

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The Effect of Auditory Spatial Attention Training on Auditory Spatial and Dichotic Processing in Subjects with Right Brain Stroke

Protocol summary

Study aim

The Effect of Auditory Spatial Attention Training on Auditory Spatial and Dichotic Processing in Subjects with Right Brain Stroke

Design

controlled clinical trial, sample size based on the pilot study: 8 subjects in each group

Settings and conduct

Research site: Rofeideh rehabilitation hospital, initial evaluation for inclusion criteria: obtaining a consent form, examination by a neurologist, conducting Mini Mental State Examination (MMSE) test, Edinburgh questionnaire, auditory spatial and dichotic tests, and SSQ questionnaire, Allocation to intervention and control groups by block randomization, intervention group: under 12 sessions of auditory lateralization training, outcome evaluation by auditory spatial and dichotic tests and SSQ questionnaire

Participants/Inclusion and exclusion criteria

Consent to participate in the study; Right Hemisphere Stroke; Stability of the Medical Condition; Lack of Other Neurological Diseases; Minimum Score of 21 in MMSE; Right Handedness, Normal Hearing

Intervention groups

Intervention group: receive 12 sessions of auditory lateralization training, the control group: they do not receive interventions.

Main outcome variables

Improving auditory spatial skills including auditory lateralization and divided attention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221016056197N1**

Registration date: **2023-01-29, 1401/11/09**

Registration timing: **prospective**

Last update: **2023-01-29, 1401/11/09**

Update count: **0**

Registration date

2023-01-29, 1401/11/09

Registrant information

Name

Zahra Eshaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-04, 1401/11/15

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Auditory Spatial Attention Training on Auditory Spatial and Dichotic Processing in Subjects with Right Brain Stroke

Public title

Auditory Spatial Attention Training in Stroke

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to participate in the study Right Hemisphere Stroke Diagnosed by a Neurologist Unilateral Spatial Neglect Diagnosed by a Neurologist Stability of the Medical Condition after the Acute Phase of Stroke Right-Handedness Normal Hearing (Average Hearing Thresholds of Frequencies 500, 1000 and 2000 Hz Less Than 25 dB HL in Both Ears and Symmetrical Hearing)

Exclusion criteria:
Other Neurological Diseases Cognitive Problems Based on Persian version of Mini-Mental State Examination (MMSE) (Minimum Score of 21)

Age
From **20 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **8**

Randomization (investigator's opinion)
Randomized

Randomization description
For random allocation, we will use 8 cards A (treatment group) and 8 cards B (control group) and put them in 16 envelopes with the same shape that is not clear inside them. After reshuffling them several times, we will mark them with serial numbers from 1 to 16. When each participant enters, an envelope is opened and the patient group is determined.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This study will investigate a number of stroke patients in two groups. One group (intervention group) receives rehabilitation and the other group (control group) don't receive any intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the University of Social Welfare and Rehabilitation Sciences

Street address

Koudakyar St., Daneshjoo Blvd., Evin

City

Tehran

Province

Tehran

Postal code

1985713871

Approval date

2020-01-14, 1398/10/24

Ethics committee reference number

IR.USWR.REC.1398.193

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

stroke

ICD-10 code description

stroke

Primary outcomes

1

Description

Number of auditory lateralization errors

Timepoint

Before the intervention, after the last session (0 to 48 hours after the last session) and one month later

Method of measurement

Interaural Time and Intensity Difference (ITD and IID) auditory lateralization test

2

Description

Spatial monosyllabic word recognition score in noise

Timepoint

Before the intervention, after the last session (0 to 48 hours after the last session) and one month later

Method of measurement

Auditory lateralization of monosyllabic words in noise test

3

Description

Right and left ear scores in Randomized Dichotic Digit Test (RDDT)

Timepoint

Before the intervention, after the last session (0 to 48 hours after the last session) and one month later

Method of measurement

Persian version of randomized dichotic digit test

4

Description

Laterality index in Randomized Dichotic Digit Test (RDDT)

Timepoint

Before the intervention, after the last session (0 to 48 hours after the last session) and one month later

Method of measurement

Persian version of randomized dichotic digit test

5

Description

Speech , Spatial , Quality of Hearing Scale (SSQ) questionnaire score

Timepoint

Before the intervention, after the last session (0 to 48 hours after the last session) and one month later

Method of measurement

Speech , Spatial , Quality of Hearing Scale (SSQ) questionnaire

6

Description

Number of auditory lateralization errors

Timepoint

Before the intervention, after the last session (0 to 48 hours after the last session) and one month later

Method of measurement

Auditory lateralization of monosyllabic words in noise test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: auditory lateralization training is performed for 12 sessions of 45 minutes. Auditory stimulus is high-pass and low-pass noise with a cut-off frequency of 2 kHz, which were simulated in 9 hypothetical spatial locations (in the form of 9 speakers in a semicircular horizontal plane) by interaural time difference (ITD) under MATLAB software. The sounds were presented binaurally with different ITDs (0, ± 220 , ± 440 , ± 660 and ± 880 microseconds) at comfortable level via headphones, to induce a sense of displacement of the sound source. Positive and negative numbers and zero indicate stimulus presentation from the right and left angles, and center position, respectively. The subjects should lateralize the sounds and point to a schematic picture of speakers in front of them with right hand.

Category

Rehabilitation

2

Description

Control group: they do not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Rofeideh hospital

Full name of responsible person

Dr. Fereydoun Layeghi

Street address

Rofeideh Rehabilitation Hospital, Shahid Nemati Alley, South Salimi St., Andarzgoo Blvd., Qaitarieh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Dr.Hamidreza khankeh

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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

University of social welfare and rehabilitation 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

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Person responsible for general inquiries

Contact

Name of organization / entity
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

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