Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the Effectiveness of Otago and Fall Proof Exercises on Balance , Fear of Falling and Quality of Life in Elderly people with Knee Osteoarthritis

Protocol summary

Study aim

Comparison of the effectiveness of FallProof and Otago exercise programs on balance and functional indices in elderly people with knee osteoarthritis, including static and dynamic balance, fear of falling, and quality of life.

Design

This study is a parallel-group, clinical trial of the before-and-after type .it has two interventions group and a control group. The sample size is 60 persons.

Settings and conduct

this study is a before-and-after trial that will be conducted randomly in three daily rehabilitation centers for the elderly in Chaharmahal and Bakhtiari province on 60 elderly people who meet the inclusion criteria

Participants/Inclusion and exclusion criteria

1. Age over 60 years 2. Mild to moderate knee osteoarthritis according to the WOMAC questionnaire 3. Informed consent to participate in the study 4. Body mass index (BMI) between 20 and 35 kg/m2 5. Sufficient cognitive ability to understand instructions 6. Motor ability (ability to walk at least 6 meters, without dependence on a walker, ability to perform exercises) 7. No inner ear disorders 8. No severe cardiovascular problems and severe heart failure 9. No neurological disorders 10. No advanced visual or hearing impairment 11. No use of strong sedatives and benzodiazepines 12.No lower limb injury in the past 12 month.

Intervention groups

Intervention group1 (Otago exercises): Participants in this group will receive 3 sessions of the Otago exercise program per week for 8 weeks. Intervention group 2 (Fall-proof exercises): Participants in this group will receive 3 sessions of the Fall-proof exercise program per week for 8 weeks. Control group: This group will not receive any intervention and will only participate in the initial and final assessments.

Main outcome variables

Static balance, dynamic balance, fear of falling, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230219057454N3**
Registration date: **2025-11-26, 1404/09/05**
Registration timing: **registered_while_recruiting**

Last update: **2025-11-26, 1404/09/05**
Update count: **0**

Registration date

2025-11-26, 1404/09/05

Registrant information

Name
Hossein Shahnazi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 31 3792 3243
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-21, 1404/08/30

Expected recruitment end date

2026-06-19, 1405/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effectiveness of Otago and Fall Proof Exercises on Balance , Fear of Falling and Quality of Life in Elderly people with Knee Osteoarthritis

Public title

Comparing the Effectiveness of Otago and Fall Proof Exercises on Balance, Fear of Falling and Quality of Life in Elderly people with Knee Osteoarthritis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 60 years Mild to moderate knee osteoarthritis based on the WOMAC questionnaire. Informed consent to participate in the study. Having a body mass index (BMI) in the range of 20 to 35 kg/m square Sufficient cognitive ability to understand instructions according to the medical record Motor ability (Ability to walk at least 6 meters, without dependence on a walker- Ability to perform exercises)

Exclusion criteria:

Presence of inner ear disorders, as documented in the medical records Presence of severe cardiovascular diseases or severe heart failure (evidenced by limited activity tolerance), as documented in the medical records. Presence of neurological disorders (such as stroke, severe Parkinson's disease, Multiple Sclerosis, dementia, or Alzheimer's), as documented in the medical records. Presence of advanced visual or hearing impairment (which would pose a risk of falling during exercises), as documented in the medical records. Current use of strong sedatives or benzodiazepines, as documented in the medical records. History of lower limb injuries within the past 12 months, as documented in the medical records

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

At first among the active elderly rehabilitation centers in Chaharmahal and Bakhtiari province, three centers will be selected by simple random method. Then, the centers will be randomly assigned to the study groups as follows: one center for the Otago exercise intervention, one center for the Fall-proof exercise intervention, and one center as the control group, which will be assigned by simple random method. Finally, among the elderly referring to each center who are eligible for inclusion in the study, samples will be selected by convenient sampling method and will participate in the study.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The allocation to study groups is as follows: two groups are considered intervention groups (one intervention group will receive Otago exercises and one intervention group will receive Fall-proof exercises) and one group is considered control and will not receive any intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Isfahan university of Medical Sciences

Street address

Isfahan city, Hazar Jarib Street, Isfahan university of Medical Sciences

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2025-11-25, 1404/09/04

Ethics committee reference number

IR.MUI.DHMT.REC.1404.159

Health conditions studied

1

Description of health condition studied

Osteoarthritis of knee

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Fear of falling score in the elderly in the (FES-I) questionnaire

Timepoint

Before the intervention, immediately after the

intervention

Method of measurement

(FES-I) questionnaire

2

Description

Quality of life score of the elderly in (SF-36) questionnaire

Timepoint

Before the intervention, immediately after the intervention

Method of measurement

(SF-36) questionnaire

3

Description

Static balance score in the elderly in Sharpened Romberg Test

Timepoint

Before the intervention, immediately after the intervention

Method of measurement

Sharpened Romberg Test

4

Description

Dynamic balance score in elderly in (TUG)

Timepoint

Before the intervention, immediately after the intervention

Method of measurement

Time Up and Go Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants in this group will receive the Otago exercise program.This program consists of 24 sessions (3 sessions per week for 8 weeks), with each session lasting approximately 45 minutes. The exercise content focuses on strengthening the lower limb muscles and performing static and dynamic balance exercises. All sessions will be conducted in a group format, under the direct supervision of the researcher, in a standard and safe environment.

Category

Treatment - Other

2

Description

Intervention group: This group will undergo the FallProof exercise program.This program is also conducted over 24 sessions (3 sessions per week for 8 weeks), with each session lasting approximately 45 minutes. The exercise content includes improving proprioception and performing exercises that shift the center of gravity in different directions. These sessions will also be held in a group format under the direct supervision of the researcher in a safe environment.

Category

Treatment - Other

3

Description

Control group: Participants in this group will only continue their usual routine activities at the center and will not receive any of the structured exercise interventions(Otago or FallProof) during the study period. To adhere to ethical considerations, upon completion of the study and the final assessments, the necessary training regarding the exercises will be provided to this group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Welfare Organization

Full name of responsible person

Razieh Dorali Beni

Street address

45 Alley, Shariati Street. Shahrekord City

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Shahrekord

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Chahar-Mahal-va-Bakhtiari

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Email

raziehdooralibeni@gmail.com

Web page address

http://www.chbehzisty.ir/index.php/fa/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asgari

Street address

Hezarjarib Ave. Isfahan university of Medical Sciences

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Web page address
http://mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Hossein Shahnazi
Position
Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
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Web page address
http://mui.ac.ir/en/school-hlth/Executive-board

Person responsible for scientific inquiries

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Full name of responsible person
Hossein Shahnazi
Position
Faculty member
Latest degree
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Web page address
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Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Razieh Dorali Beni
Position
Master's Student
Latest degree
Bachelor
Other areas of specialty/work
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http://mui.ac.ir/en/school-hlth/Executive-board

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

En All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

En Access begins after results are printed

To whom data/document is available

En All people working in academic, scientific, and industrial sectors are able to receive data

Under which criteria data/document could be used

1-Using information to conduct scientific and research studies 2- Not changing information and observing ethical standards

From where data/document is obtainable

Research project implementers and authors 2- Research assistant of the relevant university and educational institution (Isfahan University of Medical Sciences). Contact information for research project implementers: 1-Ms. Razieh Dorali Beni, Address: Shahrekord.Takhti street.Alley38.Sign 3, Contact number 09902280525,Emailaddress:raziehdooralibeni@gmail.com, 2:Mr. Dr. Hossein Shahnazi Address, Isfahan, Hezar Jerib Street, Isfahan University of Medical Sciences, School of Public Health Department of Public Health Education, Contact number: 09133360148. Email address: h_shahnazi@yahoo.com

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

En After contacting the project implementers and reviewing the applicant's scientific and ethical qualifications, the information will be provided to him/her as soon as possible.

Comments