

Improvisational music therapy for children with autism spectrum disorder assessed using brain imaging

Submission date 17/02/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 04/04/2019	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/08/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Autism spectrum disorder (ASD) is a complex neuro-developmental disorder that begins in early childhood and persists throughout adulthood. ASD affects three crucial areas of development: social communication, social interaction and creative or imaginative play. Early intensive intervention is recommended for young children who are affected by it. Previous studies indicated intact musical responsiveness in children with ASD and the interactive potential of music that can be used to improve skills in social-affective interaction in children with ASD. Up until now, most of previous early intervention studies in music therapy focused on examining behavioral changes. This study employs one of the most pragmatic trial design investigating effects of improvisational music therapy for a year exploring the children's behavioral and neurological, developmental changes, and the relationship of those changes with the mother's maternal behavior and that of the mental health state.

Who can participate?

Children with autism spectrum disorder aged between 24 – 72 months old without complication of other serious disorders such as visual and hearing impairments, attention deficit & hyper activity, schizophrenia, etc.

What does the study involve?

Improvisational music therapy plus standard care will be compared with standard care without improvisational music therapy condition. Standard care condition may involve a wide range of other treatments such as speech language therapy, early special education, behavioral cognitive therapy, kindergarten, special physical education, sensory integration therapy, etc. Some discrepancies of each child regarding standard care condition such as types of intervention, frequency and duration are expected, as we do not determine what interventions each child should receive, as this is a real world trial (pragmatic trial).

What are the possible benefits and risks of participating?

As we are recruiting children only for experimental group (improvisational music therapy) and using already existing data for control group. Research funding covers for almost all costs of

tests and once a week music therapy for a year. Majority of tests are non-invasive and improvisational music therapy employs child-centered approach. In order to conduct the child neuroimaging, sedative will be administered, and the child might experience drowsiness after the MRI procedure due to the sedative medication (pocral). During the MRI, the child might experience some anxiety and fear. In such case, the MRI procedure will be stopped. There has been no reported case of side effect in improvisational music therapy for children with ASD.

Where is the study run from?

There are six centres: Jeonju University and Seoul National University Hospital are two leading centres in this trial, and four music therapy centres (Hanvit Music Therapy Center; SookMyung Child Development Center; Susaek Child Development Center; Jiuem child development center).

When is the study starting and how long is it expected to run for?

01/08/2018 to 31/08/2020

Who is funding the study?

National Research Foundation of Korea (Korean government)

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

NRF- 2017S1A5A2A03068100

Study information

Scientific Title

Music therapy outcome study for children with Autism Spectrum Disorder through integration of child neuroimaging and neuropsychology: An exploratory study

Acronym

MANE

Study objectives

Finely tuned, sensitive, responsive and attentive use of music towards the developmental needs and state of the child with ASD will open and maintain the communicative channel with the child. The child's ability for social communication will increase positively over time and restricted and repetitive behaviours will decrease over time. Skills in social communication and self-regulation may be better in improvisational music therapy than in the standard care condition, and these behavioural changes may be reflected in overall neurological changes examined through child neuroimaging and neuropsychology.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 26/07/2018, Seoul National University College of Medicine Institutional review board (Seoul National University Hospital, Jongro-gu, Yengun-dong 128, Seoul, 03080; 82-2-2072-0694; snuhirb@gmail.com), ref: 1805-045-945

Study design

Interventional design using propensity score matching method (non-randomized), single-blinded (assessor blinded) multicenter study.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Autism Spectrum Disorder

Interventions

Music Therapy

Intervention Type

Behavioural

Primary outcome(s)

Severity of autism measured using the Autism Diagnostic Observation Schedule (ADOS) and Childhood Autism Rating Scale-2 (CARS 2) at baseline, 6 months, post-intervention (12 months)

Key secondary outcome(s)

Collected at baseline, in-between (6 month later/ approx. 24th session), and post (12 month later, 48th session):

Child questionnaires:

1. Social Responsiveness Scale (SRS)
2. Aberrant Behavior Checklist (ABC)
3. The Social Communication Questionnaire (SCQ)
4. Social Maturity Scale (SMS)
5. Child Behavior Checklist 1.5-5 (CBCL 1.5-5)

Parent's questionnaires:

6. Beck Depression Inventory (BDI)
7. State-Trait Anxiety Inventory (STAI-T/S)
8. Maternal Behavior Research Instrument (MBRI)
9. Korean Parenting Stress Index (PSI)
10. Mental Health Continuum-Short Form (MHC-SF)
11. Carer-QoL-7D / Child QoL (VAS)
12. Concomitant Treatment form

Pre and Post tests (baseline and 12 months later):

13. Neuroimaging: aMRI/DTI/rsfMRI
14. Psychoeducational Profile-Revised (PEP-R)
15. Baseline test only: Blood and Urine for detecting DNA and harmful environmental exposure
16. Post-trial in-depth interview with the mothers and the therapist (thematic analysis; qualitative study)
17. Behavioral analysis through video recording of music therapy session for establishing treatment fidelity
18. Parents/ therapists interviews after the completion of the trial

Completion date

31/10/2020

Eligibility

Key inclusion criteria

1. Aged between 24 - 72 months
2. Autism Spectrum Disorder confirmed by DSM-V and ADOS

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

24 months

Upper age limit

72 months

Sex

All

Key exclusion criteria

1. Hearing/visual impairment, congenital genetic disease (cerebral palsy)
2. Seizure and other neurological condition
3. Other psychiatric disorder such as ADHD, schizophrenia, depression, bi-polar
4. Previous and on-going experiences of music therapy
5. Medication such as risperidone, aripirazole, SSRI, etc.

Date of first enrolment

15/09/2018

Date of final enrolment

30/08/2019

Locations**Countries of recruitment**

Korea, South

Study participating centre

Seoul National University Hospital

Jongro-gu

Yengun-dong 128

Seoul

Korea, South

03080

Study participating centre

Sukmyung child development center

Kyungi-do
Jeonjeonyup
Hamilyedang 1 ro 30-9
Namyangju-si
Korea, South
12066

Study participating centre

Hanvit Music Therapy Center

Kwangjin-g
Kwangjang-dong 114
Kresco 610
Seoul
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04969

Study participating centre

Jiuem psycho-education center

Kawngjin-gu
Jayangro 130
Seoul
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05343

Study participating centre

Susaek Child-Adolescent Counseling Center

Eunpyung-gu
Susaek-dong 366-1
Seoul
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Study participating centre

Creative Arts Therapy Department, Jeonju University

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Sponsor information

Organisation

Seoul National University Hospital, IRB

ROR

<https://ror.org/01z4nnt86>

Funder(s)

Funder type

Research organisation

Funder Name

National Research Foundation of Korea

Alternative Name(s)

, National Research Foundation (South Korea), NRF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Korea, South

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date