalized Adolescent boys and girls Age 13-18 years Participants Assessed by Children depression Inventory 2 (having average/lower, high average, and elevated)</td>
<td>Any other psychiatric disorder (Schizophrenia, Bipolar Disorder, Anxiety Disorder, etc.) Hearing impairment and with an untreated active ear infection</td>
</tr>
</tbody>
</table>

The Sample size was not estimated for this feasibility trial, as it was executed to determine the practical feasibility in executing the trial. From the result of this feasibility trial, the sample size will be estimated for the large sample size study. Hence, for this pilot feasibility trial, a sample size of 12 per group were fixed as recommended. A total of 24 samples were recruited from an Orphanage Home between June 2020 to December 2020 for the study based on simple random sampling. Before the allocation into groups, baseline measures of the participant’s demographic characteristics and pre-intervention scores of the outcome measures, CDI 2, and YQOL-SF was recorded by a qualified Physiotherapist. The standard operating procedure was followed for EEG. Then they were randomly (block randomization with a 4×3 matrix) allocated into the therapeutic listening programme (TLP) group and traditional music therapy (TMT) group respectively. The blueprint of the study protocol was displayed in Figure 1. The demographics and anthropometrics of each participant were. Participants in the experimental group received therapeutic listening therapy by High-quality Sennheiser headphones which have high resistance-impedance with a minimum of 150 ohms and 23,000 Hz frequency sensitivity for the duration of 30 min per session twice a day for 5 days a week for 8 weeks. The detailed week-wise therapeutic listening protocol is listed below in Table 2. The TMT group received intervention using earphones with a duration of 2 sessions of 30 minutes each per day, 5 days a week for 8 weeks. The intervention was delivered in a quiet room. The therapist was maintaining the treatment record of each participant. Post-intervention evaluation of the outcomes was measured by using CDI 2, YQOL-SF, and EEG.
Table 2: Week-wise proposed intervention for therapeutic listening programme

<table>
<thead>
<tr>
<th>S. No</th>
<th>Total Duration</th>
<th>Mode</th>
<th>Weeks</th>
<th>Album Title</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>4 weeks</td>
<td>Engagement</td>
<td>Week 1</td>
<td>Rhythm &amp; Rhyme</td>
<td>30 min per session twice a day for 5 days a week</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Week 2</td>
<td>Peach Jamz</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Week 3</td>
<td>Nature winds</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Week 4</td>
<td>Mozart for modulation</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>2 weeks</td>
<td>Interaction</td>
<td>Week 5</td>
<td>Strawberry Jamz</td>
<td>30 min per session twice a day for 5 days a week</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Week 6</td>
<td>Vivaldi for Modulation</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>2 weeks</td>
<td>Discrimination</td>
<td>Week 7 &amp; Week 8</td>
<td>More Mozart for modulation</td>
<td>30 min per session twice a day for 5 days a week</td>
</tr>
</tbody>
</table>

Figure 1: Blueprint of the study protocol

Data analysis
The collected demographic and outcome measures were assessed for their normality using Shapiro-Wilk test. As the data does not follow normal distribution, all the descriptive were expressed in mean (95% confidence inter-
val) for continuous variables and median with interquartile ranges for discrete variables. Wilcoxon signed rank test was adopted to find out the differences within TLP Group and TMT group for pre-post intervention changes. While Mann-Whitney U test was used to compare the changes in median values of CDI-2, YQoL-SF, and EEG changes between TLP Group and TMT Group at baseline and end of 8 week intervention. The data were analysed using statistical software, statistical package for social science (SPSS), IBM SPSS version 20.0 (Armonk, NY: IBM Corp.). The p-value ≤0.05 was considered to be statistically significant.

II. RESULTS

Twenty four institutionalized adolescents suffering from depression were recruited for the study. The demographic characteristic of the institutionalized adolescents suffering from depression recruited were displayed in Table 3. There exists no significance difference between the two groups. Between the session group comparison at baseline and end of 8 weeks exercise intervention for the outcome measures CDI-2 (Figure 2) and YQoL-SF (Figure 3) were displayed. EEG Changes of the adolescent females with depression recruited in group TLP and group TMT were tabulated in Table 4.

Table 3: Demographic characteristic of the female adolescents with depression recruited in TLP group and TMT group.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>TLP (n=12)</th>
<th>TMT (n=12)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>15.0 (14.1 to 15.9)</td>
<td>14.7 (13.8 to 15.5)</td>
<td>0.630</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>48.2 (40.3 to 56.1)</td>
<td>46.8 (41.2 to 52.4)</td>
<td>0.843</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>151.0 (145.6 to 156.4)</td>
<td>151.5 (147.6 to 155.4)</td>
<td>0.932</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>20.9 (18.5 to 23.2)</td>
<td>20.4 (18.7 to 22.1)</td>
<td>0.843</td>
</tr>
</tbody>
</table>

Abbreviations: BMI – Body mass index

Figure 2: Group comparison at baseline and end of 8 weeks exercise intervention for the outcome measures CDI-2
Figure 3: Group comparison at baseline and end of 8 weeks exercise intervention for the outcome measures YQoL-SF

Table 4: EEG Changes of the adolescent females with depression recruited in group TLP and group TMT

<table>
<thead>
<tr>
<th>EEG Parameters</th>
<th>TLP (n=12)</th>
<th>p-value</th>
<th>TMT (n=12)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Post intervention</td>
<td>Baseline</td>
<td>Post intervention</td>
</tr>
<tr>
<td>F4 – Right – F (Frequency)</td>
<td>12.6 (11.3 to 13.8)</td>
<td>10.9 (9.5 to 12.2)</td>
<td>0.241</td>
<td>10.7 (9.2 to 12.2)</td>
</tr>
<tr>
<td>F4 – Right – A (micro Volt)</td>
<td>55.5 (53.5 to 57.5)</td>
<td>57.1 (53.3 to 60.8)</td>
<td>0.386</td>
<td>56.6 (52.6 to 60.2)</td>
</tr>
<tr>
<td>F3 – Left – F (Frequency)</td>
<td>13.2 (12.2 to 14.2)</td>
<td>8.5 (7.4 to 9.6)</td>
<td>0.333</td>
<td>10.8 (9.2 to 12.3)</td>
</tr>
<tr>
<td>F3 – Left – A (micro Volt)</td>
<td>56.7 (53.6 to 59.7)</td>
<td>48.2 (43.5 to 52.8)</td>
<td>0.019</td>
<td>55.3 (53.0 to 57.4)</td>
</tr>
</tbody>
</table>

III. DISCUSSION

Inferences derived from results post analysis on within group comparison states that CDI-2 and YQoL-SF both demonstrated significant improvement among the institutionalized individuals suffering from depression in TMP group when compared to TMT group. Thus the feasibility trial confirm the acceptance of alternate hypothesis and rejecting the null hypothesis, stating no significant difference between the groups.

A study done in 2019 by Apollo Kivumbi also provided significant improvement over time in the total CDI-2 score as well as for functional and emotional problems and their subscales of negative mood and/ or physical symptoms, negative self-esteem, ineffectiveness, and interpersonal problems. The pairwise analysis showed significant improvement at the postintervention time point for the total CDI-2 score and all the scales/subscales in adolescents with depression in primary care.9

QOL is defined as an individual's or a society's overall well-being, encompassing both negative and positive aspects of life. It tracks everything from physical well-being to family, schooling, jobs, income, religious views, finances, and the environment.” Keiko Shikako-Thomas et al, (2012) conducted a study on the association be-
 tween participation in leisure activities and QoL in school-aged children with Cerebral palsy. Results indicate a positive association between engagement in physical activities and both physical and psychosocial well-being.

Inferences derived from results post analysis on comparison between both TLP group and TMT group revealed a significant difference in EEG frequency of F3, but not F4 which denotes the intervention tool have not much impact on the brain level in reducing the negative emotions of right hemisphere (F4) and but has the capacity to induce positive emotions of left hemisphere (F3) in both TLP group and TMT group. Similarly, Jörg Fachner et al. (2010) found that there was improvement on Frontal alpha asymmetry at F3-F4 and FM theta after music therapy but no change on the other two Frontal alpha asymmetry measures and also asymmetry z-scores of F3-F4 increased towards more pronounced left processing.

Some of the studies have assessed the effects of group music therapy, especially using EEG in patients with schizophrenia. Myoungjin Kwon et al. (2013) found that the relative power of α waves from prefrontal, frontal, temporal, and parietal sites in the experimental group were significantly higher than those of the control group. Yang et al. (2012) also reported that EEG α waves in patients with schizophrenia and depression was significantly activated through listening to music. Fachner in his study also observed that after listening to music, α wave of patients with depression significantly increased from the areas of the frontal and temporal lobes. Alpha waves are in the frequency range of 8-12 Hz, arising through brain activity associated with being in a comfortable and relaxed or concentrated state.

Both children depression inventory and youth quality of life being a subjective based reporting outcome measure did not change statistically with the intervention tool when compared with the control group which highlights the other existing potential factors causing stress, anxiety and depression in institutionalized adolescent females other than the treatment which was not controllable by any means which could be one of the major factor for this non-significant results reported from the subjected outcomes. One of the other reasons for the non-significant results may be that adolescents were subjected to fear and insecurity due to their surrounding settings or higher authority pressure in the institution. The feasibility of conducting an experimental trial with TLP and TMT have been verified.

IV. CONCLUSION:
Feasibility of trial in treating institutionalized adolescent suffering from depression using TLP and TMT have been verified. TMT have demonstrated significant change in depression, QoL and brain activity among the institutionalized adolescent suffering from depression when compared to TLP. Further studies with large sample size are required to validate these findings.

REFERENCES
4. Jesulola E, Micalos P, Baguley JJ. Understanding the pathophysiology of depression: From monoamines to the neurogenesis hypothesis model - are we there yet? Behav Brain Res. 2018 Apr;341:79–90.

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