THERAPEUTIC LISTENING ON DEPRESSION AND PHYSICAL ACTIVITY IN SCHOOL GOING ADOLESCENTS: A RANDOMIZED CONTROLLED TRIAL PROTOCOL

[SHORT TITLE: THERAPEUTIC LISTENING ON DEPRESSION AND PHYSICAL ACTIVITY]

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Therapeutic listening on Depression and Physical activity in School going Adolescents: A randomized controlled trial protocol

ABSTRACT:

Introduction:

Depression is seen in all age groups including children and adolescents as a common mental disorder. Therapeutic listening, which is a novel tool can prove to be a low on cost, easily accessible, highly compliant app based clinical tool to help children improve their psychological well-being thus contributing to their academic performance.

Objective:

To study the changes in severity of depression, balance, physical activity and muscle strength after receiving therapeutic listening in school going adolescents.

Methods:

Thirty six school going adolescents will be recruited through the simple random sampling for the two group pretest-posttest randomized controlled trial. By block randomization, the recruited sample is equally assigned to one of the two groups namely, therapeutic listening group and dance group for 30 minutes a day, 3 days a week for 6 weeks. Participants in dance group performed, 30 minutes of dance for 3 days/week for 6 weeks. Depression, Anxiety and Stress Scale - 21 Items (DASS-21) and Beck Depression Inventory-II (BDI-II) for assessing depression, physical activity by Physical Activity Questionnaire for Adolescents (PAQ-A), balance
Results:

Descriptive statistics will be expressed in mean ± Standard deviation/ mean (95% confidence interval) with range and parametric tests/non-parametric tests, paired t-test/ Wilcoxon signed rank test and independent t-test/ Mann-Whitney U-test will be used for within and between group comparisons depend on normality.

Conclusion:

If therapeutic listening technique shown to be effective, then it would be the treatment option for treating depression and for improving physical activity, balance and strength in school going adolescents.

Keywords:
Adolescents; balance; depression; muscle strength; physical activity; therapeutic listening.

I. INTRODUCTION

Depression is seen in all age groups including children and adolescents as a common mental disorder. The Prevalence of depression and affective disorders in India ranges from 1.2 to 21% in the clinic based studies, 3%-68% in school based studies and 0.1% to 6.94% in community based studies. The prevalence of depression, anxiety and stress among school going adolescent revealed a prevalence of 65.53% (Depression), 80.85% (Anxiety), and 47.02% (Stress) options. Depression, as seen in children, is manifested as the feeling of hopelessness, sadness, boredom, low esteem and social isolation and lack of interest which are quite frequent. These symptoms can affect the interpersonal relationship and educational achievements of the child and can be persistent in adulthood. Abuse, self-harm and suicide are some risks that depression can lead to in children.

Therapeutic Listening (TL) is a type of SBT intervention which is based on developmental and neurological principles that possesses implications for improving sensorimotor functions of the brain. TL not only affects the modulation of sensory inputs, arousal and praxis, but it has also increased converged attention and academic performance. Occupational performance also has shown to increase by TL by its connections to nervous system which increases focus and attention. The auditory system serves as a path by which sound based sensory inputs are relayed to the brain and central nervous system. TL is an evidence-based therapy suitable for people with different age group. The skills like attention, sensory integration (SI), social skills, communication, balance, and perceiving and navigating space are learned while listening to specialized music on headphones.

According to research, a large proportion of school going children is suffering from Depression, Anxiety and Stress which also affects the academic performance. In current scenario the available means to improve psychological well-being of school going children are through Pharmacotherapy, Yoga, meditation, counseling and sports activities, cognitive based intervention. These available means are time consuming with its merits and demerits and also depends on the children acceptance level to various therapies for bringing positive changes in Depression. Therapeutic listening is a clinical tool which has shown to bring significant improvement in mood and behavioral problems in sensory processing Disorder population. There is lack of intervention studies and outcomes on depression in school going adolescents and Therapeutic listening, which is a novel tool on the other hand can prove to be a low on cost, easily accessible, highly compliant app based clinical tool to help children improve their psychological well-being thus contributing to their academic performance. Hence there is a need to study the effect of Therapeutic Listening on Depression and Physical Activity in School going adolescent Children. The primary objective is to study the changes in severity of depression after receiving therapeutic listening in school going adolescents. While the secondary objectives are to assess the Physical activity of school going adolescents post Therapeutic Listening, to assess the balance in school going adolescents post Therapeutic Listening and also to assess the strength of abdominal muscles in school going adolescents post Therapeutic Listening.

Study procedure

The protocol for the study was approved by the intuitional ethics committee (IEC) and following which, therapist will screen the school going adolescents from recognized school, Chitkara International School, Punjab and
recruit the study participants based on the inclusion and exclusion criteria. Thirty six school going adolescents will be recruited through the simple random sampling for the two group pretest-posttest randomized controlled trial. The list of selection criteria are as follows,

- **Selection criteria**
  - **Inclusion Criteria**
    - Both genders
    - School going adolescent aged 13 between 18 yrs
    - Participants with Depression (Assessed by Children depression Inventory 2)
  - **Exclusion Criteria**
    - Children with history of diagnosed depression by parent response
    - Children receiving antidepressant/antipsychotic medication for past 6 months
    - Children with recent history of ear infection
    - Children who refuse to participate in the study

Consent for participation in the study will be obtained from the participants and their parents/guardian prior to the start of the study. Prior to the allocation into groups, baseline measures of subject’s demographic characteristics and pre intervention scores of the outcome measures will be recorded by qualified Physiotherapist. This study will be assessor blinded randomized controlled study

**Randomization**

Total sample size 36 will be randomly allocated by Block Randomization method using sequentially numbered opaque sealed (SNOSE) envelope by Principle investigator. Randomization will be done by 6 * 6 matrix design. There will be six block in each row, totaling six rows. The participants will be allotted to group based on the generated randomized sequence. Once the block will be allotted next row block sequence will be generated. Thus equal number of participants will be assigned to both the group overtime.

**Study Intervention**

Intervention will be administered by an experienced physiotherapist who is certified and trained in therapeutic listening. The adolescents will be selected based on inclusion and exclusion criteria and randomly allotted into therapeutic listening group and dance group, of the single blinded clinical trial, using block randomization technique using SNOSE with 6 individuals (3 for control group and intervention group each). Control group will receive traditional dance for one sessions of 30 minutes a day, 3 days a week for 6 weeks. Therapeutic listening group will receive therapeutic listening program 30 minutes session per day, 3 days a week for 6 weeks. Week wise details of the program is tabulated in table 1. Participants were instructed to avoid activities that required intense focus and that would distract them from listening, such as watching TV or playing videogames during listening sessions. Participants in dance group performed, 30 minutes of dance for 3 days/week for 6 weeks. Pre and Post Outcome parameters will be assessed by independent blinder before and after 6 weeks of intervention for both the groups. If the participants develops unexpected seizures or syncope during the ongoing therapeutic listening, the study will be discontinued. The blueprint of the study is displayed in Figure 1.

**Outcome measures:**

**DASS-21:**

DASS-21, is a self-report questionnaire consists of total 21 items, with three subscale (7 items): depression, anxiety and stress. Each score range from 0 (did not apply to me at all) to 3 (applied to me very much) and total
scores were computed adding up the scores on the items per (sub) scale and then multiplying by a factor 2. Thus the total score range from 0 to 120. The cut-off scores labelled as “high” or “severe” were proposed by Lovibond and Lovibond if the Scores ≥60 (for DASS-total) and ≥21 (for the depression subscale) respectively.

Beck Depression Inventory-II

Beck Depression Inventory-II (BDI-II) is commonly used to measure depression among adolescents and adults. The BDI-II is a 21-item self-report measure to identify the depressive symptoms. Total score was arrived by adding up individual items, with reporting higher levels of depression with increasing scores.

Physical Activity Questionnaire for Adolescents (PAQ-A):

The PAQ-A is a week (7-day) physical activity recall questionnaire consists of eight-items. It was initially designed to assess the level of physical activity among the adolescents aged 14–20. Five point scale (1-5) is used to score each item, with higher score indicating high level of physical activity during past 7 days.

Star Excursion Balance Test

Dynamic postural stability is quantified clinically using the Star Excursion Balance Test (SEBT). The adolescents were asked to maintain a stable base of support on the supporting limb and to reach three specified directions, anterior (ANT), posterior-lateral (PL) and posterior-medial (PM) reach using the opposite limb. Greater the reach distance denotes, greater postural stability. The maximum reach recorded in each directions were summed up to get divided by the product of leg length and three. Thus the composite reach distance score was computed as (ANT + PM + PL)/(leg length × 3). Modified sphygmomanometer will be used to assess abdominal muscle strength of the adolescents. All the above mentioned outcome measures will be measured at baseline and at the end of 6 week intervention.

II. DATA ANALYSIS

Normality of the collected data will be analyzed using Shapiro-Wilk test as the sample size is less than 50. If the data follows normal distribution, then descriptive statistics will be expressed in mean ± Standard deviation and parametric tests, paired t-test and independent t-test will be used for within and between group comparisons. On contrary, if the data does not follow normal distribution, then descriptive statistics will be expressed in mean (95% confidence interval) with range and non-parametric tests, Wilcoxon signed rank test and Mann-Whitney U-test will be used for within and between group comparisons. For all the statistical analysis, p<0.05 will be set as significant.

III. CONCLUSION:

If shown to be effective, therapeutic listening technique would be a good first-line non-non-pharmacological treatment option for treating depression and for improving physical activity, balance and strength in school going adolescents. This feasibility study will inform a future, fully powered RCT as evaluated by success of the recruitment strategy; assessment time and acceptability; implementation and evaluation of ‘usual care’; and intervention procedures and adherence.

REFERENCES:

IV. LEGENDS:

Figure legend:

Figure 1: The blueprint of the proposed randomized controlled trial

Table legend:

Table 1: Week wise proposed intervention for the therapeutic listening program

<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>3 weeks</td>
<td>ENGAGEMENT</td>
<td>Week 1</td>
<td>Razzberry jamz</td>
<td>30 min per session once a day, 3 days a week</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Week 2</td>
<td>Nature pops</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Week 3</td>
<td>Early Mozart</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>2 weeks</td>
<td>INTERACTION</td>
<td>Week 4</td>
<td>Baroque for modulation</td>
<td>30 min per session once a day, 3 days a week</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Week 5</td>
<td>Bach for modulation</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>1 week</td>
<td>DISCRIMINATION</td>
<td>Week 6</td>
<td>Mozart strings #1</td>
<td>30 min per session once a day, 3 days a week</td>
</tr>
</tbody>
</table>
Figure 1: The blueprint of the proposed randomized controlled trial