

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

A strength and balance exercise program combined with vestibular training could improve postural stability and reduce fall risk in elderly population - a follow-up study

Protocol summary

Study aim

This study aims to explore whether a strength and balance exercise program combined with vestibular training could improve postural stability and reduce fall risk in the elderly population.

Design

A follow-up clinical trial, not randomized with a blinded outcome assessment of 30 elderly subjects, with a history of falls, regarding a decrease in fall risks.

Settings and conduct

This study consisted of 2 months of a balance rehabilitation program, with 2 sessions/ week of balance rehabilitation on the Framiral Multitest Equilibre dynamic platform, completed by 3 sessions/week of the Otago exercise program, performed at home.

Participants/Inclusion and exclusion criteria

The inclusion criteria: (a) age above 70 years, (b) subjects with a history of falling in the last year; (c) no medical or vestibular rehabilitation treatment in the previous 6 months, (d) subjects who completed the rehabilitation program. The exclusion criteria: subjects who: (a) did not want to participate in the study, (b) had conditions requiring medication potentially generating the dizziness; (c) presented limitations for the tests, and (d) those who did not attend one of the scheduled assessment sessions.

Intervention groups

The intervention group consists of 30 subjects physically inactive elderly persons in the past 6 months. They will receive 2 months of a balance rehabilitation program, with 2 sessions/ week of balance rehabilitation on the Framiral Multitest Equilibre dynamic platform, completed by 3 sessions/week of the Otago exercise program, performed at home.

Main outcome variables

Index of postural instability (IPI) Balance Outcome Measure for Elder Rehabilitation (BOOMER) The Falls

Efficacy Scale International (FES-I)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240722062512N1**

Registration date: **2024-07-27, 1403/05/06**

Registration timing: **prospective**

Last update: **2024-07-27, 1403/05/06**

Update count: **0**

Registration date

2024-07-27, 1403/05/06

Registrant information

Name

Doriana Ioana Ciobanu

Name of organization / entity

The University of Oradea

Country

Romania

Phone

+40 259 408 419

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-05, 1403/05/15

Expected recruitment end date

2024-10-31, 1403/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A strength and balance exercise program combined with vestibular training could improve postural stability and reduce fall risk in elderly population - a follow-up study

Public title
Rehabilitation in elderly fall risk assessment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 65 - 85 years; Subjects with a history of 1-3 fallings in the last year; No medical or vestibular rehabilitation treatment in the previous 6 month; Subjects who completed the rehabilitation program; Subjects who completed the three assessments;
Exclusion criteria:
Subjects who did not meet the age requirements
Subejcts who did not want to participate in the study
Subjects with conditions requiring medication potentially generating the dizziness
Subjects who presented limitations for the tests
Subjects who did not attend one of the scheduled assessment sessions

Age
From **65 years** old to **85 years** old

Gender
Both

Phase
1

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **3**
The subjects will be assessed three times, baseline, final and follow-up

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
The person designated for assessment will not be involved in the rehabilitation process nor know who will be enrolled in the study.

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee of Scientific Research Conduct and Ethics, University of Oradea

Street address

str. Universitatii, nr.1

City

Oradea

Postal code

410087

Approval date

2024-03-13, 1402/12/23

Ethics committee reference number

2/13.03.2024

Health conditions studied

1

Description of health condition studied

Impaired balance and falls in elderly

ICD-10 code

R29.6

ICD-10 code description

Repeated falls

Primary outcomes

1

Description

Increase postural stability

Timepoint

Baseline assessment, 2 months after rehabilitation program, follow-up at 6 months

Method of measurement

Index of postural instability measured by Framiral Multitest Equilibre dynamic platform

2

Description

Balance improvement

Timepoint

Baseline assessment, 2 months after rehabilitation program, follow-up at 6 months

Method of measurement

Balance Outcome Measure for Elder Rehabilitation (BOOMER) score

3

Description

Fall risk prevention

Timepoint

baseline assessment, 2 months after rehabilitation program, follow-up at 6 months

Method of measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group consists of elderly subjects, ages 65-85 years old, with a history of 1-3 falls in the last year.

Category

Rehabilitation

2

Description

Control group: The control group consists of subjects with a history of 1-3 falls within the last year. They did not receive the balance and vestibular treatment for various reasons but agreed to undergo the three assessments (baseline, final, and follow-up).

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Osteokinetomedica Rehabilitation Center

Full name of responsible person

Doriana Ioana Ciobanu

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

University of Oradea

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

University of Oradea

Full name of responsible person

Doriana Ioana Ciobanu

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Rehabilitation management

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable