Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Sep 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 tetriss 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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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 varry 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 recieve 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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School of rehabilitation of Iran university of medical sciences,Madadkaran avenue, Shahnazari street, Mirdamad bulvard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr. Seyed Abbas Motevalliyan

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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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Person responsible for scientific inquiries

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Person responsible for updating data

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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 designe, 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 sen us a massage via email or on researchgate.
Comments