Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of two training methods Otago and dynamic neuromuscular stabilization on kinetic, spatio-temporal parameters of gait and balance performance in elderly women with a history of falls

Protocol summary

Study aim

To investigate and compare the effects and durability of an 8 week Otago versus DNS on kinetic and spatio-temporal gait parameters and balance performance in elderly women with a history of falls.

Design

A single-center, three-arm parallel-group randomized controlled trial with blinded outcome assessment. Total participants will be allocated to Otago, DNS, or control groups via block randomization (block size 6).

Settings and conduct

Tehran, Iran. Assessments: in a biomechanics lab. Exercise sessions: fully supervised. The outcome assessor and statistical analyst: blinded to group allocation.

Participants/Inclusion and exclusion criteria

Women aged 65–85 with ≥1 fall in the previous 12 months, able to walk independently ≥10 m without a assistive device, and providing written informed consent. Excluded: acute neurological or lower-limb musculoskeletal disorders; severe pain or untreated visual/vestibular disorders affecting exercise/balance; inability to participate safely; or concurrent exercise/rehabilitation program. Withdrawn: consent withdrawal; missing >20% of sessions or 3 consecutive sessions; injury/acute illness preventing participation; or major medication changes affecting neuromuscular function.

Intervention groups

Otago group: 8-week structured Otago (lower-limb strengthening and balance), 3 supervised sessions/week (~45–60 min). DNS group: 8-week supervised functional DNS exercises (intra-abdominal pressure, core stability, developmental patterns), 3 sessions/week (~45–60 min). Control group: routine daily activities without structured exercise for 8 weeks. Follow-up: after 4 weeks and a follow-up assessment

Main outcome variables

Static balance (Biodex stability and sway indices; BESS), dynamic balance (Biodex limits of stability and motor control; Berg Balance Scale), and fall risk (TUG), measured at baseline, post-8-week intervention, and 4-week follow-up.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260907070953N1**
Registration date: **2026-11-22, 1405/09/01**
Registration timing: **prospective**

Last update: **2026-11-22, 1405/09/01**
Update count: **0**

Registration date

2026-11-22, 1405/09/01

Registrant information

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Ali Fatahi

Name of organization / entity

Islamic Azad Univercity, Central Tehran Branch

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-11-30, 1405/09/09

Expected recruitment end date
2027-05-09, 1406/02/19
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of two training methods Otago and dynamic neuromuscular stabilization on kinetic, spatio-temporal parameters of gait and balance performance in elderly women with a history of falls

Public title
Comparison of Otago and Dynamic Neuromuscular Stabilization (DNS) exercises on elderly
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Female gender and age range of 65 to 85 years; A history of at least one fall in the past 12 months (based on a fall history questionnaire, self-report, and regular telephone follow-up over the year); Ability to walk independently for a distance of at least 10 meters without the assistance of a fixed assistive device; Absence of acute neurological disorders (e.g., stroke, Parkinson's disease, spinal cord injury) or active musculoskeletal disorders in the lower extremities; Absence of severe chronic lower extremity pain that would prevent exercise performance; Absence of severe untreated visual and vestibular disorders; Providing written informed consent to participate in the study.
Exclusion criteria:
Excessive absence from training sessions (more than 20% of total sessions or three consecutive sessions); Injury during the exercise intervention that makes continued participation impossible; Significant changes in medication regimens affecting the neuromuscular system (e.g., sedatives or newly prescribed antihypertensive medications that affect balance); Hospitalization or occurrence of an acute illness during the study; Experiencing a re-fall with serious injury during the evaluation intervals; Initiation of concurrent participation in another exercise or rehabilitation program (confounding training); Participant's request to withdraw from the study.
Age
From **65 years** old to **85 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomized into three groups (Otago, DNS and Control) using a block randomization method with a block size of 6 to ensure equal group sizes throughout the recruitment process. The unit of randomization is the individual. Computer software (SPSS, version 26) will be used to generate the random allocation sequence. Allocation concealment will be strictly maintained using sequentially numbered, opaque, sealed envelopes (SNOSE), which will be prepared by an independent researcher who is not involved in the participants' recruitment, assessment, or intervention process. The envelopes will be opened only after the participant is enrolled in the study and baseline assessments are completed.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
A three-arm parallel-group randomized controlled trial with a follow-up assessment period

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Islamic Azad University-Central Tehran Branch
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Approval date
2026-01-08, 1404/10/18
Ethics committee reference number
IR.IAU.CTB.REC.1404.245

Health conditions studied

1

Description of health condition studied
Elderly women with a history of falls
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Balance performance (Berg Balance Scale score)
Timepoint
Will be performed at three time points: 1) baseline (before the start of the intervention); 2) immediately after the end of the 8-week intervention (week 8); 3) after 4 weeks without training (follow-up, week 12) to assess the durability of the effect
Method of measurement
The test requires a chair without armrests, a stopwatch, a ruler, and a step stool. The 14 tasks include:Sitting to standingStanding unsupported (for 2 minutes)Sitting unsupported (for 2 minutes)Standing to sittingTransfers (from chair to bed and back)Standing with eyes closed (10 seconds)Standing with feet togetherReaching forward with outstretched arm while standingRetrieving an object from the floor from a standing positionTurning to look behind over the left and right shoulders while standingTurning 360 degreesPlacing alternate foot on step or stool while standing unsupportedStanding unsupported with one foot in front (Tandem stance)Standing on one legScoring:0 = Requires maximum assistance4 = Independent and safeInterpretation: Scores of 41-56 indicate good/independent balance; 21-40 indicate medium balance/requiring assistance; 0-20 indicate poor balance

Secondary outcomes

1

Description
Spatial-temporal gait parameters:These are the unique gait characteristics of each individual, which are assessed using laboratory instruments.
Timepoint
Secondary outcomes will be measured at three time points: baseline (before the start of the intervention), immediately after the end of the 8-week intervention (week 8), and after a 4-week follow-up without training (week 12).
Method of measurement
Spatio-temporal gait parameters are measured using an instrumented treadmill with embedded force plates. The individual performs the two-minute Gait-treadmill walking test as follows: The participant walks on the treadmill for two minutes at a self-selected, preferred speed. This trial is performed three times, and the average of the three trials is recorded as the test score.

Intervention groups

1

Description
Intervention group: Otago. The group receives a structured Otago program for 8 weeks, 3 sessions per week, each lasting approximately 45 to 60 minutes, under full supervision. Each session includes a warm-up, 17 specific muscle strengthening and balance exercises (5 strengthening exercises for lower-limb muscles and 12 balance exercises), and a cool-down. Strengthening exercises are performed using ankle weights and are progressed gradually. Balance exercises include static and dynamic patterns such as standing on one leg, heel-toe walking, and sideways walking, performed at different levels of difficulty. In addition to the exercises, a walking program is also included. All sessions are held by trained instructors in a gym environment.
Category
Rehabilitation

2

Description
Intervention group: DNS,: Dynamic Neuromuscular Stabilization (DNS). This group receives functional DNS exercises for 8 weeks, 3 sessions per week, each lasting approximately 45 to 60 minutes, under full supervision. Each session includes a warm-up, specific DNS exercises, and a cool-down. The exercises emphasize generating and maintaining intra-abdominal pressure, core stability, correct activation of trunk and limb muscles, and retraining developmental movement patterns. Exercises are progressed gradually from simple stabilizing patterns to more complex functional patterns. All sessions are held by trained instructors in a gym environment.
Category
Rehabilitation

3

Description
Control group: During the 8-week study period, participants receive no structured exercise intervention and maintain only their routine daily activities. They are asked not to participate in any new structured exercise or rehabilitation program during this period. Outcome assessments are performed at the same time points as the intervention groups (baseline, week 8, and week 12).
Category
Rehabilitation

Recruitment centers

1

Recruitment center
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Sponsors / Funding sources

1

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Grant name
Research Vice-Chancellor, Tehran Central Branch, Islamic Azad University
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Individual participant data will not be shared because the dataset contains sensitive health and biomechanical information from a small sample of elderly women, and the study team does not have the infrastructure or resources to manage secure de-identification, access control, and data use agreements for IPD sharing. To protect participant confidentiality, only aggregated results will be reported in publications, while the study protocol, statistical analysis plan, analytic code, and data dictionary will be shared as described in the data sharing plan.

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

No - There is not a plan to make this available

Clinical Study Report

Not applicable

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

Title: Study Protocol Details: The full study protocol, including study design, eligibility criteria, intervention details, outcome measures, and sample size calculation, will be shared after publication of the main results as a supplementary file or upon reasonable request to the corresponding author. Title: Statistical Analysis Plan Details: The statistical analysis plan describing primary and secondary outcome analyses, between-group comparisons, handling of missing data, and statistical software will be shared after publication of the main results as a supplementary file or upon reasonable request. Title: Analytic Code Details: The statistical analysis code (e.g., R or SPSS syntax) used for all outcome analyses, containing no participant identifiers, will be shared after publication of the main results as a supplementary file or upon reasonable request. Title: Data Dictionary Details: The data dictionary including variable names, definitions, units of measurement, and coding for all outcome measures (Biodex indices, BBS, TUG, BESS, and gait parameters) will be shared after publication of the main results as a supplementary file or upon reasonable request.

When the data will become available and for how long

The shared documents and data (Study Protocol, Statistical Analysis Plan, Analytic Code, and Data Dictionary) will become available 6 months after publication of the main trial results and will remain available for 5 years from that date. Access will be provided as supplementary files with the published article and/or upon reasonable request to the corresponding author.

To whom data/document is available

Available to all researchers, including those in academic institutions and industry, for non-commercial research purposes, upon reasonable request and Ethics Committee approval.

Under which criteria data/document could be used

Available for non-commercial academic research, including verification and replication of the published analyses, upon a written request describing the intended use, review and approval by the corresponding author and the Ethics Committee, and signing a data use agreement. Re-identification, redistribution, and commercial use are prohibited.

From where data/document is obtainable

Requests should be sent by email to the corresponding author, Ali Fatahi, at alifatahi@iau.ac.ir ,Applicants are requested to include their name, institutional affiliation, the purpose of the request, and the specific document(s) or data they wish to obtain.

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

Applicants should submit a written request by email to the corresponding author, including their name, affiliation, purpose of use, and the specific documents/data requested. The request will be reviewed by the corresponding author. If approved, the applicant will be asked to sign a data use agreement confirming non-commercial academic use, secure storage, no re-identification, and no redistribution. After signing, the requested documents/data will be provided electronically. The review and approval process is expected to take approximately 4–6 weeks from receipt of a complete request.

Comments

Not applicable