

Study of the effectiveness of Auditory integration therapy in the treatment of auditory hypersensitivity in autism spectrum disorders

Submission date 24/12/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 31/08/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 31/08/2010	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Laila AL-Ayadhi

Contact details

Auditory Integration Therapy Project (AIT)
Professor of Neurophysiology
Consultant Diagnostic Neurophysiology
Autism Research and Treatment Centre (ART Centre) (99)
Department of physiology (29)
Faculty of Medicine
King Saud University
P O Box 2925
Riyadh
Saudi Arabia
11461

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

The effectiveness of Auditory integration therapy in the treatment of auditory hypersensitivity in autism spectrum disorders: A single blind randomised controlled trial study

Acronym

AIT Autism

Study objectives

Auditory integration therapy is effective in reducing the auditory hypersensitivity in autistic children

Ethics approval required

Old ethics approval format

Ethics approval(s)

The College of Medicine and King Khalid University Ethics Committee approved on the 27th of December 2009. (ref: E-09-065)

Study design

Single centre randomised controlled interventional study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Autism spectrum disorders

Interventions

The children will be assessed as follows:

1. Physician (to confirm the diagnosis) using
 - 1.1. The Developmental, Dimensional and Diagnostic interview (3DI)
 - 1.2. Childhood Autism Rating Scale (CARS)
2. Parents and Psychologist will fill the following
 - 2.1. Health questionnaire
 - 2.2. ORCA Diagnostic check list
 - 2.3. Autism Treatment Evaluation Checklist (ATEC)
3. ENT specialist

Children with a history of seizure disorder will be excluded.

Written informed consent will be obtained from the parents/guardian.

During the study period, children were not allowed to begin any new therapies or stop any current therapies, including medications and supplements.

Auditory integration training will be conducted according to the following protocol:

The listener receives 18 to 20 listening sessions lasting for 30 minutes, over a 10- to 20-day period. In most cases, with a 1- or 2-day break after 5 days of listening. During the listening

sessions, the child listens to processed music. That is, the AIT sound amplifier attenuates low and high frequencies at random from the compact discs, and then sends this modified music through headphones to the listener. This random selection of frequencies is termed 'modulation.' The intensity level (volume) during the AIT listening sessions should not exceed 85 decibels (dBA).

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Reflection in sensory hypersensitivity, assessed at baseline, 3, 6 and 9 months.

Key secondary outcome(s)

1. Increased attention
2. Better hearing
3. Increased concentration

Outcomes assessed at baseline, 3, 6 and 9 months, using the following tools:

1. Parent Questionnaire
2. Health Questionnaire
3. ORCA diagnostic checklist
4. CARS
5. ATEC

Completion date

01/01/2012

Eligibility**Key inclusion criteria**

Autism spectrum disorders with auditory sensory hypersensitivity

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

1. Epilepsy
2. Cerebral palsy
3. Tuberous sclerosis

Date of first enrolment

01/01/2010

Date of final enrolment

01/01/2012

Locations

Countries of recruitment

Saudi Arabia

Study participating centre

Auditory Integration Therapy Project (AIT)

Riyadh

Saudi Arabia

11461

Sponsor information

Organisation

King Abdul Aziz City for Science and Technology (KACST) (Saudi Arabia)

ROR

<https://ror.org/05tdz6m39>

Funder(s)

Funder type

Research organisation

Funder Name

King Abdul Aziz City for Science and Technology (KACST) (Saudi Arabia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration