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The effect of auditory integration therapy on brain cognitive function in autism

Submission date	Recruitment status	[X] Prospectively registered
18/05/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/05/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/05/2015	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Autism spectrum disorder (ASD) is a condition that usually starts to develop in childhood. ASD is characterised by symptoms such as problems with social interaction and communication, and restricted and repetitive interests or physical behaviours. There is no cure for ASD, but there are various educational and behavioural treatment programmes available that can benefit people with the condition. Once such treatment is auditory integration training (AIT), which is a form of sound therapy developed by Dr Guy Berard in 1963. AIT sessions are carried out in treatment centres across a 10-20 day period, and individuals listen to programme-designed music through modified headphones for 30 minutes, twice a day. AIT has been shown to help patients with ASD, attention deficit hyperactivity disorder (ADHD), learning disabilities, common developmental disorders, sound sensitivity and speech comprehension problems, among others. The aim of this study is to assess the effects of AIT on specific areas of brain (neurocognitive) function in children with ASD.

Who can participate?
Children diagnosed with ASD.

What does the study involve?
All participants are given AIT treatment according to the Berard method. This involves 10, twice-daily, 30 minute clinic-based AIT sessions, separated by at least 3 hours. Some participants may require an additional 10-day treatment under the same conditions. Before starting AIT, participants are trained to wear the headphones at the clinic by a Berard practitioner; parents are also given training to help their child with the headphones. Participants are asked to take part in various questionnaires and computer-based tests which are used to assess specific areas of brain function, such as memory, attention and decision making (neuropsychological tests). These tests are carried out before treatment starts, and are then repeated 1 day, 1 month and 3 months after treatment.

What are the possible benefits and risks of participating?
Possible benefits of participating in this study include improved speech, communication, social communication and social awareness. There are no risks anticipated.

Where is the study run from?
Autism Research and Treatment Center (ART), Al-Amoudi Chair for Autism (Saudi Arabia)

When is the study starting and how long is it expected to run for?
July 2015 to July 2017

Who is funding the study?
National Plan for Science and Technology (NPST)/King Abdulaziz City for Science and Technology (KACST) (Saudi Arabia)

Who is the main contact?
Prof L AL-Ayadhi

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
04

Study information

Scientific Title
The effect of auditory integration therapy on neurocognitive function in autism

Study objectives
Auditory integration therapy (AIT) can improve cognitive function in patients with autism.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of King Saud University College of Medicine and King Khalid University Hospital, 04/05/2015, ref: E-t5-t454.

Study design
Observational interventional single center study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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

Interventions
AIT, introduced by Berard Method: listening to 10 hours of modified music through headphones in 20 half-hours sessions twice daily with at least 3 hour interval between over a 10-20 day period.

Intervention Type
Other

Primary outcome measure
Measured before intervention, then again one day, one month and 3 months following AIT:
1. Cambridge neuropsychological test automated battery (CANTAB)
2. Childhood autism rating scale (CARS)
3. Social responsiveness scale (SRS)
4. Sensory profile (SP)
5. IQ

Secondary outcome measures
1. Speech
2. Communication
3. Social interaction
4. Academic performance

Overall study start date
01/07/2015

Completion date
01/07/2017

Eligibility

Key inclusion criteria
1. Children diagnosed with autism
2. Normal peripheral hearing and middle ear function assessed by audiological evaluation performed by an ear, nose and throat specialist (ENT)
3. Parental/child consent

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
100

Key exclusion criteria
1. History of seizure disorder
2. Abnormal peripheral hearing
3. Abnormal middle ear function
4. Associated neurological diseases (such as cerebral palsy and tuberous sclerosis)
5. Metabolic disorders (e.g. phenylketonuria)

Date of first enrolment
01/09/2015

Date of final enrolment
01/07/2016

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
Autism Research and Treatment Center (ART), Al-Amoudi Chair for Autism
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Sponsor information

Organisation
National Plan for Science and Technology (NPST)/King Abdulaziz City for Science and Technology (KACST)

Sponsor details
King Saud University
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Sponsor type
Government

ROR
https://ror.org/05tdz6m39

Funder(s)

Funder type
University/education

Funder Name
National Plan for Science and Technology (NPST)/King Abdulaziz City for Science and Technology (KACST) (Saudi Arabia)

Results and Publications

Publication and dissemination plan
The aim is to publish the results in international peer review scientific journals, and any related conferences.

Intention to publish date
01/01/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request