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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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 below to request a patient information sheet (in Arabic)

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

Secondary outcome measures
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 Q!uestionnaire
3. ORCA diagnositic checklist
4. CARS
5. ATEC

Overall study start date
01/01/2010

Completion date
01/01/2012

Eligibility

Key inclusion criteria
Autism spectrum disorders with auditory sensory hypersensitivity

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
100

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)

Sponsor details
Riyadh
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Sponsor type
Research organisation

Website
http://www.kacst.edu.sa

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration