ISRCTN78923965 https://doi.org/10.1186/ISRCTN78923965

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

Submission date	Recruitment status	[X] Prospectively registered
18/06/2011	No longer recruiting	[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
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Contact information

Type(s)
Scientific

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Additional identifiers

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

Primary study design
Interventional

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

Study type(s)
Treatment

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 Years

Upper age limit
6 Years

Sex
All

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
United Kingdom

Australia

Austria

Brazil

Israel

Italy

Korea, South

Norway

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

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, University of Bergen, Norway, Universitas Bergensis, UiB

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Norway

Funder Name
University of Melbourne

Alternative Name(s)
University of Melbourne in Australia, The University of Melbourne, Melbourne University, UNIMELB, UoM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Australia

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, Die Universität Wien, Uni Wien, univienna, U Wien

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, JJU

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
Fjell municipality, Fjell 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
Molloy College

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

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?
Results article	results	01/06/2015		Yes	No
Results article	pilot cohort results	01/06/2016		Yes	No
Results article	results	08/08/2017		Yes	No
Protocol article	protocol	05/01/2012		Yes	No
	editorial				

Other publications		08/08/2017		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes