

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 2026

exploring the effect of auditory training regimes with combined active listening and passive hearing on perceptual learning caused by double vowel recognition exercises

Protocol summary

Study aim

exploring the combined effect of training regimes with active and passive auditory tasks on simultaneous sound segregation

Design

RCT with control group, pragmatic, factorial, not blinded, not randomized

Settings and conduct

participants will be assessed using a behavioral test of double vowel recognition before and after a five-day-intervention. EEG signals will also be recorded while behavioral tests are performed. during assessments and active training sessions participants should specify the contents of double vowels with different degrees of F0 differences. passive training would include hearing double vowel stimuli while tetris game is played. this study will be conducted in rehabilitation school of Iran university of medical sciences.

Participants/Inclusion and exclusion criteria

being right-handed based on odinbergh handedness scale normal hearing thresholds (less than or equal to 25 dB) in 250-8000 Hz in both ears not having cognitive impairments based on MMSE questionnaire (scores equal or more than 28) negative history of suffering from neurologic, otologic and psychologic impairments

Intervention groups

Experimental group 1: receiving active double vowel training
Experimental group 2: receiving active double vowel training + additional periods of passive stimulation
Experimental group 3: receiving periods of passive stimulation
Control group: receiving no intervention

Main outcome variables

ORN (object related negativity) amplitude, Auditory late latency potentials amplitude, hit rate of double vowel recognition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181203041834N1**

Registration date: **2019-10-14, 1398/07/22**

Registration timing: **retrospective**

Last update: **2019-10-14, 1398/07/22**

Update count: **0**

Registration date

2019-10-14, 1398/07/22

Registrant information

Name

Reyhane Toufan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

toufan.r@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

exploring the effect of auditory training regimes with combined active listening and passive hearing on perceptual learning caused by double vowel recognition exercises

Public title

effect of combined active and passive listening tasks on simultaneous sound segregation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

being right-handed based on odinbergh handedness scale normal hearing thresholds (less than or equal to 25 dB) in 250-8000 Hz in both ears individuals with the age of 18-30 years old

Exclusion criteria:

having cognitive impairments based on MMSE questionnaire (scores less than 28) history of neurologic, otologic and psychologic impairments

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of medical sciences

Street address

shahnazari street-madadkaran avenue-school of rehabilitation sciences

City

tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

IR.IUMS.REC.1397.752

Health conditions studied

1

Description of health condition studied

the effect of auditory training on perception of speech in noisy environment in healthy subjects

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

double vowel recognition

Timepoint

seven days

Method of measurement

score of behavioral test of double vowel recognition

2

Description

mean amplitude of object related negativity brain potential

Timepoint

seven days

Method of measurement

recording the EEG and measuring the mean amplitude of the wave

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: active listening group who receive active listening trainings on double vowel recognition via computer for five days. each training section will last 90 minutes during which participants listen to double vowel stimuli with different amount of f0 separation (f0 difference decreases after each correct response)

Category

Rehabilitation

2

Description

Intervention group: active listening and passive hearing group who receive active listening and passive hearing

training on double vowel recognition for five days. each training section will last 90 minutes. during active listening period of training participants listen to double vowel stimuli with different amount of f0 separation and try to recognize the two of the vowels (f0 difference decreases after each correct response). During passive hearing period of the training participants will play a video game (TETRIS) while double vowel stimuli will be heard passively via earphones.

Category

Rehabilitation

3

Description

Intervention group: passive hearing group who are going to hear double vowel stimuli passively while playing a video game (TETRIS). This intervention will last for five days, 90 minutes each session. Double vowel stimuli will be presented via headphones and their F0s may vary from 0 to 5 semitones. Participants will be told not to pay attention to the auditory stimuli during playing TETRIS.

Category

Rehabilitation

4

Description

Control group: participants of control group will receive no double-vowel-training intervention between EEG recording sessions.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

School of rehabilitation of Iran university of medical sciences

Full name of responsible person

Tayebe Falahnejad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Abbas Motevalliyan

Street address

Unit 10, No. 30.1, Kordbache alley, Vida avenue, Koramshahr street

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Reyhane Toufan

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Audiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

because of small amplitude of ORN wave it can not be measured individually so a grand average will be provided and reported.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

study design, statistical analysis method and study results will be shared.

When the data will become available and for how long

data would be shared for a period of 2 month after papers publication

To whom data/document is available

related fields researchers and students

Under which criteria data/document could be used

data would be shared for running new studies. data sharing decision would be made individually after interviewing with each applicants.

From where data/document is obtainable

Reyhane Toufan

What processes are involved for a request to access data/document

Interested researchers can send us a message via email or on researchgate.

Comments