

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The effect of otago exercise program on balance and fear of falling in the elderly

Protocol summary

Balance, Fear of falling

Study aim

To determine the effectiveness of the Otago Exercise Program in improving the balance and fear of falling in the elderly

Design

Clinical trials with control group, community-based and pragmatic, With parallel groups and randomized

Settings and conduct

This research will be implemented in the Imam Reza (AS) Clinic affiliated to Shiraz University of Medical Sciences. The 88 volunteer will be randomized in two groups of 44 people. The Otago training program will be conducted by the researcher to the experimental group for a period of four weeks, two sessions per week. The control group will not receive any training. After that, the participants will run Otago at their homes for 8 weeks, and they will be in touch with researcher. At the end of the third month, again, a meeting will take place to conduct the post-test.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1-aged 60 years and older 2. Earn score 45 or lower in Berg Balance Scale 3. Not affiliated with auxiliary equipment 4. Obtain a score of 22 up in Mini Mental Status exam 5. Obtain a score of 32 in Dizziness Handicap Inventory Test Exclusion Criteria: 1- Unwillingness to cooperate in research 2. Having defective vision or hearing impairment 3. Having a disabling neurological and muscular disorder that can lead to inability to do daily activities. 4 - Neurological disorders or defective disabling of the nervous system 5. Suffering from debilitating vascular diseases 6. Take medications that may affect balance.

Intervention groups

Intervention group: recipient of the Otago exercise program in eight sessions, thirty minutes each, in a month, and performed at home for two months with the supervision of a physiatrist. Control group: They are on the waiting list and do not receive comparative sport education intervention

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131117015426N7**

Registration date: **2019-06-17, 1398/03/27**

Registration timing: **retrospective**

Last update: **2019-06-17, 1398/03/27**

Update count: **0**

Registration date

2019-06-17, 1398/03/27

Registrant information

Name

Maryam Hazrati

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-05, 1397/07/13

Expected recruitment end date

2018-10-20, 1397/07/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of otago exercise program on balance and fear of falling in the elderly

Public title

Otago Exercise Program & Balance

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

60 years and older Earning a score of 45 or lower in a Berg's equilibrium test (represents an average and downward balance of the elderly.) Not affiliated with auxiliary equipment such as walker and cane To earn a score of 22 up in the cognitive examination exam (indicates a lack of cognitive impairment in the elderly). Earn score 32 in the disability-induced disorder questionnaire (indicating no dizziness imbalance).

Exclusion criteria:

Unwillingness to cooperate in research Having defective vision or disabling hearing Having a disabling neurological and muscular disorder that can lead to inability to do daily activities. Neurological disorders or defective disabling of the nervous system Having debilitating vascular diseases Use of medications that may affect the balance of the person, including benzodiazepines, barbiturates, antidepressants, antihistamines, antipsychotics and other sedative and hypnotic tablets

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

In the present clinical trial, random allocation of the participants is done via permuted block randomization. Accordingly, A and B represent the individuals receiving and not receiving the intervention, respectively. This method is run on 22 blocks in four permutations by considering all possible quadruple permutations (ABBA, ABAB, AABB, BBAA, BAAB, and BABA) and assigning a code between 0 and 9 (based on the table of random numbers) to each permutation (AABB, code 0; ABAB, code 1; ABBA, code 2; BAAB, code 3; BBAA, code 4; and BABA, codes 5-9). Then, based on the table of random numbers, a starting point is randomly selected, 12 digits are randomly chosen (in a row or column), and the permutation assigned to each digit is written down. It should be noted that the permutations are placed next to each other from left to right. Afterwards, allocation of the 88 participants to groups A and B is determined.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Central building of Shiraz University of Medical Sciences, Zand Blvd.

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Postal code

7134814336

Approval date

2018-09-28, 1397/07/06

Ethics committee reference number

IR.SUMS.REC.1397.563

Health conditions studied**1****Description of health condition studied**

Imbalance

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Fear of falling

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

balance score in Berg's balance scale

Timepoint

Before and after the intervention

Method of measurement

Berg's Balance Scale

2

Description

Fear of falling score in Falling Efficiency Scale-International

Timepoint

Before and after the intervention

Method of measurement

Falling Efficiency Scale-International

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A group of Otago exercise program is trained by weekly program (twice a week) under the supervision of the trainer and for 30 minutes per session for Intervention group. The intervention program will include 8 training sessions in a month and then continues on exercise at home and will be followed up by phone for 2 months. This intervention is carried out under the supervision of a physiatrist.

Category

Rehabilitation

2

Description

Control group: Participants in this group are on the waiting list and do not receive comparative sport education intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Elderly Clinic of Imam Reza Clinic

Full name of responsible person

Maryam Hazrati

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Specialized Clinic and Imam Reza Specialist, Side of Blood Transfusion Organization, Namazai Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Hazrati

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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

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