

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Aug 2026

Investigating the effect of galvanic vestibular stimulation and vestibular rehabilitation on spatial memory of patients with amnesic mild cognitive impairment

Protocol summary

Study aim

Investigating the effect of galvanic vestibular stimulation (GVS) and vestibular rehabilitation (VR) on spatial memory of patients with amnesic mild cognitive impairment (aMCI)

Design

Randomized, controlled clinical trial with a parallel group design on 48 patients. Randomization was carried out with Random Allocation Software.

Settings and conduct

Patients with amnesic mild cognitive impairment, referred to School of Rehabilitation, affiliated to Tehran University of Medical Sciences, undergo Mini-Mental State Examination, Montreal Cognitive Assessment, Rey's auditory-verbal, CANTAB visual-spatial memory, video head impulse and force-plate tests before randomization. Immediately after the end of the intervention period and one month later, the tests will be repeated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosed with amnesic mild cognitive impairment; MMSE test score <21; Montreal cognitive assessment score 19 and 24. Non-inclusion criteria: Color blindness; neck pain or limitation in neck range of motion; anticholinergic drug consumption; alcoholism or addiction; orthopedic problems in the past 6 months; obvious lower extremity deformities; rheumatic and/or metabolic diseases

Intervention groups

Intervention group 1: Receiving galvanic vestibular stimulation (three 20-minute sessions; once a week) and vestibular rehabilitation (physical exercises; twice a day for 1 month) Intervention group 2: Receiving galvanic vestibular stimulation (three 20-minute sessions; once a week). Intervention group 3: Receiving vestibular rehabilitation (physical exercises; twice a day for 1 month). Control group: Receiving no intervention.

Main outcome variables

Montreal Cognitive Assessment, learning, and recall scores; percentage and latency of CANTAB correct answers; memory span; vestibulo-ocular reflex gain; displacement and velocity of displacement of center of pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160131026279N3**

Registration date: **2020-05-05, 1399/02/16**

Registration timing: **prospective**

Last update: **2020-05-05, 1399/02/16**

Update count: **0**

Registration date

2020-05-05, 1399/02/16

Registrant information

Name

Mansoureh Adel Ghahraman

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 7753 4364

Email address

madel@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of galvanic vestibular stimulation and vestibular rehabilitation on spatial memory of patients with amnesic mild cognitive impairment

Public title
Effect of rehabilitation on treatment of mild cognitive impairment

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Diagnosed with aMCI MMSE test score <21 for participants with primary school education and <23 for participants with a university degree MoCA test score between 19 and 24 Adequate visuomotor coordination based on the standard score (Z Score $\pm$ 1) in motor screening task (MOT) test Normal or modified visual acuity or with glasses (20/20) using the Snellen chart in order to correctly diagnose CANTAB test forms Normal hearing ability or corrected hearing loss with hearing aid to hear the stimulus in the force plate test
Exclusion criteria:
 Color blindness according to Ishihara test for color blindness Neck pain or limitation in neck range of motion Anticholinergic drug consumption (e.g. hyoscine and atropine) consumption Consumption of drugs affecting vestibulo-ocular reflex such as Cinnarizine , betahistine, painkillers, and tranquilizers from 48 hours prior to tests History of orthopedic problems in the last 6 months (lower extremity fractures, dislocation, and pain) Obvious lower extremity deformities such as scoliosis and kyphosis according to observation of a physiotherapist History of rheumatic and/or metabolic diseases History of alcoholism or addiction

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Individual random assignment to four equal groups with block randomization method using blocks of size 4; Randomization and random sequential allocation: done with Random Allocation Software; Allocation concealment: done with sequentially numbered, sealed, opaque envelopes

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of School of Nursing and Midwifery & Rehabilitation ,Tehran University of Medical S

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Enghelab Ave.

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1148956111

Approval date

2020-02-19, 1398/11/30

Ethics committee reference number

IR.TUMS.FNM.REC.1398.229

Health conditions studied

1

Description of health condition studied

amnesic mild cognitive impairment

ICD-10 code

G31.84

ICD-10 code description

Mild cognitive impairment, so stated

Primary outcomes

1

Description

Montreal Cognitive Assessment score

Timepoint

Before, immediately after the end of the intervention period, and one month later

Method of measurement

Montreal Cognitive Assessment (MoCA)

2

Description

learning score

Timepoint

Before, immediately after the end of the intervention period, and one month later
Method of measurement
Rey Auditory Verbal Learning Test

3

Description
immediate recall score
Timepoint
Before, immediately after the end of the intervention period, and one month later
Method of measurement
Rey Auditory Verbal Learning Test

4

Description
Delayed recall score
Timepoint
Before, immediately after the end of the intervention period, and one month later
Method of measurement
Rey Auditory Verbal Learning Test

5

Description
Percentage of correct answers in pattern recognition memory (PRM)
Timepoint
Before, immediately after the end of the intervention period, and one month later
Method of measurement
CANTAB test

6

Description
Response latency in Delayed Matching to Sample
Timepoint
Before, immediately after the end of the intervention period, and one month later
Method of measurement
CANTAB test

7

Description
percentage of correct selection in Delayed Matching to Sample
Timepoint
Before, immediately after the end of the intervention period, and one month later
Method of measurement
CANTAB test

8

Description
percentage of errors in Paired Associates Learning
Timepoint
Before, immediately after the end of the intervention

period, and one month later
Method of measurement
CANTAB test

9

Description
Spatial Span length
Timepoint
Before, immediately after the end of the intervention period, and one month later
Method of measurement
CANTAB test

10

Description
vestibulo-ocular reflex gain
Timepoint
Before, immediately after the end of the intervention period, and one month later
Method of measurement
video head impulse test (vHIT)

11

Description
percentage of overt saccades
Timepoint
Before, immediately after the end of the intervention period, and one month later
Method of measurement
video head impulse test (vHIT)

12

Description
percentage of covert saccades
Timepoint
Before, immediately after the end of the intervention period, and one month later
Method of measurement
video head impulse test (vHIT)

13

Description
Vestibulo-ocular reflex gain asymmetry
Timepoint
Before, immediately after the end of the intervention period, and one month later
Method of measurement
video head impulse test (vHIT)

14

Description
displacement of center of pressure in both anterior-posterior and medial-lateral directions in anticipation, weight transfer, and locomotion
Timepoint
Before, immediately after the end of the intervention period, and one month later

Method of measurement

force-plate test

15**Description**

velocity of displacement of center of pressure in both anterior-posterior and medial-lateral directions in anticipation, weight transfer, and locomotion

Timepoint

Before, immediately after the end of the intervention period, and one month later

Method of measurement

force-plate test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: receiving GVS and VR, GVS: Subliminal noisy GVS, 20 min, once a week, three sessions. VR: Cooksey-Cawthorne rehabilitation exercises, 30 min, twice a day for one month

Category

Rehabilitation

2**Description**

Intervention group 2: receiving VR only. VR: Cooksey-Cawthorne rehabilitation exercises, 30 min, twice a day for one month

Category

Rehabilitation

3**Description**

Intervention group 3: receiving GVS only. GVS: Subliminal noisy GVS, 20 min, once a week, three sessions.

Category

Rehabilitation

4**Description**

Control group: no intervention

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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Shabnam Noroozzadeh

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Grant name

Annual funding, School of Rehabilitation

Grant code / Reference number

98-3-103-45574

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
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

-

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

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

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

2022 and after

To whom data/document is available

All people

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 and the 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