Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Investigating the effect of galvanic vestibular stimulation and vestibular rehabilitation on spatial memory of patients with amnestic 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 amnestic 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 amnestic 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 amnestic 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)

Phone

+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 amnestic 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 ± 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

Street address
Enghelab Ave.

City
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Province
Tehran

Postal code
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
amnestic 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
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 Noroozzadeh
Street address
Tehran University of Medical Sciences (TUMS), Keshavarz Blvd.
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Postal code
1417653761
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Email
research@tums.ac.ir
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
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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
-
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