

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The surveying of effect of tai-chi chuan exercise on the balance status of the elderly men

Protocol summary

Study aim

Effect of Tai-Chi Chuan exercise on balance status of elderly men in Kashan in 2020

Design

Clinical trial with control group, no parallel group, without blinding, randomized, sample size 40

Settings and conduct

This study will be performed on 40 elderly people in Kashan`s Akramian Clinic in 2020. After selecting the samples according to the inclusion criteria and dividing them into two control and intervention groups, the intervention group will receive Tai-Chi exercises within 10 weeks.

Participants/Inclusion and exclusion criteria

inclusion criteria: The elderly over 60; Able to do Tai Chi exercise; Unexplained stroke; Unrecognized hearing and visual impairment; Resident of Kashan; Elderly not participating in similar studies; Willingness to cooperate; Lack of physical disability; Score below 25 from Fullerton Tool; No sleeping medication daily exclusion criteria: Withdrawal from attendance; Absence of more than two sessions; Election; Hospitalization; Acute and severe physical illness during study; Prescription of persistent sleep medications

Intervention groups

Intervention group: The group that will practice Tai Chi Chuan 2 sessions per week for 10 weeks. Control group: The control group will not receive any intervention from the research team.

Main outcome variables

The main outcome variable is improvement in the balance of the elderly. The researcher will use the Fullerton tool to assess the balance state. The checklist has 10 items that are assigned 0 to 4 points per item. The score from this checklist will be between zero and forty and the cut-off point for this balance will be 25.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200108046058N1**

Registration date: **2020-02-02, 1398/11/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-02, 1398/11/13**

Update count: **0**

Registration date

2020-02-02, 1398/11/13

Registrant information

Name

Hamid gholami alavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5522 3010

Email address

gholami-h@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-30, 1398/11/10

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The surveying of effect of tai-chi chuan exercise on the balance status of the elderly men

Public title

The surveying of effect of tai-chi chuan on the balance status

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

elderly men over 60 years Be able to do Tai Chi exercise Not having a history of brain stroke and other diseases that affect balance Lack of corrected visual and hearing impairment Resident of Kashan Elderly not participating in similar studies Willingness to cooperate Lack of physical disability Earn a score below 25 from the Fullerton scale Patients who do not take sleeping pills daily

Exclusion criteria:

Withdraw from attendance Absent more than 2 sessions of workouts Hospitalization Acute and severe physical illnesses during the study Prescription of permanent hypnotic medications

Age

From **60 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be selected from the clients according to the inclusion criteria in an accessible and easy manner and then randomly assigned to the experimental and control groups And a written consent is obtained from them. In addition, random allocation of the elderly to the two groups of experimental and control will be done using quadruple random blocks method. (The first 6 blocks are assigned and numbered 1 to 6. Subsequently these blocks plus duplicates of blocks 1 to 4 Regularly stacked together to achieve 10 blocks <40 cases>)

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 Kashan University of Medical Sciences

Street address

ayatollah yasrebi street. Alley of Martyr Podat, No. 12

City

kashan

Province

Isfahan

Postal code

8716863856

Approval date

2019-12-21, 1398/09/30

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1398.056

Health conditions studied

1

Description of health condition studied

tai-chi chuan exercise

ICD-10 code

ICD-10 code description

2

Description of health condition studied

balance status

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Percentage of people with a Fullerton instrument score above 25

Timepoint

Measurement of balance status at baseline (before intervention) and end of study

Method of measurement

Fullerton Advanced Balance Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: During a briefing session, research tips for the elderly in the intervention group will be described. After pre-test for all participants, the intervention group in a group under the supervision of a specialist instructor and researcher will do selected Tai

Chi Kung exercises (Tai Chi Chuan exercise is a type of traditional Chinese exercise that involves physical activity and cognitive control, performed individually or in groups. The principles of Tai Chi Kung include soft and slow movements and special attention to relaxation) for 10 weeks, 2 sessions per week and 30-40 minutes each session in Kashan akramian Clinic. Each exercise session consists of 5 minutes of warm-up, 20 minutes of Tai Chi exercises and 5 minutes of cool-down. Every workout session in elementary program sessions is 30 minutes and the final sessions will increase to 40 minutes.

Category

Rehabilitation

2**Description**

Control group: The control group will not receive any intervention from the research team.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kashan Akramian clinic

Full name of responsible person

Javad Zarei

Street address

kashan, Fifteen khordad square, 22 Bahman Ave, Atoufi alley, Akramian clinic

City

kashan

Province

Isfahan

Postal code

8715184164

Phone

+98 31 5545 3786

Email

Gholami-h@kaums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Deputy of Research and Technology, Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences - Ravandi Boulevard - Kashan University of Medical Sciences - Kashan Ravandi Boulevard

City

Kashan

Province

Isfahan

Postal code

81151-87159

Phone

+98 31 5554 0021

Email

gholamy-h@kaums.ac.ir

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

Yes

Title of funding source

Kashan 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**

Kashan University of Medical Sciences

Full name of responsible person

Hamid Gholami alavi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

12, Pudas Martyr Ave, Ayatollah Yasrebi Street, kashan

City

Kashan

Province

Isfahan

Postal code

8716863856

Phone

+98 31 5522 3010

Fax**Email**

Gholami-h@kaums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Mansour Dianti

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Qotbe Ravandi Blvd, Kashan University of Medical Sciences

City

kashan

Province

Isfahan

Postal code

81151-87159

Phone

+98 31 5554 0021

Email

Mandianati@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamid Gholami alavi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

12, Pudar Martyr Ave, Ayatollah Yasrebi Street, kashan

City

Kashan

Province

Isfahan

Postal code

8716863856

Phone

+98 31 5522 3010

Fax

Email

Gholami-h@kaums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Reporting of study findings in paper form and presentation at relevant conferences and congresses

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Reporting of study findings in paper form and presentation at relevant conferences and congresses

From where data/document is obtainable

Communication with Researcher (Hamid Gholami Alavi)
Contact number: 00989223215093 Email: gholami-h@kaums.ac.ir

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

If the request is sent by the applicant, it will finally be answered in about a week.

Comments