

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison the effect of galvanic vestibular stimulation combined with conventional vestibular rehabilitation program or virtual reality rehabilitation on cognitive and balance performance of patients with unilateral vestibular impairment

Protocol summary

Study aim

Comparison the effect of galvanic vestibular stimulation combined with conventional vestibular rehabilitation program or virtual reality rehabilitation on cognitive and balance performance of patients with unilateral vestibular impairment

Design

Randomized, clinical trial with a parallel group design on 52 patients. Randomization was carried out with Random Allocation Software.

Settings and conduct

School of Rehabilitation, TUMS Recruitment of patients based on inclusion criteria Intervention based on the group description Assessment of balance and cognitive outcomes before and after interventions

Participants/Inclusion and exclusion criteria

Patients diagnosed with uncompensated unprogressive chronic unilateral vestibular disorder

Intervention groups

Intervention group 1 (VRT): receiving vestibular rehabilitation program (Cooksey-Cawthorne exercises), 30 min, twice a day, 4 weeks Intervention group 2 (VRT+GVS): receiving vestibular rehabilitation program with noisy galvanic vestibular stimulation (subliminal, 20 min, once a week, 3 weeks) Intervention group 3 (VR): receiving virtual-vestibular rehabilitation (eight 45-minute sessions of Nintendo Wii fit plus exercises, twice a week, 4 weeks) Intervention group 4 (VR+GVS): receiving virtual-vestibular rehabilitation and GVS

Main outcome variables

Dizziness Handicap Inventory questionnaire score, results of choice reaction time test, visual stroop, working memory, verbal fluency, Corsi, treatment benefit questionnaire, video head impulse, static and dynamic posturography.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160131026279N4**

Registration date: **2021-09-02, 1400/06/11**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-02, 1400/06/11**

Update count: **0**

Registration date

2021-09-02, 1400/06/11

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

2021-04-21, 1400/02/01

Expected recruitment end date

2023-05-21, 1402/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of galvanic vestibular stimulation combined with conventional vestibular rehabilitation program or virtual reality rehabilitation on cognitive and balance performance of patients with unilateral vestibular impairment

Public title

Effect of rehabilitation and electrical stimulation on treatment of unilateral vestibular impairment

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosed uncompensated chronic unilateral vestibular disorder (such as Vestibular neuritis) with canal paralysis > 25% using caloric test, Age range of 20-50 years, No benign paroxysmal positional vertigo, Complaints of vertigo and imbalance during movement, No central nervous system involvement, No previous Vestibular rehabilitation program, Normal or corrected visual acuity with glasses (20/20) using the Snellen chart in order to view the target point on the vHIT test and perform cognitive tests, Normal hearing ability or corrected hearing loss with hearing aid in order to hear the stimulus in the force plate test, Having diploma at least.

Exclusion criteria:

Drug consumptions that result in suppressing vestibular system compensation Neck pain and limited range of motion of the neck Alcoholism or addiction Orthopedic problems in the last 6 months Obvious lower extremity deformities such as scoliosis and kyphosis according to observation of a physiotherapist Rheumatic and/or metabolic diseases Professionalism in various fields of sports, art and music because of their impact on the cognitive fields

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

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

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

Street address

Enghelab Ave.

City

Tehran

Province

Tehran

Postal code

1148956111

Approval date

2021-06-08, 1400/03/18

Ethics committee reference number

IR.TUMS.FNM.REC.1400.043

2

Ethics committee

Name of ethics committee

School of Nursing and Midwifery & Rehabilitation -
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Street address

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Approval date

2021-02-09, 1399/11/21

Ethics committee reference number

IR.TUMS.FNM.REC.1399.210

Health conditions studied

1

Description of health condition studied

Vestibular disorder

ICD-10 code

H81

ICD-10 code description

Disorders of vestibular function

Primary outcomes

1

Description

Dizziness Handicap Inventory score

Timepoint

Before and after intervention

Method of measurement

Dizziness Handicap Inventory

2

Description

Response latency

Timepoint

Before and after intervention

Method of measurement

Choice reaction time test

3

Description

Response accuracy

Timepoint

Before and after intervention

Method of measurement

Choice reaction time test

4

Description

Response latency

Timepoint

Before and after intervention

Method of measurement

Visual Stroop test

5

Description

Response accuracy

Timepoint

Before and after intervention

Method of measurement

Visual Stroop test

6

Description

Interference score

Timepoint

Before and after intervention

Method of measurement

Visual Stroop test

7

Description

Working memory span

Timepoint

Before and after intervention

Method of measurement

Backward digit span test

8

Description

Total number of correct words

Timepoint

Before and after intervention

Method of measurement

Verbal fluency test

9

Description

Response accuracy

Timepoint

Before and after intervention

Method of measurement

Serial sevens subtraction task

10

Description

Total test time

Timepoint

Before and after intervention

Method of measurement

Serial sevens subtraction task

11

Description

Visuospatial span length

Timepoint

Before and after intervention

Method of measurement

Corsi block test

12

Description

Treatment benefit score

Timepoint

Before and after intervention

Method of measurement

Treatment benefit questionnaire

13

Description

Vestibulo-ocular reflex gain

Timepoint

Before and after intervention

Method of measurement

video head impulse test (vHIT)

14

Description

Frequency of overt and covert saccades

Timepoint

Before and after intervention

Method of measurement

video head impulse test (vHIT)

15

Description

Displacement of center of pressure in both anterior-posterior and medial-lateral directions

Timepoint

Before and after intervention

Method of measurement

Static posturography on force-plate

16

Description

velocity of displacement of center of pressure in both anterior-posterior and medial-lateral directions

Timepoint

Before and after intervention

Method of measurement

Static posturography on force-plate

17

Description

Phase plane

Timepoint

Before and after intervention

Method of measurement

Static posturography on force-plate

18

Description

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

Timepoint

Before and after intervention

Method of measurement

Dynamic posturography on force-plate

19

Description

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

Timepoint

Before and after intervention

Method of measurement

Dynamic posturography on force-plate

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 (VRT): receiving vestibular rehabilitation program (Cooksey-Cawthorne exercises), 30 min, twice a day, 4 weeks

Category

Rehabilitation

2

Description

Intervention group 2 (VRT+ GVS): receiving vestibular rehabilitation program with noisy galvanic vestibular stimulation (subliminal, 20 min, once a week, 3 weeks)

Category

Rehabilitation

3

Description

Intervention group 3 (VR): receiving virtual-vestibular rehabilitation (eight 45-minute sessions of Nintendo Wii fit plus exercises, twice a week, 4 weeks)

Category

Rehabilitation

4

Description

Intervention group 4 (VR+GVS): receiving virtual-vestibular rehabilitation and GVS

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

Hanieh Rajabi

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Grant name

Research project

Grant code / Reference number

1400-1-103-50857

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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Position

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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)

Yes - There is a plan to make this available

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
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

2023 and after
To whom data/document is available
All people
Under which criteria data/document could be used
Dissertation: In accordance with Tehran University of Medical Sciences copyright Paper: In accordance with the journal's policies to access the published paper
From where data/document is obtainable
Dissertation: The library of the School of Rehabilitation, TUMS Papers: Databases
What processes are involved for a request to access data/document
For the dissertation, studying in the library For papers depends on the journal's policy.
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