

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The effect of cognitive-behavioral therapy on the stages of planning and predicting the time of movement in the elderly with fear of falling

#### Protocol summary

##### Study aim

The effect of cognitive-behavioral therapy on the stages of planning and predicting the time of movement in the elderly with fear of falling

##### Design

Clinical trial with control group, double-blind, randomized with sealed envelopes

##### Settings and conduct

Location of interventions in the nursing home daily.  
Number of courses: one blind (evaluators)

##### Participants/Inclusion and exclusion criteria

Admission requirements: Independence in daily activities  
Age between 60-80 years  
Fear of falling based on the Falls Efficacy Scale-International test  
Able to walk at least 20 meters without aids  
Exclusion criteria: Any acute or chronic disease that affects the control of balance and gait (neuromuscular diseases, visual disorders, vestibular, etc.)  
Existence of cognitive disorders (24> Mini Mental status Examination Test)  
Acute psychiatric illness and psychosis

##### Intervention groups

Individuals in the intervention group are treated with a combination of routine walking rehabilitation as well as cognitive-behavioral therapy to reduce the fear of falling. Conventional walking rehabilitation These exercises are performed twice a week for 45 minutes for 12 weeks. Cognitive-behavioral therapy in this group aims to reduce the fear of falling and improve self-efficacy. This treatment contains various parts, including the use of positive words before and after performing a motor skill to eliminate the negative attitude and reassurance in performing the skill. This treatment is done in groups (6 to 8 people in each group) once a week for 2 hours during 12 weeks. In the control group, normal gait is performed exactly the same as the intervention group twice a week for 45 minutes for 12 weeks.

##### Main outcome variables

The time difference between the mental imagination of doing movement and the actual doing of movement

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211201053248N1**

Registration date: **2022-01-19, 1400/10/29**

Registration timing: **prospective**

Last update: **2022-01-19, 1400/10/29**

Update count: **0**

##### Registration date

2022-01-19, 1400/10/29

##### Registrant information

##### Name

roghaye diveh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3324 9324

##### Email address

diveroghaye@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-21, 1400/11/01

##### Expected recruitment end date

2022-04-21, 1401/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of cognitive-behavioral therapy on the stages of planning and predicting the time of movement in the elderly with fear of falling

**Public title**

The effect of cognitive-behavioral therapy on the elderly with fear of falling

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Fear of falling without cognitive impairment  
Independence in daily activities Able to walk at least 20 meters without aids Ability to participate in treatment sessions Age between 60 and 80 years

**Exclusion criteria:**

Any acute or chronic illness that affects balance and gait control Existence of cognitive disorders Acute psychiatric illness with psychosis

**Age**

From **60 years** old to **80 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **36**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Envelopes are prepared for the number of participants in the study (36 people) which are placed inside 18 envelopes of odd numbers and in the remaining 18 envelopes of even numbers and then we combine the envelopes by chance and from this random combination Sample people select one of the envelopes and are divided into intervention and control groups, respectively, being even or odd.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This is a one-way blind study in which the statistician is an independent person who analyzes data and is unaware of the allocation of groups. And the evaluator is an independent person and evaluates the consequences and is unaware of the allocation of groups

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of School of Paramedical Sciences and Health School of mashhad Mashhad University o

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Mashhad, Azadi St., East Door of Ferdowsi University of Mashhad, University Campus, Faculty of Paramedical Sciences

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948964

**Approval date**

2021-12-11, 1400/09/20

**Ethics committee reference number**

IR.MUMS.FHMPM.REC.1400.061

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

Fear of falling

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

The time difference between the mental imagination of doing movement and the actual doing of movement

**Timepoint**

Before the intervention and 12 weeks after the intervention

**Method of measurement**

Timed Up and Go Test

**Secondary outcomes****1****Description**

Level of fear of falling

**Timepoint**

Before the intervention and 12 weeks after the intervention

**Method of measurement**

Falls Efficacy Scale International

**2****Description**

The risk of falling

### **Timepoint**

Before the intervention and 12 weeks after the intervention

### **Method of measurement**

Dynamic Gait Index

## **Intervention groups**

### **1**

#### **Description**

The "intervention group" is treated with a combination of routine walking rehabilitation as well as cognitive-behavioral therapy to reduce the fear of falling. Common walking rehabilitation includes a number of active range-of-motion exercises for all joints of the body, progressive strengthening exercises to guide the hip extensor and abductor, knee and dorsal extensors and flexors, and plantar flexors of the ankle, as well as other skills including transition from sitting to sitting. Conversely, knee squats, standing on one foot, standing back and walking, walking on heels, walking on and off, spinning, stepping on, picking up objects while walking, and on stairs. And go down. These exercises are performed twice a week for 45 minutes for 12 weeks. Cognitive-behavioral therapy in this group aims to reduce the fear of falling and improve self-efficacy. This treatment has different parts, including the use of positive words before and after performing a skill move to build a negative attitude and reassurance in performing the skill. This positivity starts as part of simple skills and progresses to more complex motor skills over distances and less support. Another part of this method is visualizing the correct pattern of a skill before doing it. For example, a correct gait pattern in the face of an environmental disturbance is taught by the therapist and the therapist is asked to visualize the ability to do so before doing so. Another part of this treatment is to improve the self-efficacy of the individual. In this case, the person discusses in his mind these questions, 'what a great success it would be if I walked in any place of fear as in the past', how he reacts to those around me against this without progress. This treatment is done in groups (6 to 8 people in each group) once a week for 2 hours for 12 weeks.

#### **Category**

Rehabilitation

### **2**

#### **Description**

Control group: Conventional gait rehabilitation is performed exactly the same as the intervention group twice a week for 45 minutes for 12 weeks.

#### **Category**

Rehabilitation

## **Recruitment centers**

### **1**

#### **Recruitment center**

#### **Name of recruitment center**

Mehr Elderly Center

#### **Full name of responsible person**

Ana Jamal Ghojoghi

#### **Street address**

Next To Navid Bar, Mehr Elderly Center. Enghelab St. Basij Square

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#### **Email**

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### **2**

#### **Recruitment center**

#### **Name of recruitment center**

Hamdelan Elderly Center

#### **Full name of responsible person**

Fateme Karimi

#### **Street address**

No. 4, Corner Of Raja 10, Shahid Rajaei St.

#### **City**

AzadShahr

#### **Province**

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## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

#### **Name of organization / entity**

Mashhad University of Medical Sciences

#### **Full name of responsible person**

Majid Ghaior Mobarham

#### **Street address**

Faculty of Paramedical Sciences, University Campus, East Door of Ferdowsi University of Mashhad, Azadi Square

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#### **Email**

Sps.Dean@mums.ac.ir

#### **Grant name**

**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Roghaye Dive

**Position**

master student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for scientific inquiries

**Contact**

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Hossein Asghar Hosseini

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for updating data

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Roghaye Dive

**Position**

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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**

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