Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of proprioceptive neuromuscular facilitation techniques in comparison with aerobic exercises on functional balance, fear of falling and quality of life in elderly-a randomized controlled trial

Protocol summary

Study aim
To investigate the effectiveness of proprioceptive neuromuscular facilitation techniques in comparison with aerobic exercises on functional balance, fear of falling and quality of life in elderly

Design
Clinical trial with control group, Parallel groups, assessor-blinded, randomized, on the 58 older adults, block balanced randomization, 4-letter blocks

Settings and conduct
Study will be done in nursing homes in Tehran province and IUMS school of rehabilitation. Participants with block balanced randomization are placed in one of two intervention groups. Primary and secondary outcomes will be recorded before starting and after the end of 4 weeks of intervention for statistical analysis. This study will be based on the blinding method in which the assessor will unaware of the grouping, not only before the intervention but also after that.

Participants/Inclusion and exclusion criteria
Inclusion critria: people over 60 years old, Mini-mental state examination score greater than or equal to 24, not to use assistive devices during walking, the ability to stand without assistive device, absence of any physical and movement restrictions in pelvic, hip and knee joints, ability to exercise for 30 minutes, Berg test score between 21 to 48. Exclusion critria: neuromusculoskeletal disease, neurological deficit, psychological disease, general medical problems, neuropathy according to diabetes, neurovestibular disease, unstable or ongoing cardiovascular/respiratory disorders, hearing and visual impairement, frequent performance of PNF techniques in the past

Intervention groups
Group A: Rhythmic stabilization and Stabilizing reversal techniques in lower trunk Group B (control): aerobic exercises (walking) Both of groups will participate in 12 sessions during 4 weeks.

Main outcome variables
Functional balance; fear of falling; quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210505051181N4**
Registration date: **2023-02-09, 1401/11/20**
Registration timing: **prospective**

Last update: **2023-02-09, 1401/11/20**
Update count: **0**

Registration date
2023-02-09, 1401/11/20

Registrant information

Name
Mehrnaz Kajbafvala

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-20, 1401/12/01

Expected recruitment end date
2023-09-21, 1402/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of proprioceptive neuromuscular facilitation techniques in comparison with aerobic exercises on functional balance, fear of falling and quality of life in elderly-a randomized controlled trial

Public title
Comparison of the effect of proprioceptive neuromuscular facilitation techniques and aerobic exercises in elderly
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
People over 60 years old Mini-Mental state examination score ≥24 Not to use assistive devices during walking The ability to stand without assistive device Absence of any physical and movement restrictions in pelvic, hip and knee joints to participate in exercises and tests Ability to exercise for 30 min Walking 30 m or more without assistance Literate people Berg test score between 21 to 48
Exclusion criteria:
Neuromusculoskeletal disease, Severe and mobility limiting arthritis, Ankle surgery and instability, Lower limb nerve injury (neuropathy), Back and lower limb injury (symptoms within the last 6 months), Structural deficit, History of lower limb fracture within the last 10 years, Severe osteoporosis Neurological deficit, Psychological disease, Anticonvulsant drug use, Dementia, Sedative use General medical problem, Neuropathy according to diabetes, Renal and liver disease, Current acute illness or pain, Cancer and autoimmune disease Neurovestibular (vestibular) disease Unstable or ongoing cardiovascular/respiratory disorders Hearing loss (do not use hearing aids) and visual impairment (cannot see) Frequent performance of PNF in the past
Age
From **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **58**
Randomization (investigator's opinion)
Randomized
Randomization description
The people of both groups are identical in terms of demographic characteristics and are randomly divided into one of the two treatment groups with a ratio of 1:1. Random allocation is done using block balanced randomization, which includes 4-letter blocks of letters A and B. This treatment allocation is placed in numbered envelopes consisting of letters A and B. The person who sit up the randomization sequence will not involved in any of the phases of research process. Group A includes rhythmic stabilization and stabilizing reversal techniques. Group B includes aerobic exercises. After initial evaluations by the assessor, numbered envelopes which were prepared based on a consecutive number are provided to each person participating in the study. In addition, therapeutic intervention is adjusted according to the letters in the envelope. The assessor will not aware of this.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The present research will be based on the blinding method in which the assessor will unaware of the grouping, not only before the intervention but also after that.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Near Milad Tower, Hemmat Highway
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۱۴۴۹۶۱۴۵۳۵
Approval date
2023-02-06, 1401/11/17
Ethics committee reference number
IR.IUMS.REC.1401.914

Health conditions studied

1

Description of health condition studied
Aging
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Functional balance
Timepoint
Before starting the intervention and after the four weeks intervention
Method of measurement
Functional balance tests:1-Berg balance scale 2-Functional reach test 3-Timed up and go test

Secondary outcomes

1

Description
fear of falling
Timepoint
Before starting the intervention and after the four weeks intervention
Method of measurement
Persian version of fall efficacy scale questionnaire-international form

2

Description
Quality of life
Timepoint
Before starting the intervention and after the four weeks intervention
Method of measurement
Persian version of World Health Organization quality of life questionnaire-Older Adults Edition

Intervention groups

1

Description
Intervention group (group A):The elderly will treat 3 days a week for 4 weeks having a total of 12 sessions. Before starting the exercises, 5 to 7 minutes active warm-up is be done. Each exercise has 3 repetitions and each repetition takes 15 seconds. 1- Whole body stretch (clasped hands are stretched above the head). 2- Upper trapezius muscle stretch 3- Wrist flexor muscles stretch 4- Wrist extensor muscles stretch 5- Lunge movement. Then the rhythmic stabilization technique is performed in lower trunk. After 2 minutes of rest, the stabilizing reversal technique is performed in the same body part. Each technique is performed in 3 sets and there are 10 repetitions in each set. There are 60 seconds rest between sets and 30 seconds rest between repetitions. Performing and holding each repetition of both rhythmic stabilization and stabilizing reversal techniques takes 10 seconds. Rhythmic Stabilization Technique: This technique utilizes isometric agonist and antagonist muscles co-contraction. Performing this technique, we don’t have any movement. As a result, the older adult has a verbal command like: "Don't let me move you. Hold on." The person is in a sitting position and this technique will be perform on the trunk flexors and extensors. Stabilizing Reversal Technique: The position of the person to perform this technique is similar to rhythmic stabilization technique, there is just a difference. This technique utilizes alternating isotonic contractions of first agonist muscle, then without any rest antagonist muscle. The time needed to perform all PNF techniques is about 40 minutes. Ending the exercises we require a 6-minute cool-down, which includes:1. performing a stretching exercise in supine position, where the person bends the knees and holds them with both hands and will pull them towards himself. There are 2 repetitions, each repetition takes about 20-30 Seconds.2.The person will relax the body in supine position while closing eyes for 5 minutes (shavasana relaxation).
Category
Rehabilitation

2

Description
Control group (group B): The elderly will treat 3 days a week for 4 weeks and there will be a total of 12 sessions. Before starting the exercises, we have 5 to 7 minutes of active warm-up so that there are 3 repetitions of each exercise and each repetition holds for 15 seconds. 1. Whole body stretch (clasped hands are stretched above the head.) 2- Upper trapezius muscle stretch 3- Wrist flexor muscles stretch 4- Wrist extensor muscles stretch 5- Lunge movement. Then the elderly will walk for 40 minutes outdoors under the supervision of the therapist. While walking, the Accupedo Pedometer software will use as a step counter application. Consequently, the elderly will encourage to increase the number of steps. Ending the exercises, we have a 6-minute cool-down, which includes 1. Performing a stretching exercise in supine position, where the person bends the knees and holds them with both hands and will pull them towards themselves. There are 2 repetitions and each repetition takes 20-30 seconds.2.The person will relax the body in supine position closing eyes for 5 minutes (shavasana relaxation).
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
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Full name of responsible person
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2

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Sponsors / Funding sources

1

Sponsor
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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
Iran 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
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1545913487
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Email
ansari77mina@gmail.com

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
Data can be shared after making participants unrecognizable.
When the data will become available and for how long
Start access period 6 months after the results publication
To whom data/document is available
People in medicine and rehabilitation field
Under which criteria data/document could be used
Performing any analysis to any data resulted form this study will be allowed only with the permission of corresponding author.
From where data/document is obtainable
Email the researcher- Mina Ansari Eshlaghi- ansari77mina@gmail.com
What processes are involved for a request to access data/document
6 months after the publication of the results, information will be given to the applicant within a week by emailing the researcher.
Comments