

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Evaluation of the effect of simple balance exercise on falling prevention in elderly women

#### Protocol summary

##### Summary

The aim of present study is to investigate the simple balancing exercises' effects on increasing the balance ability and decreasing falls among the elderly women. The study was a randomized controlled clinical trial (RCT). For this purpose, 60 elderly people were randomly divided into two 30-member intervention and control groups in Razi psychiatric hospital. Inclusion criteria: all patients with chronic schizophrenia, age range between 60-84 years and consuming mild psychotic drugs (none of the participants of invasive procedures such as shock therapy, fixed and do not use). For all patients, demographic data including age, marital status, length of stay, height, weight, BMI, education, the family background of the disease, history of falls, smoking, cause of admission, etc. were extracted. Before beginning the study, "Timed up and go" test was completed for each patient. The patients in intervention group were trained about simple balance exercises by an occupational therapist via 30-minutes sessions, three times a week for 12 weeks. The control group did not receive any special treatments throughout the study. At the end of the study, all patients were assessed again by Time Up and go test. Primary outcomes in this study were the velocity of sitting down and standing up.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016041827448N1**  
Registration date: **2016-07-15, 1395/04/25**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-07-15, 1395/04/25

#### Registrant information

##### Name

Masome Rezaie Evrigh

##### Name of organization / entity

Qazvin Univercity Of Sciences Medical

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28333360015

##### Email address

khz@qums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Qazvin University of Medical Sciences

#### Expected recruitment start date

2016-01-08, 1394/10/18

#### Expected recruitment end date

2016-03-17, 1394/12/27

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation of the effect of simple balance exercise on falling prevention in elderly women

#### Public title

The effect of simple balance exercise on falling prevention

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: women aged 60-84 years diagnosed with chronic schizophrenia hospitalized in the Razi Psychiatric Hospital; Permanent treatment with

antipsychotic medication; Ability to move without help and absence of physical illness; written consent.  
Exclusion criteria: being absent for more than three sessions; physical illness; death.

#### Age

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

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

accident numerics chart

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

##### Street address

The next Justice, Bahonar street, Qazvin

##### City

Qazvin

##### Postal code

#### Approval date

2016-11-13, 1395/08/23

#### Ethics committee reference number

IR.QUMS.REC.1394.197

## Health conditions studied

### 1

#### Description of health condition studied

fall

#### ICD-10 code

R29.6

#### ICD-10 code description

Tendency to fall, not elsewhere classified

## Primary outcomes

### 1

#### Description

Primary outcome: Sitting down and standing up speed

#### Timepoint

Before and one week after intervention

#### Method of measurement

up to go criterion

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention groups: Education of simple balance training for patients will be held up. Educational sessions will be ran as 30-minute sessions, three times a week up to 12 weeks.

#### Category

Prevention

### 2

#### Description

Control group: we do not do for them anything

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Razi Psychiatric Center, Tehran University of Social Welfare

##### Full name of responsible person

Dr.Azam Soleymani

##### Street address

Shahid Rastegary street, Amin abad ,Rey

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for research of Qazvin University of Medical Sciences

##### Full name of responsible person

Dr.Fateme Mohammadi

##### Street address

Next Court of Law, Bahonar street ,Qazvin

##### City

Qazvin  
**Grant name**  
-  
**Grant code / Reference number**  
-  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Vice Chancellor for research of Qazvin University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
*empty*  
**Domestic or foreign origin**  
*empty*  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

### Contact

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*