

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

Submission date 03/01/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 10/02/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 16/09/2020	Condition category 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
Thomas.rabeyron@univ-lorraine.fr

Contact information

Type(s)
Scientific

Contact name
Prof Thomas Rabeyron

ORCID ID
<http://orcid.org/0000-0003-4117-4683>

Contact details
23 Boulevard Albert Premier
Nancy
France
54000
+33 372743058
Thomas.rabeyron@univ-lorraine.fr

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

30 boulevard Jean Monnet

Nantes

France

44093 Nantes Cedex 1

+33 0253482653

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?
Results article	results	01/11/2020	16/09/2020	Yes	No