ISRCTN43661994 https://doi.org/10.1186/ISRCTN43661994

Auditory response improvement in young adults by digital auditory training program

Submission date
25/01/2024

Recruitment status
Recruiting

Registration date
26/02/2024

Overall study status
Ongoing

Last Edited
14/02/2024

Condition category
Ear, Nose and Throat

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

Plain English summary of protocol

Background and study aims
Auditory Training (AT) has mainly been used since the early 2000s. Two primary assessments have been carried out to evaluate AT performance. The first assessment aimed to measure improvements in tasks defined by auditory abilities. It involved pre- and post-training evaluations, with task results and behavioral tests compared to assess progress. These tasks have encompassed audiological assessments and specific training techniques unique to each study. The second assessment focused on electrophysiological responses before and after AT, primarily using auditory evoked potentials (AEPs). In a smaller number of cases, training performance was evaluated using alternative tests, some of which examined the usability and validation of the applied methodology. The effects of AT on auditory response and perception have been studied using various means and methodologies. It has been proven to be effective in enhancing auditory skills, including general sensory, social, and cognitive skills, among individuals with hearing impairment, intervention rehabilitation needs, and auditory disorders. A substantial body of literature exists on AT, using diverse training skills for different populations. A recent addition to this field involves assessing the usability and experience of interfaces in the context of AT effects. The effects of this structure, as highlighted by the authors, primarily hinges on auditory experience. Auditory tasks and exercises, even the simplest ones, are influenced by higher-level functions such as memory, motivation, and decision-making. Furthermore, it has been demonstrated that long-term changes in auditory cortical neuronal single-unit or population activity, integral to the sound acoustic experience, primarily result from the differential engagement of similar neural mechanisms. This study aims to measure improvement in auditory discrimination response in game-based AT and compare it to traditional AT methodology performance.

Who can participate?
Healthy volunteers aged between 18 and 30 years old

What does the study involve?
The study aims to recruit and enrol a total of 75 participants, with an anticipated sample rejection of around 20%. Each participant will be randomly assigned to one of three groups—

non-game-based auditory training (AT), game-based AT, and previous stimulation game-based AT. The training will be conducted remotely over 12 weeks using participants' personal computers.

Electrophysiology (EEG) will be employed to measure auditory discrimination, including pitch, intensity, localization, and time, both before and after the training sessions.

What are the possible benefits and risks of participating?
Potential participant benefits of AT are to improve auditory processing discrimination skills (pitch, localization, intensity and time). Within these benefits, participants will be able to improve in distinguishing between two different sounds with tiny differences.

All registers and assessments including audiometry and AEPs are non-invasive, which will not place participants at higher risk other than listening.
Any medical or clinical occurrence related to or not to the research procedure, will be managed as an adverse event, and treated or reported according to institutional health services protocol, mainly considering participant safety and health.

Where is the study run from?
Tecnologico Monterrey

When is the study starting and how long is it expected to run for?
January 2024 to January 2026

Who is funding the study?
Monterrey Institute of Technology and Higher Studies (Instituto Tecnológico y de Estudios Superiores de Monterrey)

Who is the main contact?
Sergio Mora Camargo, A01336974@tec.mx

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
EHE-2023-11

Study information

Scientific Title
Neuro-audiological measurement of the auditory system response after digital auditory training

Study objectives
Game-based auditory training provokes better auditory system responses than conventional tranining methodologies.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/11/2023, Comite Institucional de Etica en la Investigacion Instituto Tecnologico y de Estudios Superiores de Monterrey (Av. Eugenio Garza Sada 2501 Sur, Tecnologico, Monterrey, N.L., 64849, Mexico; +52 81 8358 2000; mario.alvarez@tec.mx), ref: EHE-2023-11

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Auditory training for normal-hearing young adults

Interventions
A total of 75 participants will be recruited and enrolled in the study predicting a sample rejection of 20%. Each of them will be randomly assigned to one of three groups (non-game-based auditory training (AT), game-based AT and previous stimulation game-based AT) depending on the training methodology they will receive for the following 12 weeks, remotely using their PC. Auditory discrimination (pitch, intensity, localization and time) will be measured by electrophysiology (EEG) before and after training. Assignments of each participant will be randomized using a simple randomization 1:1:1 allocation ratio to select the group for the training methodology, avoiding bias in trials.
No blinding will be involved within participants or personnel who analyze data since they must know which group they belong to, so instructions can be explained and clearly understood.

Intervention Type

Behavioural

Primary outcome(s)
Auditory hearing and discrimination thresholds are measured using audiometry (perceptual auditory responses (level and frequencies)) and auditory evoked potentials (auditory brainstem response (ABR; amplitude and latency), mismatch negativity (MMN; amplitude and latency), and P3 (parietal amplitude and latency)) at baseline and 3 months

Key secondary outcome(s))
Secondary auditory training performance measured using data collected about key performance indicators (time, hit rate, attempts) during training (three months duration)

Completion date
14/02/2026

Eligibility

Key inclusion criteria
1. Healthy volunteers aged between 18 and 30 years old
2. Normal hearing pure-tone thresholds ≤20 dB HL across frequencies 125-8000 Hz previously evaluated by audiometry

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
30 years

Sex
All

Key exclusion criteria
1. Participants who do not sign the informed consent
2. Participants who present with hearing loss or impairment pure-tone average >30 dB HL, that cannot fulfil the required time for the AT
3. Pregnancy
4. Frequently consuming medicines that can alter the participant's state

Date of first enrolment
01/02/2024

Date of final enrolment
01/03/2026

Locations

Countries of recruitment
Mexico

Study participating centre
Tecnologico Monterrey
Av. Eugenio Garza Sada 2501 Sur, Tecnológico
Monterrey, N.L.
Mexico
64849

Sponsor information

Organisation
Consejo Nacional de Humanidades, Ciencias y Tecnologías

ROR
https://ror.org/059ex5q34

Funder(s)

Funder type
Research organisation

Funder Name
Instituto Tecnológico y de Estudios Superiores de Monterrey

Alternative Name(s)
Tecnológico de Monterrey, Tec de Monterrey, Monterrey Institute of Technology, Monterrey Institute of Technology and Higher Education, ITESM, Tec

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location

Results and Publications

Individual participant data (IPD) sharing plan

With transparency purposes participants' measurements data will also intended to be published by the end of 2025 in publicly database repository, so it can be available for further research.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			14/02/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes