

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Effect of Physical Activity on Static and Dynamic Balance among the Elderly

#### Protocol summary

##### Study aim

: with advancing age, and the impact of age-related chronic diseases, a decline in balance as a cognitive capability function is also observed. Therefore, this study aimed to investigate the effect of physical activity on the static and dynamic balance of the elderly living in the nursing home

##### Design

: In this study, 36 healthy subjects with no history of regular exercise ( $71.8 \pm 5.6$  years old and body mass index  $23.4 \pm 6.8$ ) were selected by convenient sampling. After obtaining informed written consent and the physician permission, qualified subjects were enrolled in the study and were examined before and after physical exercise. To evaluate dynamic and static balance of the subjects, we used TUG and Sharpend-Romberg tests. The exercises were progressively implemented for 8 weeks and 3 hours per week. To analyze the data, appropriate statistical tests at the significant level of  $P < 0.05$  and SPSS version 20 were used.

##### Settings and conduct

After the physical activity was completed, the eligible elderly were visited by a physician at the nursing home and obtained a permission to participate in the research. Finally, written informed consent was obtained from the subjects for participation in the study. After initial tests and physician permission, 41 elderly (26 women, 15 men) declared their readiness to participate in the research. Initially, all subjects were evaluated by a tool for measuring static and dynamic balance measurements and data obtained were recorded. The elderly were trained for 8 weeks and 3 sessions per week in group. Sampling was carried out in December 2016 and January 2017.

##### Participants/Inclusion and exclusion criteria

Prior to entering the program, the elderly were evaluated for physical activity using a physical activity readiness questionnaire. According to this questionnaire, elderly patients with history of heart disease, hypertension,

physician's order for non-doing exercise or workout, nerve dysfunction, dizziness, eye and ear diseases (other than presbyopia and presbycusis), previous fractures of the involved bones in the balance (femur, tibia and fibula) and the BMI greater than 36, the absence of more than 3 sessions in the exercise were excluded from the study

##### Intervention groups

his is a quasi-experimental study in which 36 elderly people in the age range of 60 to 85 years (age  $71.6 \pm 5.6$ ), body mass index ( $23.4 \pm 6.8$ ), residence for more than 3 months in the nursing home of Sabzevar and without a history of falling were investigated through a pre-test and post-test comparisons

##### Main outcome variables

, the presence of nurses with the elderly and sometimes living with them has made it more tangible for nurses to take a step for providing preventive care. In this study, we sought to demonstrate that by offering proper physical exercises and simple and low cost sports equipment, caring nurses at home or nursing home can take steps to prevent falls and increase the balance of the elderly. Using exercises at home or nursing home can reduce the level of falling among the elderly and prevent further complications in them.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140429017491N2**

Registration date: **2018-02-26, 1396/12/07**

Registration timing: **retrospective**

Last update: **2018-02-26, 1396/12/07**

Update count: **0**

##### Registration date

2018-02-26, 1396/12/07

## Registrant information

### Name

nadereh naderiravesh

### Name of organization / entity

### Country

Iran (Islamic Republic of)

### Phone

+98 88465512

### Email address

n.naderiravesh@sbmu.ac.ir

## Recruitment status

### Recruitment complete

## Funding source

## Expected recruitment start date

2018-12-22, 1397/10/01

## Expected recruitment end date

2019-02-20, 1397/12/01

## Actual recruitment start date

2016-12-21, 1395/10/01

## Actual recruitment end date

2017-02-19, 1395/12/01

## Trial completion date

empty

## Scientific title

Effect of Physical Activity on Static and Dynamic Balance among the Elderly

## Public title

Effect of Physical Activity on Static and Dynamic Balance among the Elderly

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Aged between 60 and 85 years old • were living in Sabzevar seniors' homesteads • have lived in the center for more than three months • obtained a full grade score by completing the test for physical activity (answered all questions) . • No history of falling or falling down. • Body mass index below 35.

### Exclusion criteria:

During the study, the researcher will find that he or she will be on regular basis for the day. • The research sample will fall during the study. • The research sample during the study due to an ear infection will be impaired in the balance of the individual. • There are no more than three consecutive sessions in the physical training session. • More than 6 absent training sessions.

## Age

From **60 years** old to **84 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **35**

Actual sample size reached: **36**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

After the initial tests and the doctor's permission, 32 elderly people will be satisfied to participate in the research. Initially, all subjects will be evaluated by means of a static equilibrium and dynamic equilibrium measuring instrument, and the information will be recorded. Seniors are practicing in groups for 8 weeks and 3 sessions a week. Sampling will be carried out in two consecutive months. Also, the implementation of all examinations and exercises will be carried out by direct supervision of the Master of Physical Education. During the research phase, subjects who are excluded from the study will be excluded from the study. The training will be conducted for 40 minutes in the first 4 weeks of the week and 1 hour in the final week. To ease the exercise and focus more elderly, the subjects will be divided into 5 groups of 6 to 8 groups. In order to influence the training of time, the intensity of exercises, the stimulation of effective balance sensations, such as sight and deep tendon, and hemodynamic symptoms during the intervention, will gradually increase. At the end of the intervention, all subjects will be subjected to static and dynamic equilibrium tests. And the average results before and after the comparison and conclusion.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Etics committee of Shahid Beheshti University of Medical Sciences, Tehran, Iran//number: IR.SBMU.PHN

##### Street address

Velenjak, 7th Floor, Bldg No.2 SBUMS, Arabi Ave. 19839-6311

##### City

tehran

##### Province

Tehran

##### Postal code

info@sbmu.ac.ir

#### Approval date

2016-01-08, 1394/10/18

#### Ethics committee reference number

IR.SBMU.PHNM.1394.335

## Health conditions studied

1

### Description of health condition studied

imbalance in the elderly

### ICD-10 code

### ICD-10 code description

## Primary outcomes

1

### Description

balance

### Timepoint

2 months

### Method of measurement

Static and dynamic balance valuation tools

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: 32 elderly people will be subjected to physical training in an intervention group

### Category

Rehabilitation

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Nursing Home of Sabzevar

#### Full name of responsible person

Dr.nadere naderiravesh

#### Street address

kashefi St. 22 bahman St. nursing home of mother

#### City

Sabzevar

#### Province

Razavi Khorasan

#### Postal code

http://www.salmandan

#### Phone

+98 51 4428 8012

#### Email

f.shegofte@gmail.com

## Sponsors / Funding sources

1

### Sponsor

### Name of organization / entity

Shahid Beheshti University of Medical Sciences

### Full name of responsible person

Nadere naderi ravesh

### Street address

Vali-asr steriet

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### Fax

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### Email

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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

Shahid Beheshti University of Medical Sciences

### Proportion provided by this source

50

### 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

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Nadere Naderi Ravesh

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nursery

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## Person responsible for scientific inquiries

### Contact

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Dissatisfaction with the participants

**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**

No - There is not 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**

The analysis of the information obtained from the results of the training is published

**When the data will become available and for how long**

No time limit

**To whom data/document is available**

Researcher and research team

**Under which criteria data/document could be used**

For training and use

**From where data/document is obtainable**

Researcher

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

An email request is made and the reason for the need for data and permission to access information is Have

**Comments**