

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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 -  
Tehran University of Medical Sciences

##### Street address

Enghelab Ave.

##### City

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##### Province

Tehran

##### Postal code

1148956111

#### 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

##### **Street address**

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##### **City**

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##### **Province**

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##### **Postal code**

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+98 21 7753 0636

##### **Email**

madel@tums.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Hanieh Rajabi

##### **Street address**

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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## Person responsible for scientific inquiries

**Contact**

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Mansoureh Adel Ghahraman

**Position**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

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**Position**

Assistant Professor

**Latest degree**

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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**