

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The Effects of Dynamic Spatial Hearing Rehabilitation Combined with Transcranial Electrical Stimulation on Speech Perception in Noise in Elderly Men with Normal Hearing

Protocol summary

Study aim

Determining The Effects of Dynamic Spatial Hearing Rehabilitation Combined with Transcranial Electrical Stimulation on Speech Perception in Noise in Elderly Men with Normal Hearing

Design

4 groups Sample size: 80 Randomization: assign to four equal groups with a Quadruple random blocks method. Phase: no applicable

Settings and conduct

Dynamic spatial hearing rehabilitation in twelve weeks (two sessions weekly, one hour each) at the center and on a daily basis at home For tDSC, the direct current which increases from a 0.5 mA intensity gradually to 2 mA (9 v), is presenting by a pair of carbon-rubber electrodes with a diameter of 21 mm and an area of 3.5 cm² dissolved in salt water, anode/right-cathod/left on the superior temporal gyrus area including planum temporale and auditory cortex (T7 and T8 regions according to the electrodes method 10-20) in three months (In the first two weeks, four sessions a week and then a weekly session), and each session will be presented 20 minutes Location: Audiology clinic, School of Rehabilitation, Tehran University of Medical Sciences

Participants/Inclusion and exclusion criteria

Elderly men aged between 60-75 years with normal hearing and speech perception difficulty.

Intervention groups

1. dynamic spatial hearing rehabilitation (DSHR) 2. DSHR and tDCS 3. Control 4. Sham

Main outcome variables

signal to noise ratio loss index (SNR Loss) Spatial Release from Masking index The total and subscale scores of the SSQ questionnaire P1, N1, P2 latencies N1-P2 amplitude

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160131026279N2**

Registration date: **2019-03-07, 1397/12/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-07, 1397/12/16**

Update count: **0**

Registration date

2019-03-07, 1397/12/16

Registrant information

Name

Mansoureh Adel Ghahraman

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7753 4364

Email address

madel@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-04, 1397/12/13

Expected recruitment end date

2019-09-04, 1398/06/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Dynamic Spatial Hearing Rehabilitation Combined with Transcranial Electrical Stimulation on Speech Perception in Noise in Elderly Men with Normal Hearing

Public title

Rehabilitation and tDCS in geriatric speech perception

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Elderly men aged between 60-75 years . The average thresholds of frequencies of 500, 1000, 2000 Hz are less than or equal to 25 dB HL in both ears, and the thresholds of each of the higher frequencies alone are less than or equal to 40 dB HL (31) and the auditory symmetry in both ears (mean difference of threshold About dB 5 HL). Normal middle ear: Type A Tympanogram and Static Compliance between 0.3 and 1.6 Right handedness (based on Edinburgh Handedness Inventory) Farsi language and Monolingual Lack of cognitive problems (obtaining a minimum score of 21 out of 30 Mini-Mental State Examination (MMSE) having problem of speech perception in noisy environments based on the participant's statement No pacemaker due to interference with electrical stimulation Lack of neurological disease. Lack of uncontrolled high blood pressure or diabetes

Exclusion criteria:

Normal results of all evaluations and tests used in this study before any intervention Reluctant to continue cooperation in research

Age

From **60 years** old to **75 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assign to four equal groups with a Quadruple random blocks method.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Nursing and Midwifery & Rehabilitation - Tehran University of Medical Sciences

Street address

Enghelab Ave.

City

Tehran

Province

Tehran

Postal code

1148956111

Approval date

2018-04-15, 1397/01/26

Ethics committee reference number

IR.TUMS.FNM.REC.1397.073

Health conditions studied

1

Description of health condition studied

Auditory processing disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

signal to noise ratio loss index (SNR Loss)

Timepoint

Before, immediately after completing intervention, and one month after the completion of intervention

Method of measurement

Quick Speech in Noise (QSIN) Test

2

Description

Spatial Release from Masking index

Timepoint

Before, immediately after completing intervention, and one month after the completion of intervention

Method of measurement

Binaural Masking Level Difference Test (BMLD)

3

Description

The total and subscales score of the SSQ questionnaire

Timepoint

Before, immediately after completing intervention, and one month after the completion of intervention

Method of measurement

Persian version of speech, spatial and qualities of hearing scale (SSQ)

4

Description

P1, N1, P2 latencies

Timepoint

Before, immediately after completing intervention, and one month after the completion of intervention

Method of measurement

Recording auditory late latency responses (LLR)

5

Description

N1-P2 amplitude

Timepoint

Before, immediately after completing intervention, and one month after the completion of intervention

Method of measurement

Recording auditory late latency responses (LLR)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: receiving dynamic spatial hearing rehabilitation in twelve weeks (two sessions weekly, one hour each) at the center and on a daily basis at home

Category

Rehabilitation

2

Description

Intervention group 2: receiving dynamic spatial hearing rehabilitation and tDCS. Dynamic spatial hearing rehabilitation in twelve weeks (two sessions weekly, one hour each) at the center and on a daily basis at home. For tDCS, the direct current which increases from a 0.5 mA intensity gradually to 2 mA (9 v), is presenting by a pair of carbon-rubber electrodes with a diameter of 21 mm and an area of 3.5 cm² dissolved in salt water, anode/right-cathod/left on the superior temporal gyrus area including planum temporale and auditory cortex (T7 and T8 regions according to the electrodes method 10-20) in three months (In the first two weeks, four sessions a week and then a weekly session), and each session will be presented 20 minutes.

Category

Rehabilitation

3

Description

Control group: no intervention

Category

Rehabilitation

4

Description

Sham group: not receiving spatial hearing rehabilitation and is placed in the tDCS sessions of the electrode, but no electrical stimulation is applied.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Audiology clinic, School of Rehabilitation, Tehran University of Medical Sciences

Full name of responsible person

Mansoureh Adel Ghahraman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shabnam Noroozadeh

Street address

Tehran University of Medical Sciences (TUMS), Keshavarz Blvd.

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1417653761

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research@tums.ac.ir

Grant name

Annual funding, School of Rehabilitation

Grant code / Reference number

97-02-32-38674

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

Yes

Title of funding source

Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mansoureh Adel Ghahraman
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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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

No more information

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Reporting as a PhD dissertation and papers

When the data will become available and for how long

2019 and after

To whom data/document is available

All

Under which criteria data/document could be used

In accordance with Tehran University of Medical Sciences
copyright

From where data/document is obtainable

Databases for papers Library of the School of
Rehabilitation, TUMS, for dissertation

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

For papers depends on the journal's policy For the
dissertation, studying in the library

Comments