

# 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**  
No. 134, 9th Ave., Tachara Blvd.  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7175957111  
**Phone**  
+98 71 3625 5909  
**Email**  
web@zagros-salmandan.com  
**Web page address**  
http://salmandan-zagros.com/

**2**

**Recruitment center**

**Name of recruitment center**  
Yas-haye-sepeed Elderly Home  
**Full name of responsible person**  
Zahra Farrokh Mehr  
**Street address**  
6th street, Hosin Abad Town, Sanaye Square  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7196743197  
**Phone**  
+98 71 3635 4799  
**Fax**  
+98 71 3635 8037  
**Email**  
salmandan.yashayesepid@gmail.com

**3**

**Recruitment center**

**Name of recruitment center**  
Shiraz Elderly Home  
**Full name of responsible person**  
Abdol Majid Jamshidi  
**Street address**

Parsian Blvd., Akbar abad Town  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7149675511  
**Phone**  
+98 71 3242 4074  
**Email**  
sarayesalmandan\_shiraz@gmail.com

**4**

**Recruitment center**

**Name of recruitment center**  
Farzangan elderly home  
**Full name of responsible person**  
Shahzad Etemaad  
**Street address**  
After science and technology park, Arian town, Shiraz, Iran.  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7197687876  
**Phone**  
+98 71 5800 3227  
**Email**  
Shiraz.farzanegan@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Dr. Younes Ghasemi  
**Street address**  
Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd.  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7134814336  
**Phone**  
+98 71 3235 7282  
**Fax**  
+98 71 3230 7594  
**Email**  
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**

Shiraz

**Province**

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**Postal code**

13119-71936

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+98 71 3647 4254

**Fax****Email**

shirazifa@sums.ac.ir

**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**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

School of Nursing and Midwifery (SA), Namazi Square,  
Namazi Hospital

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**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Fatemeh Shirazi

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

Shiraz University of Medical Sciences

**Full name of responsible person**

Fatemeh Shirazi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

School of Nursing and Midwifery (SA), Namazi Square

**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