

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

<b>Submission date</b> 18/05/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/05/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/05/2015	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

### Contact name

Professor Laila AL-Ayadhi

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### Contact details

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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**

P O Box 2959

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Saudi Arabia

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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