Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Email address

dciobanu@uoradea.ro

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 rehabiliation 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 rehabiliation 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 rehabiliation program, follow-up at 6 months

Method of measurement

The Falls Efficacy Scale International (FES-I)

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
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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
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Other areas of specialty/work
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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