Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Street address

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
City
Gonbad Ghabos
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Postal code
4979188517
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Email
Mdade767@gmail.com

2

Recruitment center
Name of recruitment center
Hamdelan Elderly Center
Full name of responsible person
Fateme Karimi
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No. 4،Corner Of Raja 10، Shahid Rajaei St.
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AzadShahr
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Karimii.Hamdelan91@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghaıor Mobarham
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Faculty of Paramedical Sciences، University Campus، East Door of Ferdowsi University of Mashhad، Azadi Square
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Province
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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

Name of organization / entity
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Full name of responsible person
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Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Roghaye Dive

Position
Master student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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Diveroghaye@gmail.com

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