# Trial of improvisational music therapy's effectiveness for children with autism

Submission date	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
18/06/2011		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
04/08/2011	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
12/10/2017	Mental and Behavioural Disorders			

# Plain English summary of protocol

Background and study aims

Autism spectrum disorders (ASDs) involve impairments or delayed development in social interaction and communication skills. A wide range of different approaches have been used to help children with ASD develop these skills. However, there is little evidence of effectiveness for most of these methods. Music therapy has been used to treat ASD for a long time, and there are many studies suggesting that music therapy may enhance social communication skills. The aim of this study is to find out about the effects of improvisational music therapy on the social communication skills of children with ASD. Additional aims are to examine if changing the number of music therapy sessions per week affects the outcome of therapy, and to determine cost-effectiveness.

## Who can participate?

Children aged between 4 years and 6 years 11 months diagnosed with ASD. Participating children must not be affected by serious sensory disorders (blindness, deafness) and must not have received music therapy in the last 12 months

#### What does the study involve?

Participants are randomly allocated to one of three groups:

- 1. High-intensity music therapy (improvisational music therapy sessions three times per week for five months, and three sessions of parent counselling).
- 2. Low-intensity music therapy (improvisational music therapy sessions once a week for five months, and three sessions of parent counselling).
- 3. Standard care (three sessions of parent counselling).

Improvisational music therapy is a flexible, child-centred method where a trained therapist reacts musically to the childs (musical or other) behaviour and expression and uses various improvisational techniques to engage the child, establish contact, and enter a dialogue with him /her. While engaging in joint musical activities within a shared history of interaction, the child is offered opportunities to develop and enhance skills that are associated with later development in language and social competency.

What are the possible benefits and risks of participating? There are no direct benefits or risks involved with participating in this study. Where is the study run from?

Uni Research Health, The Grieg Academy Music Therapy Research Centre (GAMUT), Bergen (Norway)

When is the study starting and how long is it expected to run for? August 2011 to December 2016

Who is funding the study?

- 1. The Research Council of Norway (Norway)
- 2. POLYFON Knowledge Cluster for Music Therapy, The Grieg Academy Department of Music, University of Bergen (Norway)
- 3. Melbourne Conservatorium of Music, The University of Melbourne (Australia)
- 4. Danish Council for Independent Research/Humanities (FKK) (Denmark)
- 5. Doctoral Programme in Music Therapy, Aalborg University (Denmark)
- 6. Faculty of Psychology, University of Vienna (Austria)
- 7. Research Incentive Fund (FIPE) of the Hospital de Clínicas de Porto Alegre (HCPA) (Brazil)
- 8. IRCCS Stella Maris Foundation, Pisa (Italy)
- 9. University of Pisa (Italy)
- 10. Research Institute of Health and Science, Jeonju University (Korea)
- 11. Health Authority of Western Norway (Norway)
- 12. Bergen municipality, Bergen culture school (Norway)
- 13. Fjell municipality, Fjell culture school (Norway)
- 14. National Institute for Health Research (UK)
- 15. Cambridge and Peterborough Foundation NHS Trust (UK)
- 16. The Evelyn Trust (UK)
- 17. Cambridgeshire Music (UK)
- 18. Anglia Ruskin University (UK)
- 19. Molloy College (USA)
- 20. Mid-Atlantic Region of the American Music Therapy Association (USA)

Who is the main contact? Prof. Christian Gold christian.gold@uni.no

#### Study website

http://uni.no/en/uni-health/gamut/trial-of-improvisational-music-therapys-effectiveness-for-children-with-autism-time-a/

# **Contact information**

# Type(s)

Scientific

#### Contact name

Prof Christian Gold

#### Contact details

Uni Research Health GAMUT - The Grieg Academy Music Therapy Research Centre Postboks 7810 Bergen Norway 5020 +47 (0)975 01 757 christian.gold@uni.no

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

**Secondary identifying numbers** N/A

# Study information

#### Scientific Title

Randomised controlled Trial of Improvisational Music therapy's Effectiveness for children with Autism spectrum disorders (TIME-A)

#### Acronym

TIME-A

# Study objectives

Music therapy is superior to standard care in improving social communicative skills in children with autism spectrum disorders (ASD) as assessed by blinded clinicians at the end of the treatment period

#### Secondary hypotheses

- 1. Music therapy is superior to standard care in improving social responsiveness in children with ASD as assessed by parents/guardians at the end of the treatment period
- 2. Change in social communicative skills and social responsiveness varies with variation of treatment intensity
- 3. Changes in social communicative skills and social responsiveness are sustained until seven months after ending of treatment

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Approval by the responsible ethics committees will be secured before the start of participants enrolment at each site

# Study design

Multi-centre three-arm single (rater) blind randomised controlled trial of intervention

# Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Other

#### Study type(s)

Treatment

#### Participant information sheet

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

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

Autism spectrum disorders

#### **Interventions**

- 1. Individual improvisational music therapy over a period of 5 months, one session (low-intensity) or three sessions (high-intensity) per week
- 2. Standard care in all treatment arms: 3 sessions of parent counselling at 0, 2, and 5 months

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome measure

Autism Diagnostic Observation Schedule (ADOS) Social Affect score at 5 months

#### Secondary outcome measures

- 1. ADOS at 2 and 12 months
- 2. ADOS subscales: Communication, Reciprocal Social Interaction, Imagination/Creativity, Stereotyped Behaviors and Restricted Interests, at 2, 5, and 12 months
- 3. Social Responsiveness Scale (SRS) as rated by parents/guardians at 2, 5, and 12 months
- 4. SRS subscales: Social Awareness (receptive aspects of social behavior), Social Cognition (social information processing), Social Communication (capacity for reciprocal social communication), Social Motivation (social anxiety/avoidance), Autistic Mannerisms (autistic preoccupations and traits)
- 5. Cost-effectiveness ratios and incremental cost-effectiveness ratios for the different alternatives (Cost will be measured as real resources used in treatment, in terms of personnel hours of work; effectiveness is measured by ADOS)

# Added 05/06/2017:

- 6. Ratings of quality of life of the child and of the family as a whole, respectively, at 2, 5 and 12 months
- 7. Adverse events
- 8. Binary analysis of proportion of participants who improved on the primary outcome

#### Overall study start date

#### Completion date

31/12/2016

# Eligibility

# Key inclusion criteria

- 1. Aged 4 years to 6 years, 11 months
- 2. With a diagnosis of autism spectrum disorder according to ICD-10 criteria as assessed by a child psychiatrist or clinical psychologist; diagnosis of ASD needs to be reconfirmed in the baseline assessment with children fulfilling diagnostic criteria for ASD on both the Autism Diagnostic Observation Schedule (ADOS) and the Autism Diagnostic Interview-Revised (ADI-R)

#### Participant type(s)

**Patient** 

#### Age group

Child

#### Lower age limit

4 Years

### Upper age limit

6 Years

#### Sex

Both

#### Target number of participants

300 (75 in each intervention arm, 150 in the standard care condition)

# Key exclusion criteria

- 1. Children with serious sensory disorders (blindness, deafness)
- 2. Children who have had any previous experience of music therapy

#### Date of first enrolment

01/11/2011

#### Date of final enrolment

10/11/2015

# Locations

#### Countries of recruitment

Australia

Austria

Brazil

Israel

Italy

Korea, South

Norway

**United Kingdom** 

United States of America

# Study participating centre Grieg Academy Music Therapy Research Centre (GAMUT)

Bergen Norway 5015

# Sponsor information

# Organisation

GAMUT - The Grieg Academy Music Therapy Research Centre

# Sponsor details

Uni Research Health Postboks 7810 Bergen Norway 5020

# Sponsor type

Research organisation

#### Website

http://helse.uni.no/

#### **ROR**

https://ror.org/03zga2b32

# Funder(s)

# Funder type

Research council

#### **Funder Name**

Norges Forskningsråd

#### Alternative Name(s)

Forskningsrådet, Norwegian Research Council, Research Council of Norway, The Research Council of Norway

#### **Funding Body Type**

Government organisation

# **Funding Body Subtype**

National government

#### Location

Norway

#### **Funder Name**

Universitetet i Bergen

#### Alternative Name(s)

University of Bergen, UiB

# Funding Body Type

Government organisation

# **Funding Body Subtype**

Local government

#### Location

Norway

#### Funder Name

University of Melbourne

#### Alternative Name(s)

University of Melbourne in Australia, The University of Melbourne, Melbourne University, UNIMELB

#### **Funding Body Type**

Government organisation

#### Funding Body Subtype

Universities (academic only)

#### Location

#### Funder Name

Det Frie Forskningsråd

#### Alternative Name(s)

Danish Council for Independent Research, Independent Research Fund Denmark, Det Frie Forskningsrad, DK Frie Forsk.fond, DFF

# **Funding Body Type**

Government organisation

# **Funding Body Subtype**

National government

#### Location

Denmark

#### **Funder Name**

Aalborg Universitet

#### Alternative Name(s)

Aalborg University, AAU

# **Funding Body Type**

Private sector organisation

# **Funding Body Subtype**

Universities (academic only)

#### Location

Denmark

#### **Funder Name**

Universität Wien

# Alternative Name(s)

University of Vienna, univienna

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

Universities (academic only)

#### Location

Austria

#### **Funder Name**

Hospital de Clínicas de Porto Alegre

# Alternative Name(s)

Hospital of Clinics of Porto Alegre, Hospital de Clínicas, Porto Alegre, HCPA

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

Universities (academic only)

#### Location

Brazil

#### Funder Name

IRCCS Stella Maris Foundation, Pisa

#### **Funder Name**

Università di Pisa

#### Alternative Name(s)

Università degli Studi di Pisa, Universidad de Pisa, University of Pisa, UniPi

#### **Funding Body Type**

Government organisation

# **Funding Body Subtype**

Universities (academic only)

#### Location

Italy

#### **Funder Name**

Jeonju University

# Alternative Name(s)

JJ

#### **Funding Body Type**

Private sector organisation

# **Funding Body Subtype**

Universities (academic only)

#### Location

Korea, South

#### **Funder Name**

Helse Vest

#### Alternative Name(s)

Western Norway Regional Health Authority, WNRHA, Helse Vest Regionalt Helseføretak, Helse Vest RHF

#### **Funding Body Type**

Government organisation

## **Funding Body Subtype**

Local government

#### Location

Norway

#### **Funder Name**

Bergen municipality, Bergen culture school

#### Funder Name

Fiell municipality, Fiell culture school

#### **Funder Name**

National Institute for Health Research

#### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

#### **Funding Body Type**

Government organisation

# **Funding Body Subtype**

# National government

#### Location

**United Kingdom** 

#### **Funder Name**

Cambridge and Peterborough Foundation NHS Trust

#### **Funder Name**

**Evelyn Trust** 

# Alternative Name(s)

# **Funding Body Type**

Private sector organisation

# **Funding Body Subtype**

Other non-profit organizations

#### Location

**United Kingdom** 

#### **Funder Name**

Cambridgeshire Music

#### **Funder Name**

Anglia Ruskin University

# Alternative Name(s)

# **Funding Body Type**

Private sector organisation

# **Funding Body Subtype**

Universities (academic only)

#### Location

**United Kingdom** 

#### **Funder Name**

#### Funder Name

American Music Therapy Association

#### Alternative Name(s)

American Music Therapy Association, Inc., AMTA

#### **Funding Body Type**

Government organisation

## **Funding Body Subtype**

Associations and societies (private and public)

#### Location

United States of America

# **Results and Publications**

#### Publication and dissemination plan

Planned publication in a peer-reviewed journal.

# Intention to publish date

31/12/2017

# Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the study will be stored in a publically available repository (NSD - Norwegian Centre for Research Data, http://www.nsd.uib.no/nsd/english/index.html).

# IPD sharing plan summary

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/01/2012		Yes	No
Results article	results	01/06/2015		Yes	No
Results article	pilot cohort results	01/06/2016		Yes	No
Other publications	editorial	08/08/2017		Yes	No
Results article	results	08/08/2017		Yes	No