Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effects of Pink Noise Induction and Differential Resistance Exercise on Motor Performance Indicators and Balance in Elderly Individuals

Protocol summary

Study aim

To compare the effect of pink noise induction, differential resistance training, their combination, and a control condition on the Root Mean Square (RMS) of postural sway in the anterior-posterior (A-P) and medial-lateral (M-L) axes in older adults. To compare the effect of the four interventions on the duration of anticipatory postural adjustments (APAs). To compare the effect of the four interventions on the amplitude of compensatory postural adjustments (CPAs). To compare the effect of the four interventions on the frequency structure (spectral analysis) of the biceps brachii muscle activity during elbow flexion.

Design

A randomized, factorial, single-blind, sham-controlled clinical trial with four intervention groups (Pink Noise, Differential Training, Combined, and Control) conducted in a single phase. The study aims to enroll 48 community-dwelling older adults allocated via stratified block randomization with concealed allocation.

Settings and conduct

Single-center lab trial with one-session assessments before/after a 30-minute intervention. Single-blind: participants are blinded via identical sham/active devices; the outcome assessor is unblinded.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Aged 65 years or older. Ability to stand independently without assistive devices. No diagnosed neurological or musculoskeletal disorders affecting balance. Exclusion: Vestibular disorders or severe visual/hearing impairments. Recent history of falls (within the past 6 months).

Intervention groups

Pink Noise Group (nGVS only) Differential Training Group (Exercise only) Combined Group (nGVS + Exercise) Sham Control Group

Main outcome variables

Postural control and balance/ Anticipatory and compensatory postural adjustments/ Postural stability/ Balance performance in older adults/

General information

Reason for update

Acronym

nGVS

IRCT registration information

IRCT registration number: **IRCT20251124068097N1**
Registration date: **2026-05-28, 1405/03/07**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-28, 1405/03/07**
Update count: **0**

Registration date

2026-05-28, 1405/03/07

Registrant information

Name

Ahmadreza Dehghani

Name of organization / entity

Shiraz University

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-02-19, 1404/11/30

Expected recruitment end date

2026-09-21, 1405/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Pink Noise Induction and Differential Resistance Exercise on Motor Performance Indicators and Balance in Elderly Individuals

Public title

Neuromodulation Techniques and Improving Balance

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Aged 65 years or older Ability to stand independently without assistive devices Ability to follow simple instructions and perform basic movements No diagnosed neurological or musculoskeletal disorders affecting balance. Willing to provide informed consent Resident of Shiraz and accessible for follow-up

Exclusion criteria:

History of severe cardiovascular, respiratory, or metabolic diseases Use of medications that significantly affect balance or muscle function Recent history of falls (within the past 6 months) Vestibular disorders or severe visual/hearing impairments Participation in another structured exercise program in the past 3 months Inability to complete the training protocol or attend sessions regularly

Age

From **60 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

After baseline assessments and confirmation of eligibility criteria, eligible participants will enter the randomization process. To ensure balanced group sizes and reduce the risk of selection bias, participants will be allocated using a block randomization method. The random allocation sequence will be generated using computer-based randomization software, and variable block sizes (e.g., blocks of 4 and 8) will be used to minimize predictability of group assignment for both researchers and participants. After enrollment, participants will be randomly assigned to one of the following four study groups: Pink Noise Galvanic Vestibular Stimulation group (nGVS only) Differential Resistance Training group (exercise only) Combined Intervention group (nGVS + Differential Resistance Training) Control (Sham) group The random sequence generation and maintenance of allocation codes will be performed by a researcher who is not involved in participant recruitment, outcome assessment, or implementation of the interventions. To ensure allocation concealment, group assignments will be placed in sequentially numbered, opaque, sealed envelopes. After completion of baseline assessments and final enrollment of each participant, the corresponding envelope will be opened by the responsible researcher to determine the assigned study group. All participants will have an equal chance of being allocated to any of the four study groups. In addition, the outcome assessor will remain blinded to participants' group assignments in order to minimize assessment bias.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will use a single-blind design. Participants will be blinded to their assigned intervention group, and they will not be informed about the differences between the active and control conditions. In the sham control group, electrodes will be placed on the mastoid processes in the same manner as in the active stimulation group, and the preparation procedures and session duration will be identical to those of the intervention groups, except that no effective electrical current will be delivered. Therefore, participants will not be aware of whether they are receiving active or sham stimulation. Due to the nature of the exercise intervention, the researcher responsible for administering the training sessions and interventions will be aware of group allocation, and complete blinding of the intervention provider is not feasible. However, outcome assessments will be conducted using standardized and identical procedures for all participants in order to minimize assessment bias. In addition, data analysis will be performed using coded group labels to help maintain objectivity during interpretation of the results.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethic committee shiraz university

Street address

Eram street. Shiraz university

City

shiraz

Province

Fars

Postal code

7156837144

Approval date

2025-07-09, 1404/04/18

Ethics committee reference number
IR.US.REC.1404.006

Health conditions studied

1

Description of health condition studied
Primary Health Condition: Age-related decline in balance and postural control (pre-frailty/frailty associated with aging). Related Terms (for visibility): Fall risk in elderly, Sarcopenia, Sensorimotor decline, Postural sway, Neuromuscular aging
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Root Mean Square (RMS) of the Center of Pressure (COP) in the anterior-posterior (AP) axis during quiet standing (eyes open), measured in millimeters (mm).
Timepoint
The primary outcome (RMS of COP in the AP axis) will be measured at two time points: Baseline (T0): Immediately before the start of the 30-minute intervention session. Post-Intervention (T1): Immediately after the completion of the same 30-minute intervention session.
Method of measurement
The primary outcome variable (RMS of COP in the AP axis) will be measured using a force platform (force plate). Participants will stand quietly on the plate for 30 seconds, and ground reaction force data will be sampled at 1000 Hz. The center of pressure (COP) trajectory will be calculated from this data, and its root mean square (RMS) value in the anterior-posterior direction will be derived using signal processing software (e.g., MATLAB).

Secondary outcomes

1

Description
Secondary Outcome Variables:COP Dynamics: Mean velocity of COP displacement, sample entropy of COP, and Romberg ratio in both anterior-posterior and medial-lateral axes.Postural Control: Duration and amplitude of anticipatory postural adjustments (APA) and amplitude of compensatory postural adjustments (CPA).Neuromuscular Function: Maximum torque of the elbow joint during isokinetic flexion, and the frequency structure (spectral analysis) of biceps brachii EMG activity during elbow flexion.
Timepoint
The secondary outcome variables will be measured at the same two time points as the primary outcome:Baseline (T0): Immediately before the start of the 30-minute intervention session.Post-Intervention (T1): Immediately after the completion of the same 30-minute intervention session.
Method of measurement
Secondary Outcome Measurement Methods: COP Dynamics (Velocity, Sample Entropy, Romberg Ratio): Measured using the same force platform as the primary outcome, with data processed in MATLAB. Postural Control (APA & CPA): Measured using a force platform synchronized with surface EMG and an accelerometer attached to a pendulum. The EMG onset and amplitude from trunk/leg muscles are analyzed before and after a predictable perturbation (pendulum hit). Neuromuscular Function (Torque & EMG Spectrum): Measured using an isokinetic dynamometer for maximum elbow flexion torque and surface EMG on the biceps brachii muscle. The EMG signal is processed via Fast Fourier Transform (FFT) to analyze its frequency structure.

Intervention groups

1

Description
Intervention group: Pink Noise Galvanic Vestibular Stimulation (nGVS only) Participants receive 30 minutes of subsensory, transcutaneous pink noise electrical stimulation via electrodes on the mastoid processes.
Category
Treatment - Devices

2

Description
Intervention group: Differential Resistance Training (exercise only). Participants perform 30 minutes of variable medicine ball throwing/catching exercises with constant changes in stance and movement pattern.
Category
Behavior

3

Description
Intervention group: Combined Intervention (nGVS + Exercise) Participants simultaneously receive both the 30-minute pink noise nGVS and the 30-minute differential resistance training.
Category
Treatment - Other

4

Description
Control group: Sham: Participants undergo an identical 30-minute setup with electrodes placed but receive zero current stimulation and perform no exercise.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Soroush Daily Rehabilitation Center for the Elderly

Full name of responsible person
miss Sokut

Street address
Shiraz, Mirza Shirazi Boulevard, 16 Meters Dinkon (Alley), Opposite Alavi Park, No. 30.

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there isn't

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University

Full name of responsible person
Dr. Maryam Koushkie Jahromi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
university (professor's grant)

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
Shiraz University

Full name of responsible person
Ahmadreza Dehghani

Position
PhD candidate

Latest degree
Master

Other areas of specialty/work
Exercise Physiology

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Full name of responsible person
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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All deidentified individual participant data (IPD) collected for the primary and secondary outcomes in this study will be shared. This includes: Baseline demographic data (age group, sex, and fall risk category). Pre- and post-intervention data for: Primary Outcome: RMS of COP in AP axis. Secondary Outcomes: All other COP measures (velocity, sample entropy, Romberg ratio in AP/ML), APA/CPA parameters, maximum elbow torque, and biceps EMG frequency spectrum indices. Group allocation code.

When the data will become available and for how long

Availability Start Date: The deidentified IPD and supporting documents will become available 6 months after the publication of the primary results of this trial in a peer-reviewed journal. Availability Period: The data and documents will be made available for a minimum period of 5 years from the start date.

To whom data/document is available

Deidentified IPD and supporting documents will be shared with any qualified researcher worldwide, irrespective of their affiliation (academic, commercial, or non-profit), provided they submit a methodologically sound research proposal for approval. Eligible Recipients: Researchers from academic institutions, healthcare organizations, industry (e.g., medical device or pharmaceutical companies), and independent research consortia. Access Criteria: Requestors must submit a detailed proposal outlining the scientific objective, analysis plan, and ethical considerations to the study's principal investigator or a designated data access committee. Access will be granted for legitimate scientific inquiry aimed at validation, meta-analysis, or novel secondary analysis. Requestors will be required to sign a data use agreement prohibiting attempts to re-identify participants or misuse the data.

Under which criteria data/document could be used

Types of Analyses: Data will be shared for purposes of scientific validation, meta-analysis, or novel secondary research related to aging, sensorimotor function, neurorehabilitation, and balance. Proposals for commercial product development require explicit justification and additional oversight. Review Process: All data access requests will be reviewed by a two-tier committee: Tier 1 (Feasibility & Ethics): The Principal Investigator (PI) and the study's ethics committee representative. Tier 2 (Scientific Merit): An independent panel of two experts in motor control, geriatrics, or biostatistics. Review Criteria: Proposals will be evaluated based on Scientific Rigor: Sound methodology and a clear analysis plan. Ethical Alignment: No intent for re-identification or harmful use. Resource Feasibility: Reasonable scope that can be supported by the provided data. Non-Redundancy: The analysis should not duplicate already published work from the primary team. Access Mechanism: Approved researchers will be granted access via a secure, cloud-based data repository (e.g., Figshare, Zenodo, or a university-managed platform). Data will be provided in standard formats (e.g., .csv, .sav) along with a comprehensive data dictionary and analysis codebook. Agreement: Successful applicants must sign a Data Transfer/Use Agreement (DTUA) legally binding them to the approved use, data security standards, publication ethics (including co-authorship or acknowledgment as per contribution), and destruction of data after the project.

From where data/document is obtainable

Primary Contact & Communication: All requests for data and documents must be initiated via email to the designated study contact. Contact Person: Ahmadreza Dehghani, Ph.D. in Exercise Physiology Email:

adehghani4d@gmail.com/Shiraz University Subject Line: Data Access Request: Pink Noise & Balance Study Secondary Contact (Administrative): For procedural inquiries, a research coordinator can be contacted. Professor Maryam Koushkie Jahromi Email: koushkie53@yahoo.com

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

Access Timeline: Approved applicants can expect to receive the data files approximately 2 weeks after their proposal is formally approved and the signed data use agreement is returned.

Comments

Intellectual Property: Researchers using the shared data are encouraged to collaborate with the original study team. Co-authorship on publications will be offered based on substantial intellectual contribution, as per ICMJE guidelines. All publications must acknowledge the original study and funding source. Costs: There is no fee for accessing the data. However, requestors are responsible for any costs associated with data analysis, secure storage, and their own publication fees. Updates: The shared data will be the final, cleaned version used for the primary publication. Corrections or updates will be versioned and noted in the repository. Ethical Re-Use: Any secondary research using this data must obtain its own ethical approval if required by the researcher’s institution or local regulations.