

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The effect of the simulated balance exercises using smart computer (xbox Kinect) on balance and fear of falling in older adults with high risk of falling in the nursing homes

Protocol summary

Study aim

Determining the effect of the simulated balance exercises, using smart computer on balance and fear of falling in older adults with high risk of falling in the nursing homes

Design

Parallel group randomized trial in which participants will be divided into two groups by permuted block randomization. Sample size was calculated 54.

Settings and conduct

All interested elderlies in Shiraz nursing homes will be invited to participate in the study. After that, the balance of participants will be assessed using Time up and going (TUG) scale. Ones with TUG grade 14 or higher seconds will be selected for the study. Then the fear of falling, balance status and physical function of participants will be assessed using "Falling efficacy", "Burg" and "TUG" scales. Then participants will be divided into two groups by permuted block randomization. Intervention group will undertake twice a week simulated balance exercises for 6 weeks and control group will receive routine cares. At the end, the balance status, physical function and fear of falling of all participants in both groups are assessed and compared with the data before intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Subjects older than 60 years and at risk of falling Exclusion criteria: - Past medical history of any acute or chronic physical, cognitive or mental disease that prevent doing exercise - Participating in other similar exercise

Intervention groups

Intervention group will undertake twice a week simulated balance exercises for 6 weeks and control group will receive routine nursing homes cares.

Main outcome variables

Balance status; fear of falling

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190727044347N1**

Registration date: **2019-08-17, 1398/05/26**

Registration timing: **prospective**

Last update: **2019-08-17, 1398/05/26**

Update count: **0**

Registration date

2019-08-17, 1398/05/26

Registrant information

Name

Fatemeh Shirazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4254

Email address

shirazifa@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the simulated balance exercises using smart computer (xbox Kinect) on balance and fear of falling in older adults with high risk of falling in the nursing homes

Public title

The effect of the simulated balance exercises on balance and fear of falling in older adults

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

subjects older than 60 years old Older adults with high risk of falling according to the TUG test (time > 14 seconds) Subjects who can walk with/without any aid Getting permission from the nursing home's physician Being interested to participate in the study

Exclusion criteria:

Past medical history of any acute or chronic physical, cognitive or mental disease that prevent doing exercise Participating in other exercise that are similar to this study intervention Having problems that cause banning on exercise Not treated hearing and vision loss Having balance disorders related to cerebellar and vestibular disorders

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting eligible individuals to participate in the study based on inclusion criteria, these individuals will be assigned to two study groups based on double randomized permutation block with foursome blocks. The random list is generated by a statistician using "Random Allocation" software. Foursome blocks are the combination of different status such as: ABBA, BAAB, BABA, ABAB, BBAA, AABB. Using random list that is generated by computer, 15 blocks are selected for forming the two study groups.

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

Research Ethics Committee of Shiraz University of Medical Sciences

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2019-06-23, 1398/04/02

Ethics committee reference number

IR.SUMS.REC.1398.573

Health conditions studied

1

Description of health condition studied

Older adults with high risk of falling

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Balance status score based on Berg Balance Scale

Timepoint

At the beginning of the study (before intervention) and after 6 weeks of intervention

Method of measurement

Berg Balance Scale

2

Description

Fear of falling score based on falling efficacy scale

Timepoint

At the beginning of the study (before intervention) and after 6 weeks of intervention

Method of measurement

Falling efficacy scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group will do simulated computerized balance exercise for 6 weeks. Exercises are twice weekly for 30 -60 minutes in each session. Simulated exercises like tennis, golf and skiing will be used. Each session covers various aspects of balance in elderly.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Zagros Elderly Rehabilitation Center

Full name of responsible person

Majid Jalali

Street address

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2

Recruitment center

Name of recruitment center

Yas-haye-sepeed Elderly Home

Full name of responsible person

Zahra Farrokh Mehr

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3

Recruitment center

Name of recruitment center

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Full name of responsible person

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4

Recruitment center

Name of recruitment center

Farzangan elderly home

Full name of responsible person

Shahzad Etemaad

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After science and technology park, Arian town, Shiraz, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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vcrdep@sums.ac.ir

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

City

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Person responsible for general inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Shirazi

Position

Assistant professor

Latest degree

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Other areas of specialty/work

Nursery

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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