ISRCTN26821793 https://doi.org/10.1186/ISRCTN26821793

Evaluating the brain basis of a music intervention in autism

Submission date	Recruitment status
07/07/2016	No longer recruiting
Registration date	**Overall study status**
18/07/2016	Completed
Last Edited	**Condition category**
29/10/2018	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Autism Spectrum Disorder (ASD) is the name for a group of disorders that affect the way that a person communicates and relates to others. It is a spectrum condition the level of disability is spread across a wide range, from almost unnoticeable to completely debilitating. In general however, the difficulties sufferers experience tend to fall into social communication (speech and body language), social interaction (recognising and expressing emotions) and social imagination (being able to understand and predict other people's behaviour). ASD is common, affecting around 1 in every 68 children in North America. Current treatment strategies for autism often rely on addressing behavior and target mostly very young infants and toddlers. There is an urgent need to develop effective, easy to administer interventions for school age children with autism. Music therapy offers such an approach. Studies have shown that musical activities activate large areas of the brain and brain scan (neuroimaging) studies in children with ASD have shown intact or even enhanced processing of music. Given the motivational value of music and the effect it can have on the brain and behavior, it is important to conduct further studies for establishing the effectiveness of music in ASD. The aim of this study is to investigate whether musical based therapy can better improve social and communication skills in children with ASD than non-musical based therapy.

Who can participate?
Children aged 6-12 years with ASD.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in the musical programme for 12 weeks. This involves using various musical instruments and songs to engage the children and try to improve social and communication skills. Those in the second group take part in a non-musical programme for 12 weeks which involves using toys, books and other non-musical accessories to try to improve social and communication skills. All sessions (for both groups) take place every week and last for around 45 minutes. They are one-to-one and are led by an experienced music therapist. At the start of the study and then again after 12 weeks, participants in both groups complete a number of questionnaires to test their social and communication skills. In addition, at the same times, participants have an MRI scan of their brains to find out if the therapy has caused new brain connections to form.

What are the possible benefits and risks of participating?
There are no notable benefits or risks involved with participating in this study.

Where is the study run from?
1. University of Montreal (Canada)
2. McGill University (Canada)
3. Westmount Music Therapy (Canada)
4. Montreal Neurological Institute (Canada)

When is the study starting and how long is it expected to run for?
March 2013 to May 2014

Who is funding the study?
Quebec Bioimaging Network (Canada)

Who is the main contact?
Dr Megha Sharda
megha.sharda@umontreal.ca

Contact information

Type(s)
Scientific

Contact name
Dr Megha Sharda

ORCID ID
http://orcid.org/0000-0003-1288-9225

Contact details
University of Montreal
International Laboratory for Brain, Music and Sound Research (BRAMS)
1430 Mont-Royal Boulevard
Montreal
Canada
H2V 2J2
+1 514 343 6111
megha.sharda@umontreal.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomized control trial of a music-based intervention for children with autism - brain and behavioural mechanisms of efficacy

Study objectives
Children with autism spectrum disorder (ASD) receiving the music intervention will have larger gains in terms of social and communication skills compared to those receiving a non-music intervention. These gains will be reflected in differences in brain connectivity in fronto-temporal regions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
McGill University Health Centre (MUHC) and the Montreal Neurological Institute and Hospital (MNI/H), 19/02/2016, ref: NEU-10-030

Study design
Single-centre single-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Autism Spectrum Disorder

Interventions
Participants are randomized to one of two groups. The first 20 participants will be randomized using simple coin toss. Subsequent randomization will be conducted using the covariate adaptive randomization method to ensure balance of demographic factors such as age, sex and language ability between the two groups. MinimPy software will be used to conduct this randomization by one member of the team not involved in experimental testing. All other experimenters will be blind at all times to the assignment of participants.

Intervention group: Participants take part in the music-based intervention, which involves attending individual 45 minute sessions once a week for 12 weeks. The sessions involve use of song, rhythmic cues and instruments to target socio-communicative, emotional and sensorimotor outcomes.

Control group: Participants take part in a non-music control intervention which relies on existing behavioural interventions with no music. It is conducted in the same setting and by the same therapist as the musical intervention and will target similar outcomes, but without the use of any musical activities. Sessions involve play activities targeting social interaction, communication, emotional regulation and sensorimotor integration but without the use of any musical instruments. Toys, books, and other non-musical accessories will be used to engage the child.

All sessions (music and control sessions) will be video recorded for post-hoc analysis. Participants in both groups are followed up at the end of the intervention period (12 weeks) at which time they undergo an MRI scan.

Intervention Type
Behavioural

Primary outcome measure
1. Socio-communicative responsiveness (in the domains of Social Awareness, Social Cognition, Social Communication, Social Motivation, Restricted Interests and Repetitive Behavior) is measured using the Social Responsiveness Scale-2 at baseline and 12 weeks
2. Pragmatic language and communication skills are measured using the Children's Communication Checklist-2 at baseline and 12 weeks
3. Receptive vocabulary is measured using the Peabody Picture Vocabulary Test at baseline and 12 weeks
4. Functional brain connectivity was measured using resting-state functional MRI at baseline and at 12 weeks

Secondary outcome measures
1. Family quality of life is measured using the Beach Family Quality of Life Scale at baseline and at 12 weeks
2. Gross and fine-motor skills are measured using the Motor skills subdomain of the Vineland Adaptive Behaviour Scales (II) at baseline and at 12 weeks
3. Inhibitory control is measured by the Flanker and Go-No Go task at baseline and at 12 weeks
4. Musical abilities are measured by the Montreal Battery of Evaluation of Musical Abilities at baseline and at 12 weeks

Overall study start date
01/02/2016

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Children aged 6-12 years
2. Diagnosis of Autism Spectrum Disorder

3. No co-morbid neurological disorder
4. No hearing impairment
5. No experience of music therapy in the 6 months preceding the start of the study

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
50 participants, with n=25 in each arm.

Key exclusion criteria
1. Co-morbid neurological condition
2. Metallic implant in body
3. Hearing impairment
4. Experience of music therapy in the 6 months preceding the start of the study

Date of first enrolment
01/04/2016

Date of final enrolment
30/12/2016

Locations

Countries of recruitment
Canada

Study participating centre
University of Montreal
International Laboratory of Brain Music and Sound (BRAMS)
1430 Mont-Royal Boulevard
Montreal
Canada
H2V 4P3

Study participating centre
McGill University
School of Communication Sciences and Disorders
845 Rue Sherbrooke Ouest
Montreal
Canada
H3A 1G1

Study participating centre
Westmount Music Therapy
4695 Maisonneuve Boulevard West
Westmount
Canada
H3Z 1L9

Study participating centre
Montreal Neurological Institute
3801 Rue University
Montreal
Canada
H3A 2B4

Sponsor information

Organisation
University of Montreal

Sponsor details
International Laboratory for Brain, Music and Sound Research (BRAMS)
1430 Mont-Royal Boulevard
Montreal
Canada
H2V 2J2
+1 514 343 6111
info@brams.umontreal.ca

Sponsor type
University/education

Website
www.brams.umontreal.ca

ROR

https://ror.org/0161xgx34

Funder(s)

Funder type
Industry

Funder Name
Quebec Bioimaging Network

Results and Publications

Publication and dissemination plan
1. Publication of research findings in peer-reviewed open access journals
2. Presentation of findings at international and local scientific conferences
3. Permitted versions of articles will be made readily available on lab websites and through university repositories
4. Through local autism community organizations, parent workshops will be held to increase awareness about music-related services and the efficacy of these services for children with difficulties

Intention to publish date
01/07/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/10/2018		Yes	No