

Auditory response improvement in young adults by digital auditory training program

Submission date 25/01/2024	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/02/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/02/2024	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

Mr Sergio M-Cam

Contact details

13 mayo no 17

CDMX

Mexico

03820

+525526904740

A01336974@tec.mx

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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 training methodologies.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 13/11/2023, Comité Institucional de Ética en la Investigación Instituto Tecnológico y de Estudios Superiores de Monterrey (Av. Eugenio Garza Sada 2501 Sur, Tecnológico, 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

Secondary study design

Randomised controlled trial

Study setting(s)

School

Study type(s)

Efficacy

Participant information sheet

See study outputs table

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 measure

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

Secondary outcome measures

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

Overall study start date

14/02/2022

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

30 Years

Sex

Both

Target number of participants

3 clusters of 25 participants each

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

Sponsor details

Av. Insurgentes Sur 1582

Mexico City

Mexico

03940

+52 5553227700

cca@conahcyt.mx

Sponsor type

Government

Website

<https://conahcyt.mx/>

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

Mexico

Results and Publications

Publication and dissemination plan

With scientific dissemination purposes, once analysis is concluded research it is intended to publish results as original research paper, analyzing auditory processing discrimination results through AT performance and electrophysiological measurements. Research would be published in journals related to auditory health, auditory neuroscience, or physiological acoustics by the end of study. With transparency purposes participants' measurements data will also intended to be published by the same date, so it can be available for further research.

Intention to publish date

01/02/2026

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