Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of locomotor training and aerobic exercise on balance, fear of falling, and lower limb strength in elderly women locomotive syndrome

Protocol summary

Study aim
Determining the effect of locomotor and aerobic exercise on balance, fear of falling, and lower limb strength in elderly women with Locomotive syndrome

Design
The clinical trial will have two experimental groups and a control group. It will be a single-blind, randomized trial on 45 elderly women with Locomotive syndrome.

Settings and conduct
The (Locomotor Exercises) group will perform locomotor exercises for 8 weeks (three sessions per week), including: standing on one leg, squats, heel raises, and forward lunges. The (Locomotor and Aerobic Exercises) group: In addition to locomotor exercises, this group will perform aerobic exercises for 30 minutes. The control group will not receive any intervention. This trial will take place in a gym in Arak.

Participants/Inclusion and exclusion criteria
Elderly women withLocomotive syndrome, 60 years and older Having individual independence in performing personal and health matters No history of surgery in the lower extremities within the past 2 years No history of degenerative joint diseases

Intervention groups
Experimental group 1. Locomotor and aerobic exercises. Experimental group 2. Locomotor exercises. Group 3. Control

Main outcome variables
Locomotor and aerobic exercise training have an effect on balance, fear of falling, and lower limb strength in elderly women with Locomotive syndrome.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230619058528N2**
Registration date: **2025-04-10, 1404/01/21**
Registration timing: **registered_while_recruiting**

Last update: **2025-04-10, 1404/01/21**
Update count: **0**

Registration date
2025-04-10, 1404/01/21

Registrant information

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Zahra Geramipour

Name of organization / entity
The univesity of arak

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-05, 1404/01/16

Expected recruitment end date
2025-06-06, 1404/03/16

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of locomotor training and aerobic exercise on balance, fear of falling, and lower limb strength in elderly women locomotive syndrome

Public title
The effect of locomotor training and aerobic exercise on

elderly people with locomotive syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Elderly women with Locomotor syndrome, 60 years and older Having individual independence in personal and health matters No history of lower limb surgery within the past 2 years. No history of degenerative joint diseases

Exclusion criteria:

Inability to perform daily activities and health care History of fractures and surgery in the lower extremities within the last 2 years Elderly people with MS or Parkinson's disease Absence of more than 3 training sessions

Age

From **60 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

The research population will consist of 45 women aged 60 and above with Locomotor syndrome. The number of samples was obtained using G-power software for each of the three groups of 45 people (locomotor exercises combined with aerobic exercises (15 people), locomotor exercises (15 people), and control (15 people)). The groups will be selected by simple random selection.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants are unaware of the division into control and experimental groups.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University

Street address

Arak University, Karbala Boulevard, Basij Square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848177584

Approval date

2025-03-12, 1403/12/22

Ethics committee reference number

IR.ARAKU.REC.1403.092

Health conditions studied

1

Description of health condition studied

Locomotive syndrome

ICD-10 code

G12.29

ICD-10 code description

Other motor neuron disease

Primary outcomes

1

Description

Dynamic balance

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Time to get up and go test

2

Description

Static balance

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Four-Step Balance Test (FsBT)

3

Description

Fear of falling

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Fear of Falling Questionnaire (FES-I)

4

Description

Lower limb strength

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement
30-second sit-to-stand test (30sCST)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1: Locomotor Exercises Combined with Aerobic ExercisesThe locomotor exercises include four types of movements:1. Single-leg stance: This exercise is performed for one minute. If the elderly participants feel unsteady, they can hold onto a chair for support.2. Squats: Performed by bending the knees to a 90-degree angle while holding onto a chair for support. This exercise is done in three sets of six repetitions.3. Heel raises: Executed in three sets of ten repetitions, with a four-count lift and a four-count lower.4. Forward lunges: Taking a step forward as far as possible while maintaining an upright posture. This exercise is performed in three sets of five repetitions.Aerobic exercises for the elderly include activities with low to moderate intensity (40–70% of maximum heart rate) to improve cardiorespiratory endurance, strengthen muscles, and maintain joint flexibility. This section includes:5 minutes of warm-up20 minutes of brisk walking5 minutes of recoveryThese exercises will be conducted for 8 weeks, three sessions per week, with 15 participants.
Category
Prevention

2

Description
Intervention Group 2: (Locomotor Exercises)These exercises include four types of movements:1. Single-leg stance: This exercise is performed for one minute. If the elderly participants feel unsteady, they can hold onto a chair for support.2. Squats: Performed by bending the knees to a 90-degree angle while holding onto a chair for support. This exercise is done in three sets of six repetitions.3. Heel raises: This exercise is performed in three sets of ten repetitions with a four-count lift and a four-count lower.4. Forward lunges: Taking a step forward as far as possible while maintaining an upright posture. This exercise is performed in three sets of five repetitions.These exercises will be conducted for 8 weeks, three sessions per week, and with 15 participants.
Category
Prevention

3

Description
Control Group:This group will include 15 participants who will not receive any intervention for 8 weeks.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Hygia Corrective Exercise Center
Full name of responsible person
فرید ثاقبی
Street address
Hygia Corrective Exercise Center, Golha Alley, Abbas Abad Street, Arak
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University
Full name of responsible person
Mohammad Ali Badaghifard
Street address
Karbala Boulevard, Basij Square, Sardasht, Arak University, Arak
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3848177504
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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
Arak 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

Contact

Name of organization / entity

Arak University

Full name of responsible person

Shahnaz Shahrjerdi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Full name of responsible person

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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

There is no further information.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data will be available after the research is published.

When the data will become available and for how long

Since 1404

To whom data/document is available

Everyone from university researchers to professors can receive this research.

Under which criteria data/document could be used

A person who intends to study this research can send a message to the researcher via email. The person can

also use the information in the article.

From where data/document is obtainable

First, email shahrjerdi.shahnaz@gmail.com, then call the following number: 09161520974, and finally, you can visit the Arak University Library.

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

The applicant can receive the documents after sending an email to the researcher and receiving confirmation from the researcher.

Comments