

# Evaluating the brain basis of a music intervention in autism

|                                        |                                                               |                                                      |
|----------------------------------------|---------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>07/07/2016   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
|                                        |                                                               | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>18/07/2016 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                               | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>29/10/2018       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> 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  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

## 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

### **Primary study design**

Interventional

### **Study design**

Single-centre single-blind randomized controlled trial

### **Study type(s)**

Treatment

### **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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

6 Years

**Upper age limit**

12 Years

**Sex**

All

**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

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Canada

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**Study participating centre****McGill University**

School of Communication Sciences and Disorders

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**Study participating centre****Westmount Music Therapy**

4695 Maisonneuve Boulevard West

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**Study participating centre****Montreal Neurological Institute**

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## Sponsor information

### Organisation

University of Montreal

### ROR

<https://ror.org/0161xgx34>

## Funder(s)

### Funder type

Industry

### Funder Name

Quebec Bioimaging Network

## Results and Publications

### 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 23/10/2018   |            | Yes            | No              |