

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 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 be unaware of the grouping, not only before the intervention but also after that.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 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 criteria: neuromusculoskeletal disease, neurological deficit, psychological disease, general medical problems, neuropathy according to diabetes, neurovestibular disease, unstable or ongoing cardiovascular/respiratory disorders, hearing and visual impairment, 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

Country

Iran (Islamic Republic of)

Phone

+98 21 2304 6688

Email address

kajbafvala.m@iums.ac.ir

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

City

Tehran

Province

Tehran

Postal code

1449614030

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

School of rehabilitation, Iran University of Medical Sciences

Full name of responsible person

Dr. Mehrnaz Kajbafvala

Street address

Department of Physiotherapy, School of rehabilitation Iran University of Medical Sciences, Madadkaran St., Shah Nazari Ave, Madar Square, Mirdamad Blvd

City

Tehran

Province
Tehran
Postal code
1545913487
Phone
+98 21 2222 2059
Email
rehab@iums.ac.ir

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

2

Recruitment center

Name of recruitment center
Fereshtegan Fajr Asemani Charity Residence
Full name of responsible person
Mina Ansari Eshlaghi
Street address
Fereshtegan Fajr Asemani Charity Residence, Behind
the Gas Station, Shahid Ehsani Rad Street,
Hasanabad-e Khaleseh, Ahmadabad-e Mostowfi
City
Ahmadabad-e Mostowfi
Province
Tehran
Postal code
3313185585
Phone
+98 21 5627 6795
Email
info@mkffa.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Hossein Keyvani
Street address
Iran University of Medical Sciences, Shahid Hemmat
Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2504
Email
research@iums.ac.ir
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

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mina Ansari Eshlaghi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
Department of Physiotherapy, School of Rehabilitation
Science, Iran University of Medical Sciences,
Madadkaran St., Shah Nazari Ave, Madar Square,
Mirdamad Blvd
City
Tehran
Province
Tehran
Postal code
1545913487
Phone
+98 21 2222 2059
Email
ansari77mina@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Mehrnaz Kajbafvala
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Shahid Dastgerdi (Zafar) Ave, Aliasghar Children
Hospital
City
Tehran
Province
Tehran
Postal code
1919816766

Phone

+98 21 2304 6688

Email

kajbafvala.m@iums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Mina Ansari Eshlaghi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

Department of Physiotherapy, School of Rehabilitation
Science, Iran University of Medical Sciences,
Madadkaran St., Shah Nazari Ave, Madar Square,
Mirdamad Blvd

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 2059

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 from 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