Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of two methods of behavioral cognitive therapy and exercise of Tai Chi on the fear of falling elderly retiree

Protocol summary

Study aim
The Effect of Two Methods of Cognitive-Behavioral Therapy and Tai Chi Sports on Fear of Falling Elderly

Design
Clinical trials have been randomized. The population of the study is 120 retired national retirees who randomly divided into three groups. The intervention group includes cognitive-behavioral therapy, Tai Chi and control group .

Settings and conduct
The National Pension Center has more than 5,000 members in Kerman. Member information is systematically available at the hub. Based on the initial investigations and coordination with the authorities, 120 members were selected based on the inclusion criteria using the sample size formula.

Participants/Inclusion and exclusion criteria
elderly persons in the national retirement center of Kerman with the following criteria 1-Being the age over 60 years 2-The absence of diseases such as stroke, dementia, multiple sclerosis and orthopedic problems impair balance and fear of falling 3. Non-residing in the elderly houses or other institutions

Intervention groups
Participants in the Tai Chi Sports Team will be conducting sporting activities twice a week for 8 weeks, under the supervision of an instructor. The duration of the exercises in each session depends on the physical and mental abilities of the elderly, which is assessed by the coach, between 45 and 60 minutes. The physical environment is the performance of sporting activities in one of the sports halls in Kerman, which is coordinated and monitored by professional mentors of Ms. and Aqa, who have a history of work with the elderly. Participants in the second intervention group receive eight sessions, each session lasting 60-70 minutes during 8 weeks of cognitive behavioral therapy (by a psychologist).

Main outcome variables
Based on the findings of the study . Can be introduced as a simple, inexpensive and uncomplicated way to relieve the fear of falling in the elderly

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190129042548N1**
Registration date: **2020-03-19, 1398/12/29**
Registration timing: **retrospective**

Last update: **2020-03-19, 1398/12/29**
Update count: **0**

Registration date
2020-03-19, 1398/12/29

Registrant information

Name
Fatemeh Hoseinzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3226 6898

Email address
nurse.googooloo@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-03, 1397/12/12

Expected recruitment end date
2019-04-09, 1398/01/20

Actual recruitment start date
2019-03-03, 1397/12/12

Actual recruitment end date
2019-04-09, 1398/01/20

Trial completion date
2019-05-10, 1398/02/20

Scientific title
Comparison of two methods of behavioral cognitive therapy and exercise of Tai Chi on the fear of falling elderly retiree

Public title
"Investigating the Effect of Cbt on the fear of Falling in Elderly", "Examining the Effects of Tai Chi Practices on the Fear of falling in Elderly''

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Being at over the age of 60 years Being at the appropriate level of cognitive function(minimum AMT test 8 grades) Being able to read and write Full fluency in Farsi language Having written consent to attend the research

Exclusion criteria:
Residence in elderly house or other institutions Cases of diseases such as stroke, dementia, multiple sclerosis, and orthopedic problems impair balance and fear of falling (information through interviewing and assessing the health status of the elderly)

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**
Actual sample size reached: **115**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Rafsanjan University of Medical Sciences.REC.1397.128

Street address
Imam Ali ;Blvd

City
Rafsanjan

Province
Kerman

Postal code
7717933777

Approval date
2018-10-29, 1397/08/07

Ethics committee reference number
IR.RUMS.REC

Health conditions studied

1

Description of health condition studied
fear of falling in elderly

ICD-10 code
F40.9

ICD-10 code description
A group of disorders in which anxiety is evoked only, or predominantly, in certain well-defined situations that are not currently dangerous.

Primary outcomes

1

Description
Fear of falling

Timepoint
Immediately after the intervention and 8 months after the intervention

Method of measurement
SAFFE scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:: Participants in the Tai Chi Sports Team are trained at least twice a week under supervision skilled trainer

Category
Rehabilitation

2

Description
Intervention group: Participants in the second intervention group receive eight sessions, each session for 60 to 70 minutes during 8 weeks of cognitive behavioral therapy.:

Category
Rehabilitation

3

Description
Control group: The control group will receive guidance and counseling for routine interventions in old age and will be provided with explanations about physical problems such as hypertension and blood sugar control.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Country retirement club
Full name of responsible person
Mr. Hakimullah Elahy
Street address
No.12
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Kerman
Province
Kerman
Postal code
7613756777
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info@cspf.ir
Web page address
https://www.cspf.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Ali Shamsizadeh
Street address
Fassandjan, Imam Ali Blvd, Central Office of Rafsanjan University of Medical Sciences, Rafsanjan, Dept. of Research and Technology,
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Province
Kerman
Postal code
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Phone
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Email
vcrt@rums.ac.ir
Web page address
http://www.rums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rafsanjan 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
Rafsanjan University of Medical Sciences
Full name of responsible person
Fatemeh Hoseinzadeh
Position
Nurse practitioner
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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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