Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The assessment of mental practice's effects on balance and quality of life in elderly men (60-80yrs)

Protocol summary

Summary

The purpose of this study is the assessment of mental practice on balance and quality of life in eldery men (60-80yrs). This is a Randomized Controlled Trial (RCT) study, single blind , and carried out on 44 eldery men. The volunteers were assigned in two control and experimental (Mental Practice) groups after the initial assessment using a random block method. The balances of all the elderly during the 4 different phases were assesed using functional balance tests (six-minute walk Test and Timed Get up & Go, Berg Balance Scale). The balance assessments will be performed before and at the beginning of the intervention (initial assessment), immediately after the end of the intervention (post-treatment assessment) , Two weeks after the end of intervention (Short-term follow-up) and 3 months after the end of intervention (long-term follow-up). In addition, The assessments of quality of life will be done by SF36 Test; before the beginning of intervention treatment (initial assessment) , Two weeks after the end of intervention (Short-term follow-up) and 3 months after the end of intervention (long-term follow-up). The treatment period is 3 days a week and will lasts 4 weeks. During this time, the elderly in the trial group will be treated by mental practice intervention.The period of treatment intervention is 15 minutes and will be performed as following: a relaxing excercises and thereafter mental Exe. (5 minutes and 10 minutes respectively).

General information

Acronym

No

IRCT registration information

IRCT registration number: **IRCT201107041722N3**
Registration date: **2012-04-18, 1391/01/30**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2012-04-18, 1391/01/30

Registrant information

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Samira Karimpour
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

This study, was sponsored by a grant from the postgraduate Studies and Research Program, Tehran University of Medical Sciences (TUMS)

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-02-20, 1390/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment of mental practice's effects on balance and quality of life in elderly men (60-80yrs)

Public title

The assessment of mental practice's effects on balance and quality of life in elderly men (60-80yrs)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Ages 60-80 years old;ability to read and write;Interest to participate in the research;The mean of rank as a result of two questionnaires of VVIQ and VMIQ for the assessment of capability of mental imaging less than 3/5 (Cook-Shumway, 2001);Berg's balance test screen less than 45, meaning there is a risk of falling for the elderly (fear of falling) Perell, 2001; Teresa, 2002; Susan, 2008 and Scott, 2007);The elderly has, at least, fallen once during the past 6 months;The elderly must have complete sight and hearing or one correctable with aids. Those with incorrectable insufficiencies wili not be included;No specific neurological or orthopedic disease, this must be confirmmed by a nursing home doctor, as well as any other malignancy, fracture and orthopedic side effects that might have negative effect on patient's balance. It's worth saying that ,here, by " disease" , it dose not mean age- related side effects. 9) The elderly must obtain cognitive 's score of 22 or more in MMSE Test(Sayyedian, 2007);No adminstration of anti-psychotic, anti-convulsion drugs;Patients must not use walker, etc. Exclusion Criteria: Any condition that interefer The participation of elderlies in the study;No interest of elderly for continiuing the research

Age

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

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Tehran University of Medical Sciences (TUMS)

Street address

The Sixth Floor-Main Building of Tehran University of Medical Sciences-Ghods Str-Keshavarz Boulevard

City

Tehran

Postal code

Approval date

2012-03-07, 1390/12/17

Ethics committee reference number

130/2452/90/د

Health conditions studied

1

Description of health condition studied

falling

ICD-10 code

w18

ICD-10 code description

Other fall on same level

2

Description of health condition studied

falling

ICD-10 code

W19

ICD-10 code description

Unspecified fall

3

Description of health condition studied

falling

ICD-10 code

W17

ICD-10 code description

Other fall from one level to another

4

Description of health condition studied

falling

ICD-10 code

W10

ICD-10 code description

Fall on and from stairs and steps

5

Description of health condition studied

falling

ICD-10 code

W01

ICD-10 code description

Fall on same level from slipping, tripping and stumbling

6

Description of health condition studied

falling

ICD-10 code

R29.6

ICD-10 code description

Tendency to fall, not elsewhere classified

7

Description of health condition studied
Senility
ICD-10 code
R54
ICD-10 code description
Senility

Primary outcomes

1

Description
Balance
Timepoint
before the beginning of the intervention (initial assessment), immediately after the end of intervention (post-treatment assessment) , Two weeks after the end of intervention (Short-term follow-up) and 3 months after the end of intervention (long-term follow-up)
Method of measurement
Berg Balance Scale،Timed Get Up&GO، Six-Minute Walk Test

2

Description
quality of life
Timepoint
before the beginning of the intervention (initial assessment), Two weeks after the end of intervention (Short-term follow-up) and 3 months after the end of intervention (long-term follow-up)
Method of measurement
SF36, LEIPAD

Secondary outcomes

empty

Intervention groups

1

Description
Performing the mental practice exe. as form of TUG test in the intervention group. The elderly will be asked to follow all the stages of TUG (as mental practice) as follows: sitting on a chair, then standing from the chair and go a 3-meters distance for reaching to a determined point. Then without any pause, the person should return to the chair. Afterward, it will be asked the person to do the task as much as faster with more skill.
Category
Rehabilitation

2

Description
During the intervention phase,the control group did not do certain exercises and just like the intervention group at the end of intervention phase Tests to assess balance and quality of life will be taken.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Kahrizak Nursing home
Full name of responsible person
Mr.Pezeshki
Street address
Kahrizak Nursing Home -1 & 2 Banafsheh Block
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Postgraduate and Research Programs, Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Jalili
Street address
The Seventh Floor- Main Building Tehran University of Medical Sciences-Ghods Str-Keshavarz Boulevard
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Postgraduate and Research Programs, Tehran 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
Name of organization / entity
Rehabilitation faculty, Tehran University of Medical Sciences
Full name of responsible person

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Position

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Other areas of specialty/work

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Position

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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