Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Investigation of the Effect of Mental Practice on Fear Of Falling during n Activity of Daily Living and Satisfaction in the Community-Dwelling Elderly

Protocol summary

Study aim

Determining the Effect of Mental Practice on Fear Of Falling during Activity of Daily Living in the Community-Dwelling Elderly. Determining the Effect of Mental Practice on satisfaction in the Community-Dwelling Elderly

Design

In this study, 40 Community-Dwelling elderly eligible based on inclusion criteria, referred to Yas Rehabilitation Center and Seyyed-Khandan cultural center in Tehran was selected. Participants were divided into two intervention and control group and a code was allocated to each participant.

Settings and conduct

This study is an experimental, randomized clinical trial in which Community-Dwelling elderly are selected and randomly assigned into two groups (control/ treatment).This study is designed as single-blind in which participants are not aware of being in control or intervention group.

Participants/Inclusion and exclusion criteria

score 21 or higher of MMSE; chronological age of 80-60 years; minimum score of 24 from the (FES-I); score less than 33 in the internal visual imagery subscale, less than 20 in the external visual imagery subscale, and less than 21 in the kinesthetic imagery subscale of the VMIQ-2 questionnaire; fear of falling in at least one of the activities listed in the SAFFE Test; absence of neurological diseases such as dementia, Alzheimer's, stroke, Parkinson's and MS that cause cognitive or balance impairment (confirmed by geriatric physician); absence of specific visual or hearing impairment, or being modifiable with adaptable equipment if present (based on medical records of the center); reading and writing skills; Not Using disruptive equilibrium drugs.

Intervention groups

The intervention group include 20 community-dwelling elderly, who will receive mental practice with balance exercises. For the intervention group, mental practice in the presence of therapist for 15 minutes and balance exercises for both intervention and control groups will be performed for 30 minutes, 3 times per week and within 4 weeks. The control group include 20 community-dwelling elderly who will receive only balance exercises.

Main outcome variables

Fear of falling in the activity of daily living; satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150721023277N6**
Registration date: **2018-07-29, 1397/05/07**
Registration timing: **prospective**

Last update: **2018-07-29, 1397/05/07**
Update count: **0**

Registration date

2018-07-29, 1397/05/07

Registrant information

Name

Laleh Lajevardi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2018-07-31, 1397/05/09
Expected recruitment end date
2018-09-14, 1397/06/23
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Investigation of the Effect of Mental Practice on Fear Of Falling during n Activity of Daily Living and Satisfaction in the Community-Dwelling Elderly

Public title
The Investigation of the Effect of Mental Practice on Fear Of Falling in the Community-Dwelling Elderly .
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having a score 21 or higher from MMSE cognitive test being at the age of 80-60 years Having a minimum score of 24 from the Efficiency Scale, International Form (FES-I). Having a score less than 33 in the internal visual imagery subscale, less than 20 in the external visual imagery subscale , and less than 21 in the kinesthetic imagery subscale of the VMIQ-2 questionnaire. Having fear of falling at least in one of the activities listed in the SAFFE Test. absence of specific visual or hearing impairment , if present, being modifiable with adaptable equipment (based on medical records of the center). Reading and writing skills.
Exclusion criteria:
Using disruptive equilibrium drugs. Having neurological diseases such as dementia, Alzheimer's, stroke, Parkinson's and MS that causes cognitive or balance impairment (geriatric physician confirmation).
Age
From **60 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, a simple randomization method will be used in which a table of random number will be used.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is designed as single-blind in which participants are not aware of being in control or intervention group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
School of Rehabilitation, Shahid Shahnazari Street, Madar Square, Mirdamad Blvd, Tehran
City
Tehran
Province
Tehran
Postal code
15459-13487
Approval date
2017-08-28, 1396/06/06
Ethics committee reference number
IR.IUMS.FMD.REC 1396.9511355004

Health conditions studied

1

Description of health condition studied
old age - fear of falling
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Score of fear of falling in activity of daily living in the Activities-specific Balance Confidence questionnaire
Timepoint
Measure fear of falling in activity of daily living at the beginning of the study (before the intervention) and 28 days (4 weeks) after the intervention.
Method of measurement
Activities-specific Balance Confidence questionnaire

2

Description
Satisfaction in activity of daily living, the score derived from the Canadian Occupational Performance Measure.
Timepoint
Measuring satisfaction degree in activity of daily living at

the beginning of the study (before the intervention) and 28 days (4 weeks) after the intervention.

Method of measurement

Canadian Occupational Performance Measure Inventory

Secondary outcomes

1

Description

Balance Score in Berg Balance Scale and Functional Reach Test.

Timepoint

Measurement of balance at the beginning of the study (before the intervention) and 28 days (4 weeks) after the intervention.

Method of measurement

Berg Balance Scale and Functional Reach Test Questionnaire

2

Description

Functional mobility score in Time UP and GO test.

Timepoint

Measurement of functional mobility at the beginning of the study (before the intervention) and 28 days (4 weeks) after the intervention.

Method of measurement

Time UP and GO test to measure functional mobility.

Intervention groups

1

Description

Intervention group: First the researcher becomes familiar with the physical condition of the participants' home by observing the video which recorded by care giver and visiting their homes. This is done to increase the researchers awareness about the layout of the objects and the type of architecture of the home environment to facilitate the preparation and presentation of mental practice program specifically. According to SAFFE questionnaire, activities which participants have fear of falling facing them, will be selected and exercises will be provided in form of these activities and tailored to the circumstances of each participant's home. They will be asked to imagine their selected activities as kinetic imagery in their minds. Intervention takes place 3 days per week (Sunday, Tuesday, Thursday), which lasts for 4 weeks. Each treatment session will be held between 8 -12 in the morning. The participants will attend in a therapeutic program for intervention in a calm and well-prepared room. Each intervention session lasts 15 minutes. The first 5 minutes are relaxation exercises, such as breathing relaxation techniques to increase comfort and concentration of participants, as well as readiness for doing mental practice. The participant is placed on an appropriate bed and then closes his/her eyes. He/She is asked to think about the chosen activity based on the SAFFE questionnaire step by step with researcher guidance. In the following, he/she is asked to try to do this with more speed and skill at any period of intervention sessions. Duration of mental practice is calculated by stopwatch. Additionally, the traditional rehabilitation program in the form of balance exercises will also be provided to the intervention group by written instructions and consultation for exercising at home. These exercises will be performed at home in form of activities of daily living to increase balance for 4 weeks, three days per week about half an hour a day. Every 4 sessions, home interventions will be monitored by researcher through a video check of each session recorded by caregivers.

Category

Rehabilitation

2

Description

Control group: The traditional rehabilitation program in the form of balance exercises will also be provided to the control group by written instructions and consultation for exercising at home. These exercises will be performed at home in form of activities of daily living to increase balance about half an hour a day, three days per week for 4 weeks. Every 4 sessions, home interventions will be monitored by researcher through a video check of each session recorded by caregivers.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas Rehabilitation Comperhensive Center

Full name of responsible person

Fatemeh Komijani

Street address

next to the guard station, Tarasht Power Station (Alstom), Sattarkhan Ave.

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http://yasrehab.ir

2

Recruitment center

Name of recruitment center

Seyyed-khandan cultural center

Full name of responsible person
Samaneh Ghaderi Zare

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Seyyed Kazam Malakoti

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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Laleh Lajevardi

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Occupational Therapy

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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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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

playgerism

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

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the primary and secondary outcome measures

When the data will become available and for how long

After publishing the articles

To whom data/document is available

Researchers intending to research in this field.

Under which criteria data/document could be used

Obtaining written permission from the research team - Mention the source of information

From where data/document is obtainable

Maryam Hosseini: School of Rehabilitation, Shahid Shahnazari Street, Madar Square, Mirdamad Blvd, Tehran. Email Adress: hosseinimaryam.ot@gmail.com - Dr. Laleh Lajevardi: School of Rehabilitation, Shahid Shahnazari Street, Madar Square, Mirdamad Blvd, Tehran. Email Adress: Lajevardi.l@iums.ac.i

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

After sending the email to the researcher and requesting the document, the researcher will request the opinion of other members of the research team regarding the provision of this information and, if the members agree, the documents will be sent as soon as possible but sending the documents requires the acceptance of the criteria mentioned above.

Comments