

# A trial of music therapy compared to music listening for children with autism spectrum disorders

<b>Submission date</b> 03/01/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 10/02/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/09/2020	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

This study addresses a fundamental, so far unanswered question: is Music Therapy more effective than just music listening? This question is very important, because its answer has so far only been assumed, and could encourage or discourage the use of music therapy. The question is addressed through a trial of music therapy compared to music listening for children with autism spectrum disorders. The number of participants and intervention length (25 sessions over 8 months) raises the standards of existing, similar studies.

### Who can participate?

Children aged 4 to 7 years with a diagnosis of ASD

### What does the study involve?

The study involves either 25 sessions of music therapy with a qualified music therapist or 25 sessions of music listening with no therapy. These 25 sessions take place over a period of 8 months and at the start and end of the study, participants will be evaluated on the basis of overall functioning and autistic symptom severity.

### What are the possible benefits and risks of participating?

There are no known risks of musicotherapy for children suffering from autism disorder. The potential benefits are improvements in social skills and speech expression and reduced anxieties and repetitive behaviors.

### Where is the study run from?

Nantes Child Psychiatric Hospital (France)

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

May 2014 to June 2015

### Who is funding the study?

Entreprendre pour Aider (France) and the Académie Française (France)

Who is the main contact?  
Professor Thomas Rabeyron  
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## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
010914

## Study information

**Scientific Title**  
A randomized controlled trial of 25 sessions of music therapy in autism spectrum disorders:  
MUSICAUTISM

**Acronym**  
MUSICAUTISM

**Study objectives**  
Music Therapy will be more effective than Music Listening in general clinical evaluations.

Music Therapy will be more effective than Music Listening in general clinical evaluations for symptoms related to interactions in ASD-specific dimensions

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 12/05/2014, the ethics committee of the Nantes University Hospital Centre (5 allée de l'île gloriante 44000 Nantes Immeuble Jean Monnet, RH, 30 boulevard Jean Monnet 44093 Nantes Cedex 1; bp-uupea@chu-nantes.fr; +33 0253482653), ref: 015321653

### **Study design**

An interventional, longitudinal, single-centre, single-blinded, randomized controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

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

Treatment

### **Participant information sheet**

No participant information sheet available

### **Health condition(s) or problem(s) studied**

Autism spectrum disorders

### **Interventions**

Children were randomly assigned to one of the two groups: music therapy (MT) or music listening (ML), using a generated randomization list for each group.

At enrolment baseline evaluations to assess global functioning took place.

Half of the participants were assigned to the MT group where they received 25 sessions of MT with a qualified music therapist. The other half were assigned to the ML group which involved 25 sessions of ML with no therapeutic intervention. The 25 sessions for each group took place over a period of 8 months.

A second evaluation was performed for both groups after 8 months.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Improvement in patient global functioning measured by the Clinical Global Impressions Scale (CGI) at baseline and 8 months

### **Secondary outcome measures**

Autistic symptom severity measured by the Childhood Autism Rating Scale (CARS) and the Autism Behaviour Checklist (ABC) at baseline and 8 months

### **Overall study start date**

01/05/2014

### **Completion date**

06/06/2015

## **Eligibility**

### **Key inclusion criteria**

1. Childhood Autism Rating Scale (CARS)-validated diagnosis of ASD
2. Aged 4 to 7 years

### **Participant type(s)**

Patient

### **Age group**

Child

### **Lower age limit**

4 Years

### **Upper age limit**

7 Years

### **Sex**

Both

### **Target number of participants**

37

### **Total final enrolment**

36

### **Key exclusion criteria**

1. Auditory impairment
2. Known somatic and neurological diseases (with the exception of stabilized epilepsy)
3. Psychotropic medication that was modified less than 6 months prior to the study
4. Behavioral disturbance incompatible with an MT or ML session

### **Date of first enrolment**

01/07/2014

**Date of final enrolment**

01/09/2014

## **Locations**

**Countries of recruitment**

France

**Study participating centre****Nantes Child Psychiatric Hospital**

Immeuble Jean Monnet

RH

30 boulevard Jean Monnet

Nantes

France

44093 Nantes Cedex 1

## **Sponsor information**

**Organisation**

Unité universitaire de psychiatrie de l'enfant et de l'adolescent

**Sponsor details**

Immeuble Jean Monnet

RH

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olivier.bonnot@gmail.com

**Sponsor type**

Hospital/treatment centre

**Website**

<https://www.chu-nantes.fr/unite-universitaire-de-psychiatrie-de-l-enfant-et-de-l-adolescent-37370.kjsp>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Entreprendre pour Aider

**Funder Name**

Academie Francaise

## Results and Publications

**Publication and dissemination plan**

The Journal of Child Psychology and Psychiatry

**Intention to publish date**

15/01/2020

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analyzed during the current study are/will be available upon request from Juan-Pablo Robledo del Canto. Datasets consist of Excel files containing the different measurements at t0 and t1. Raw data for all measurements and analysis will be sent by mail. Because consent was obtained from participants, anonymized data will be shared at the researcher's discretion.

**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	01/11/2020	16/09/2020	Yes	No