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MusT-In Therapy (Effect of Music Therapy and Interaction with Typically Developing Peers) for improving social interaction in children with severe autism spectrum disorder - Study protocol.

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Abstract:

Background: *Autism Spectrum Disorder (ASD) affects 1 out of every 54 children in the United States, impairing their social skills and independence. Current evidence from clinical trials and meta-analyses suggests that, individually, both music therapy and interaction with typically developing peers (TD) can improve social skills in children with ASD. However, there are no clearly defined parameters the combined efficacy of these interventions and its long term effects. Therefore, conducting new studies in this area is of utmost importance not only for the scientific community, but also to children with ASD and their caregivers. Objective: To evaluate the effect of a new add-on therapy on improving social interaction skills in children with severe ASD –the MusT-In Therapy– which combines music therapy and interaction with TD peers.*

Methods: *This is a phase II single-center, two-arm, parallel-group, randomized 1:1, assesor-blinded trial. 116 children with severe ASD (3-6 years old) will be assigned to either the standard of care or 30 weekly sessions of the MusT-In therapy plus standard of care. Improvement in social interaction will be assessed after 30 therapy sessions with the Vineland Scale 3rd edition as the primary outcome. Follow-up assessment of the outcome will be at 1 and 3 months after the intervention has finished.*

Discussion: *Given the lack of robust evidence-based therapies for ASD, the development of new treatments is paramount. Children with severe ASD have been underrepresented in previous trials and parental burden increases with the severity of the spectrum. If our intervention proves to be effective it could be the basis of a new treatment option.*

Keywords: *Autism spectrum disorder, music therapy, interpersonal skills, socialization, peer group, children.*

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INTRODUCTION

Children with autism spectrum disorder (ASD) can display persistent impairment in social interaction, verbal and non-verbal communication, and restricted repetitive behaviors, interests, or activities (DSM V; 2013). Its prevalence has tripled over the last 20 years, currently affecting 1 in 54 children in the United States (Maenner et al., 2020).

Severe ASD has a great impact on the healthcare system and increases the burden on the caregivers

Abbreviations:
ASD: Autism Spectrum Disorder
TD: Typically developing peers
MTDA: Music Therapy Diagnostic Assessment scale
ADOS-2: Autism Diagnostic Observation Schedule™, Second Edition.
ADI-R: Autism Diagnostic Interview-Revised.

(Marsack-Topolewski & Maragakis, 2020). The ability of children with ASD to live independently is affected by their skills to engage in social interactions, maintain relationships, and respond to environmental outputs (Drmic et al., 2018). Previous research has established that early interventions are associated with better outcomes by improving neuro-psychomotor skills (Hyman et al., 2020; Steinbrenner et al., 2020). Moreover, children with ASD respond better to structured and specialized programs with multi-disciplinary approaches (Hyman et al., 2020; "NIMH » Autism Spectrum Disorder", 2020).

Previous trials testing interventions with Music Therapy (MT) (Geretsseger et al., 2016) as well as interaction-based therapy with typically developing (TD) peers (Kasari et al., 2012) suggest both techniques independently improved social skills in children with ASD. Furthermore, interaction-based therapy with TD peers focuses on establishing relationships and encouraging social reciprocity (Kasari et al., 2012). There is a lack of strong evidence regarding the long-term effectiveness of these therapies. Moreover, children with severe ASD are rarely enrolled in research trials. Lastly, to our knowledge, there are no trials assessing the combination of therapeutic add-on interventions, and thus, high-quality methodological studies with large samples and longer follow-up periods are still needed.

We hypothesize that combining music therapy and interaction with TD peers could increase the overall treatment effect. Therefore, the objective of our protocol is to assess the efficacy of a new add-on therapeutic approach (MusT-In Therapy) for improving social interaction skills of children with severe ASD aged 3 up to 6 years old.

METHODS

Trial Design

This is a phase II, randomized, assessor-blinded, single-center, prospective, superiority trial with two parallel arms. Participants in the intervention arm will receive MusT-In therapy in addition to the standard of care, while the control group will receive standard of care only in a 1:1 allocation ratio. The primary objective is to assess the efficacy of MusT-In as an add-on therapeutic approach on social skills in children with severe non-syndromic ASD. The intervention is 30 weeks long with a 3-month follow-up period. **Figure 1** shows the timeline and the main stages of the trial.

Study Setting

The trial will be conducted in the U.S., which has a high prevalence of ASD, in order to preserve the validity of

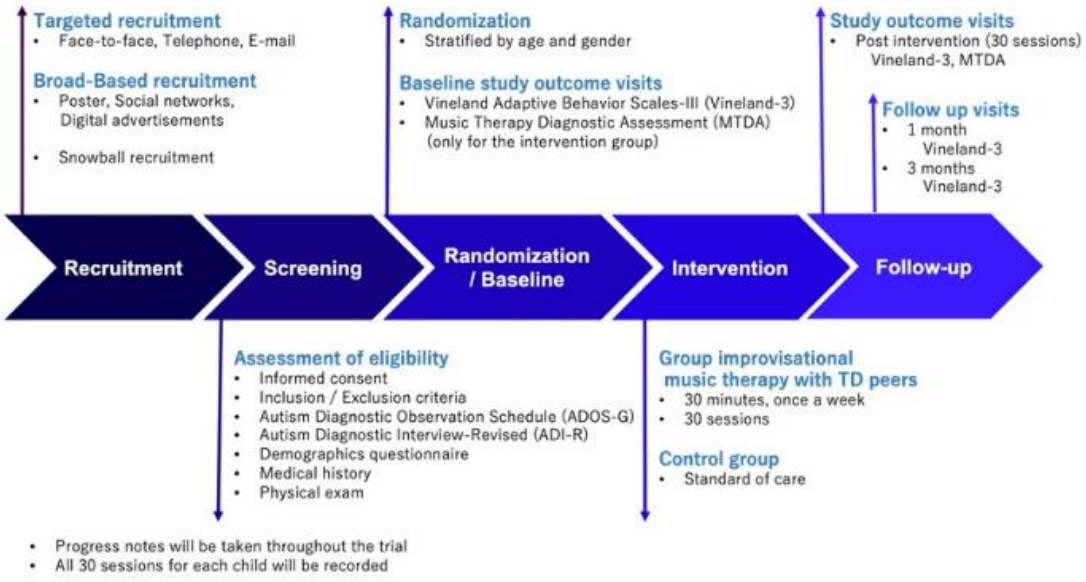

Figure 1. Timeline

the outcome assessment scale, and to address better recruitment rates. Hence, we recommend the Autism Spectrum Center at Boston Children Hospital.

Randomization

A computer-based random number generator (SealedEnvelope) will assist the randomization process and allocation concealment. Participants will be stratified by age and gender, using varied permuted block sizes of 2, 4, and 6.

The Trial Coordination Center will generate the randomization code and send it to the assistant music therapist (in charge of the patient) who then will allocate the patient in the respective group arm. Outcome assessors will not be informed about the allocation of patients.

Blinding

Due to the nature of the intervention, only the outcome assessors and data analysts will be blinded. All study personnel and parents will be advised not to disclose the subject's allocation status to assessors or data analysts. Three trained psychologists will assess participants and their caregivers at specified time points to avoid interaction with other trial staff. Each participant and his caregiver will be assessed by the same psychologist throughout the trial. Before the trial begins, all qualified assessors will be trained to standardize their assessments. If unintentional unblinding occurs, it will be registered and specified for which participants and arm, and post-hoc analysis will be performed adjusting for this status.

Eligibility Criteria

Inclusion criteria

To be eligible, children must fit all of the following criteria:

1. Age from 3 to 6 years, diagnosed with severe ASD (for more details, see section Screening and Consent).
2. Availability of a parent or other reliable caregiver. The same parent or caregiver must agree to give feedback and provide information about the participant's behavior and symptoms.
3. Caregivers shall have basic skills in spoken and written English.

Inclusion Criteria for Typically Developing (TD) Participants:

1. TD children aged from 3 through 6 years old.

Exclusion Criteria for all participants:

1. Hearing impairment.
2. Previously diagnosed syndromic ASD.
3. Patients with any medical condition that might interfere with the conduct of the study, confound interpretation of results or endanger their own or others' well-being.
4. Patients with unstable epileptic disorders in the previous 6 months.
5. Severe motor disability.
6. Previous experience in receiving music and/or other kinds of group therapy over the last 12 months. Other forms of therapies will not result in exclusion: however, concomitant treatments will be documented for post-hoc analysis. Patients will be requested to withhold music therapy outside the study context.

Recruitment Strategy

Participants will be enrolled from tertiary care and autism centers. Recruitment strategies will be targeted and broad-based such as face-to-face contact, phone calls, and email notifications to multi-disciplinary teams of ASD specialists, organizations, communities, and patient support groups and associations, posters on display in hospitals, clinics, and support groups. Additional strategies will be implemented via ASD social networks and digital advertisements. Snowball recruitment will also be implemented. TD peers will be volunteers recruited from music schools and will be rewarded with free music classes for their collaboration. Therapy sessions will be established once every four participants have been recruited, respecting the allocation of 2 children with ASD and 2 TD peers.

Screening and Consent

After the recruitment phase, children who meet the diagnostic criteria for ASD according to the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition, Text Revision (DSM-V) will have the diagnosis confirmed by a member of the study staff with expertise in the field using the Autism Diagnostic Observation Schedule (ADOS-2) and the Autism Diagnostic Interview-Revised (ADI-R). Severity will be defined by the ADOS-2 Comparison Score (CS) of 8 to 10. The CS converts ADOS-2 raw total scores to reflect level of autism symptoms in comparison to others of the same age and language level. Then, parents or legal guardians of children with severe ASD as well as of TD peers must provide informed consent for their children to be involved in the study.

Adherence

Two days prior to each session reminders will be sent to caregivers as text messages or email, via an automated application. A phone line will be available to parents during working hours for doubts, concerns, or notifications. Transportation costs will be reimbursed, snacks will be provided at the end of each appointment. Every 3 months, all children will receive reward badges. At the end of the trial, TD participants will be awarded certification for volunteering. After trial completion, an appreciation day will be held with all children and caregivers. Investigators will encourage study completion by emphasizing the importance of subsequent sessions.

Interventions

Control group:

The control arm will only receive the standard of care which comprises all the therapies applied by the care center, except music or group therapy with TD peers. Since therapies are tailored individually, they may vary among children and throughout the trial. However, based on CDC recommendations (Centers for Disease Control and Prevention, 2019), treatments are usually classified into these categories: behavior and communication approaches; dietary approaches; medication; complementary and alternative medicine.

Intervention group:

The participants randomized to the intervention arm will receive the standard of care and 30 weekly sessions of 45 minutes each will be held by one of three board-certified licensed music therapists experienced in treating children with ASD. Each session will be in groups of four children (two children with ASD and two TD peers). A support staff of two co-therapists will help during the sessions. Caregivers will not participate in the session as this is not a family-based intervention, and their presence could influence the treatment effect. However, caregivers should be within reach during sessions.

All sessions will be video recorded to assess the quality and compliance of the therapists throughout the intervention for all groups. TD volunteers and their caregivers will be instructed on how to interact and respond to children with severe ASD through talk-teach sessions with the therapists during a two-week pre-trial familiarization.

Therapy sessions will include a playground environment with different musical toys and instruments, a stage, music-themed costumes, a dance floor, and sound equipment. Different musical improvisation techniques will be used according to the interests of children with ASD. Those techniques may include rhythmic grounding, shaping the music played to encourage participation, extemporizing on musical motifs and themes, frameworking musical elements or styles, imitation, mirroring, elaboration, regulation, variation, matching, sustaining, or complementing features of the child's behavior, among others (Geretsegger et al., 2016).

Modification/Discontinuation

In case that unexpected disruptive behaviors happen during the therapy sessions, the healthcare staff will be guided to remove the participant from the session and contact the caregivers. Before the following session, the affected participant will be evaluated by a psychologist to assess the possibility of reintroduction, which will be based on a joint decision between caregivers and the specialist. If the reintroduction fails more than 2 consecutive times, investigators will discuss treatment interruption with the Scientific Advisory Board. If so, participants will be removed from the trial and missing data protocol will be applied. If this happens before the 15th session, the group will be rearranged to include a new participant. Otherwise, the group will remain with at least 1 child with ASD and 1 TD peer. Discontinuation can be requested by the participant's tutor. Moreover, the therapist can shorten the session duration if necessary.

Outcomes

The primary outcome is improvement in social interaction skills through music therapy, promoted by interpersonal engagement between children with severe ASD and TD children. It will be measured by the Vineland Adaptive Behavior Scales, Third Edition (Vineland-3; 2016; Pepperdine et al., 2018) assessed at baseline and after completion of 30 sessions. Vineland-3 is an excellent progress monitoring tool as it is sensitive to small changes in adaptive functioning (Pepperdine & McCrimmon, 2018). Of the three Vineland-3 domains (communication, socialization and daily living), the socialization domain was chosen to assess the primary outcome. It comprises three subdomains of which only two will be used: Interpersonal Relationships and Play and Leisure Time. This decision was based on the results by Thompson (2012) with the Vineland SEEC. The first sub-domain consists of 43 items with a maximum score of 86 points, while the second addresses 31 items with a maximum

score of 62 points. Each item is scored from 0 to 2 according to how the child performs during social interaction. The total raw score for each subdomain will be calculated. We will compare the score mean difference (between completion of 30 sessions and baseline) for each subdomain between groups. A positive increase from baseline will indicate improvement in the level of functioning of social adaptive behavior.

For the secondary outcomes, the receptive and expressive sub-domains of Vineland-3 communication domain will be used. The former consists of 39 items with a maximum score of 78 points, and the latter of 49 items and a maximum score of 98 points. Scoring will be in accordance with the Vineland-3 protocol, where the effect size is determined by comparing the post- and pre-intervention scores from the Vineland-3 interviewer form.

Children's engagement during the sessions will be assessed using The Music Therapy Diagnostic Assessment (MTDA). It contains 12 items that can be graded as 0, 1 or 2 points each (lower score sums show more engagement). An independent evaluator, different from the primary outcome assessor, will review two video recordings of the sessions, one during the 1st month and the other during the 6th month of the trial according to the MTDA protocol. All 30 sessions for each child will be recorded.

All assessors will be trained before the trial begins to standardize the evaluations.

After the 30 weeks intervention period, treatment effect will be assessed with Vineland-3 scale twice, at 1- and 3-month follow-ups.

Data Management and Monitoring

Data will be collected using REDCapTM electronic data capture (EDC) research databases by data entry personnel, without direct involvement in the study. Data integrity will be maintained by using an individualized username and password. Data accuracy will be ensured through double data entry. All the data will be safeguarded in the REDCap system.

Periodic reports will be submitted to the Institutional Review Board who will monitor unexpected occurrences, such as disruptive or aggressive behavior between children, dropouts, and adherence.

Considering the nature of the intervention, the relatively short period of time of the trial, and the moderate sample size, the authors did not identify reasons to raise a data monitoring committee.

Sample Size Calculation

To assess whether there are changes in social adaptive behavior, we will use raw scores instead of v-scores since the latter may not reflect the changes achieved by the patients in the period chosen for our study.

We designed our study to have 80% power to detect a Cohen´s d of 0.70 which corresponds to an improvement of 5 points, similar to Geretsegger et al. (2014).

The sample size was estimated using a standard deviation of 7.106 based on the study of Thompson (2012).

Alpha level was adjusted through the Bonferroni method given that the primary endpoint will be measured using two subdomains of the Social Domain of Vineland-3 and we will perform two tests (two-tailed) to compare each subdomain between groups. Thus, the alpha level for each test will be 0.025.

Considering the possibility that the data may not follow a normal distribution, we computed the minimally required sample size for a non-parametric test as Mann-Whitney, increasing the required sample size calculated by 15%. Finally, considering the possibility of a 20% dropout rate, we obtained the required sample size of 116 patients in total. This was based on previous trials and modified given the nature of our intervention which is longer in duration, center-based instead of home-based, and group intervention instead of individual.

Statistical Analysis for primary and secondary outcomes

Demographic variables, primary, and secondary outcomes will be summarized by descriptive statistics: for continuous variables, mean and standard deviation will be used if normally distributed, or median and IQR if not normally distributed. For categorical variables, absolute and relative frequencies will be used.

We will perform two statistical tests, one for each subdomain of the Vineland-3 scale, to compare the mean change score between both groups from baseline to the end of the intervention after the completion of 30 sessions. The vineland-3 scale will be assumed as a continuous variable. Data distribution will be assessed through visual representation, a Shapiro Wilk normality test, and checking skewness and kurtosis. If normal distribution of data is a reasonable assumption, we will use the Student's T-Test. Otherwise, we will use the Mann-Whitney U test. For both tests, we will use two-sided p-values with a global alpha level of 0.05.

As for the secondary outcomes, to assess the time trend we will fit linear regression mixed models with the scores of each Vineland subdomain as dependent variables (one for each model) and for independent variables, we will evaluate: the intervention received, age, gender, number of sessions attended, category of standard of care received during the trial (Centers for Disease Control and Prevention, 2019), time, and interaction between trial arm and time. For those children in the intervention group, we will measure the child's engagement throughout the music therapy sessions using the MTDA tool (mean change score from baseline to 30 sessions).

All statistical analyses will be performed using STATA/IC software version 17.

Considering the therapeutic area and characteristics of the MusT-In trial, our missing data is expected to be treated as missing at random (MAR) and a multiple imputation method will be used to account for missing data. Sensitivity analysis for data robustness will be performed.

DISCUSSION

The development of innovative and effective treatments for severe ASD is paramount. We believe that the interaction with TD peers through music therapy in an enjoyable environment could help children with ASD improve their social skills and everyday interactions.
Previous trials evaluating these therapies separately tested the intervention during short periods and the persistence of the treatment effect has been variable across studies. For this study, we planned a 30-session intervention with 3 months of follow-up to assess the efficacy of longer therapy and its durability. Furthermore, children with severe ASD have been underrepresented. These children and their families are in need of more effective therapies. Adherence and follow-up are inherently difficult for children with severe ASD and pose many challenges; therefore, we plan to conduct our intervention in a weekly manner to decrease the family burden.

We deemed blinding of the participants as not feasible given the nature of our intervention. As the primary outcome assesses parents' perspective of their child's adaptive behavior, we acknowledge the lack of blinding as a limitation. To decrease ascertainment bias we intend to blind the outcome assessors.

Our study will yield relevant information on the effect of music therapy with TD peer interaction on children with ASD. There is a strong need for research and development of alternative treatments for ASD. We will provide a basis for further research regarding sample size and magnitude of effect using the latest version of the Vineland-3 scale. If our intervention proves to be effective, it could be the basis for a new treatment paradigm.

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Conflict of Interest

None.

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