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Exploring attention mechanisms in children with cochlear implants: a study on neural markers

Submission date
17/04/2025

Recruitment status
No longer recruiting

Registration date
17/04/2025

Overall study status
Completed

Last Edited
17/04/2025

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study looks at how children with cochlear implants (CIs) process sounds and pay attention compared to children with normal hearing. The aim is to understand why some children with CIs do better than others in hearing and understanding speech, especially in noisy situations.

Who can participate?
1. Children aged 7-13 years with bilateral cochlear implants who were deaf before learning language.
2. Children with normal hearing in the same age range.
Participants must not have additional disabilities, neurological disorders, cognitive impairments, or attention deficit disorders.

What does the study involve?
Participants will:
1. Complete listening tasks while their brain activity is recorded
2. Perform speech recognition tests in noisy conditions
3. Complete memory tasks
All testing was completed in one session

What are the possible benefits and risks of participating?
Benefits:
1. Contributing to a better understanding of how cochlear implants affect attention
2. Helping improve future treatments for children with cochlear implants
Risks:
No known risks beyond minor fatigue from completing the tasks
All procedures are non-invasive

Where is the study run from?
Hadassah Medical Center (Israel)

When is the study starting and how long is it expected to run for?
May 2020 to January 2024

Who is funding the study?
University of Haifa (Israel)

Who is the main contact?
Prof. Catia Adelman, cahtiaa@hadassah.org.il

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Ms Ola Badarni-Zahalka

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Neural Markers of Attention Processing in Cochlear Implant Users (NMAP-CI): an event-related potential study

Acronym
NMAP-CI

Study objectives

Paediatric cochlear implant users would demonstrate a distinct pattern of neural attention processing. Specifically, they predicted impaired automatic attention would manifest as reduced Novelty P3 amplitudes and longer latencies, while controlled attention would remain preserved, shown by normal Target P3 amplitudes and latencies. Additionally, they expected these P3 components would correlate with behavioural performance measures such as speech perception and memory.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/07/2021, Helsinki Committee at Hadassah Medical Center (Hadassah Medical Center Ein Karem, jerusalem, 91120, Israel; +972 (0)2 677 7242; VHelsinki@hadassah.org.il), ref: 0881-20-HMO

Study design
Observational cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital, Laboratory

Study type(s)
Efficacy

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

Health condition(s) or problem(s) studied
Auditory attention processing in prelingually deaf children with bilateral cochlear implants

Interventions
This cross-sectional study examines neural mechanisms of attention in pediatric cochlear implant users through event-related potentials, focusing on the Novelty P3 (automatic attention) and Target P3 (controlled attention) components. The study compares prelingually deaf children with early bilateral cochlear implants (n = 25) to normal-hearing controls (n = 28), matched for gender and age (7-13 years). Participants complete an oddball paradigm during ERP recording and perform speech-in-noise and memory tasks.

Participants underwent ERP measurements while performing auditory attention tasks, focusing on two distinct P3 components: Target P3 (in response to infrequent stimuli requiring response) and Novel P3 (in response to unexpected environmental sounds to be ignored). Additionally, participants completed speech-in-noise and memory tasks. No interventional treatments were administered.

Intervention Type
Other

Primary outcome measure
1. Automatic attention processing is measured using frontal Novelty P3 amplitudes and latencies from ERP recordings during an oddball paradigm at one testing session
2. Controlled attention processing is measured using parietal Target P3 amplitudes and latencies from ERP recordings during an oddball paradigm at one testing session

Secondary outcome measures
1. Speech perception in noise is measured using the Speech-in-Noise test at one testing session
2. Short-term memory capacity is measured using Forward Digit Span and working memory capacity is measured using Backward Digit Span (test at one testing session)

Overall study start date
15/05/2020

Completion date
09/01/2024

Eligibility

Key inclusion criteria
Cochlear Implant (CI) Group:
1. Prelingually deaf children
2. Bilateral cochlear implant users
3. Age range 7-14 years
4. Minimum 4 years of CI experience
5. Regular CI users with consistent device use

For Normal-Hearing (NH) Control Group:
1. Age-matched children:
2. Normal hearing thresholds (≤20 dB HL across frequencies)
3. No history of hearing disorders
4. No neurological disorders

General Criteria for Both Groups:
1. No additional disabilities
2. Normal cognitive development
3. Written informed consent from parents/guardians
4. Ability to follow test instructions
5. Native language (Hebrew or Arabic speakers, balanced between groups)

Participant type(s)
Healthy volunteer, Other

Age group
Child

Lower age limit

7 Years

Upper age limit
13 Years

Sex
Both

Target number of participants
A total of 53 participants, consisting of 25 prelingually deaf children with bilateral cochlear implants and 28 normal-hearing controls

Total final enrolment
53

Key exclusion criteria
For Both Groups:
1. Additional disabilities beyond hearing loss (for the CI group)
2. Diagnosed neurological disorders
3. Cognitive impairments
4. Attention deficit disorders
5. Inability to complete all testing sessions

Specific to CI Group:
1. Irregular/inconsistent CI use
2. Device complications or malfunctions
3. Post-lingual deafness
4. Unilateral cochlear implant

Specific to NH Control Group:
1. Any history of hearing loss
2. Hearing thresholds >20 dB HL at any frequency
3. History of middle ear pathology
4. Current or recent use of medications affecting cognitive function

Date of first enrolment
10/08/2022

Date of final enrolment
09/01/2024

Locations

Countries of recruitment
Israel

Study participating centre
Hadasah University Medical Centre
jerusalem

Israel
91120

Sponsor information

Organisation
Hadassah Medical Center

Sponsor details
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Sponsor type
University/education

Website
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ROR
https://ror.org/01cqmqj90

Funder(s)

Funder type
University/education

Funder Name
University of Haifa

Alternative Name(s)
UofHaifa, ,

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Israel

Results and Publications

Publication and dissemination plan
The article has been submitted for publication.

Intention to publish date
01/07/2025

Individual participant data (IPD) sharing plan
The de-identified participant data can be requested from Prof. Catia Adelman (cahtiaa@hadassah.org.il) and Ola Badarni-Zahalka (Obadar01@campus.haifa.ac.il).
The type of data that will be shared: de-identified ERP recordings, behavioral test scores (speech-in-noise and memory tasks), and demographic information.
Dates of availability: data will be available from publication date through 5 years post-publication.
Whether consent from participants was required and obtained: written informed consent was obtained from all participants' parents/guardians
Comments on data anonymization: All personal identifiers have been removed. Participants are identified only by code numbers. No identifying information, such as names, addresses, or dates of birth, is included
Any ethical or legal restrictions, Data access requests must comply with Helsinki Committee guidelines. Use is limited to research purposes only.

IPD sharing plan summary
Available on request