

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparing the effectiveness of vestibular rehabilitation with and without galvanic vestibular stimulation on dizziness and postural control in patients with persistent postural-perceptual dizziness: A randomized controlled trial

Protocol summary

Study aim

Comparing the effectiveness of vestibular rehabilitation with and without galvanic vestibular stimulation on dizziness and postural control in patients with persistent postural-perceptual dizziness (PPPD): A randomized controlled trial

Design

Randomized controlled trial with parallel group on 27 patients. Randomization was carried out with Random Allocation Software.

Settings and conduct

Setting: Basra Teaching Hospital After baseline evaluations including the Modified Clinical Test of Sensory Interaction on Balance, dizziness handicap inventory, and Hospital Anxiety and Depression Scale, each patient will be randomly assigned to three groups VRT, VRT+GVS, and GVS (n= 9 in each group, n=27 total). All patients will be re-evaluated after intervention. The trial is not blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Diagnosed with persistent perceptual-postural dizziness with 3 months duration or more 2. 18 to 65 years of age Exclusion criteria: Catch a disease affecting the vestibular system during the study

Intervention groups

1- VRT group: receiving individualized vestibular rehabilitation 30 minutes twice a day for 6 weeks 2- VRT+GVS group: receiving individualized vestibular rehabilitation 30 minutes twice a day for 6 weeks and at the same time receiving noisy galvanic vestibular stimulation 30 minutes, one session per week for six weeks 3- nGVS group: receiving noisy galvanic vestibular stimulation 30 minutes, one session per week for six weeks

Main outcome variables

Path length (anteroposterior, mediolateral, and angle),

dizziness handicap inventory score, and Hospital Anxiety and Depression scale score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160131026279N6**

Registration date: **2023-09-18, 1402/06/27**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-18, 1402/06/27**

Update count: **0**

Registration date

2023-09-18, 1402/06/27

Registrant information

Name

Mansoureh Adel Ghahraman

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7753 4364

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-13, 1402/06/22

Expected recruitment end date

2025-08-13, 1404/05/22

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of vestibular rehabilitation with and without galvanic vestibular stimulation on dizziness and postural control in patients with persistent postural-perceptual dizziness: A randomized controlled trial

Public title
The effect of rehabilitation and galvanic vestibular stimulation on the treatment of persistent postural-perceptual dizziness (PPPD)

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosed with PPPD according to Barany Society Committee diagnostic criteria. The symptoms of 3 months duration or more No previous experience with vestibular exercises or rehabilitation 18 to 65 years of age Lack of previous drug or alcohol addiction No Current neurological disorder Lack of drug consumption that results in suppressing vestibular system compensation Not pregnant woman No current vestibular disease coexist with PPPD patients Lack of musculoskeletal issues that impair gait Absence of cognitive impairment No vestibular paroxysmia
Exclusion criteria:
Fatigue or unwillingness of the patient to continue the test Catch a disease affecting the vestibular system during the study

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **27**

Randomization (investigator's opinion)
Randomized

Randomization description
Method of randomization: block Unit of randomization: size 3, three equal groups Tools used in randomization: Random allocation software Random sequence generation: Random allocation software Allocation concealment: none Patients will be allocated to groups indicated in the sequence in order of enrolling in the study. For example, in a sequence of group 3, group 1, and group 2, the first patient will be allocated to group 3, and so on.

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

2023-09-03, 1402/06/12

Ethics committee reference number

IR.TUMS.FNM.REC.1402.124

Health conditions studied

1

Description of health condition studied

persistent postural-perceptual dizziness

ICD-10 code

H81.8

ICD-10 code description

Other disorders of vestibular function

Primary outcomes

1

Description

Path length (anteroposterior and mediolateral)

Timepoint

Before and after intervention

Method of measurement

The Modified Clinical Test of Sensory Interaction on
Balance

Secondary outcomes

1

Description

Angle of path length

Timepoint

Before and after intervention

Method of measurement

The Modified Clinical Test of Sensory Interaction on Balance

2**Description**

Dizziness handicap inventory score

Timepoint

Before and after intervention

Method of measurement

Dizziness handicap inventory

3**Description**

Hospital Anxiety and Depression Scale score

Timepoint

Before and after intervention

Method of measurement

Hospital Anxiety and Depression Scale

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

Intervention group 1 (VRT): receiving individualized vestibular rehabilitation 30 minutes twice a day for 6 weeks, in which the rehabilitation exercises are planned based on the patient's complaints and test results. Exercises include adaptation, gaze stabilization, and habituations which involve eye, head, and body movements.

Category

Rehabilitation

2**Description**

Intervention group 2 (VRT+GVS): receiving individualized vestibular rehabilitation 30 minutes twice a day for 6 weeks and noisy GVS 30 minutes, one session per week for six weeks, in which the rehabilitation exercises are planned based on the patient's complaints and test results. Exercises include adaptation, gaze stabilization, and habituations which involve eye, head, and body movements. The electrical stimulation (random bandwidth of less than 30 Hz, bipolar current, and sub-threshold intensity) is applied through electrodes placed over mastoid processes.

Category

Rehabilitation

3**Description**

Intervention group 3 (nGVS): receiving noisy GVS 30 minutes, one session per week for six weeks, in which the electrical stimulation (random bandwidth of less than 30 Hz, bipolar current, and sub-threshold intensity) is applied through electrodes placed over mastoid processes.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Basra Teaching Hospital

Full name of responsible person

Samer Sami Azeez Al-Saad

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Jaza'er, Abbasiyah

City

Basra

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42001

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Hamid Dalvand

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

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Grant name**Grant code / Reference number****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

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Audiology

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Full name of responsible person

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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

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

Data files containing all data will be uploaded via <https://zenodo.org/> after the deidentification of participants, named "Dataset of Comparing the effectiveness of vestibular rehabilitation with and without galvanic vestibular stimulation on dizziness and postural control in patients with persistent postural-perceptual dizziness: A randomized controlled trial"

When the data will become available and for how long

After the study ends and the paper is published for one year at least

To whom data/document is available

Public

Under which criteria data/document could be used

None

From where data/document is obtainable

<https://zenodo.org/>

What processes are involved for a request to access data/document

Searching the file name or author names in

<https://zenodo.org/> and downloading the file.
Comments