Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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)

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+98 21 7753 4364

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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.

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Tehran

Province
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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 - Tehran University of Medical Sciences

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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School of Rehabilitation, Pich-e-Shemiran, Enghelab Ave.

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pajoheshyar@sina.tums.ac.ir

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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Ph.D.

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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.

Comments