

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Investigation the effect of Qigong on depression, anxiety, stress and activity of daily living in elderly referring to comprehensive health center in Rafsanjan 2020

Protocol summary

Study aim

If doing gong exercise can reduce the level of depression, anxiety, stress and increase daily activity in the elderly, it can be suggested as a practical and low-cost method.

Design

Clinical trial with control group, no blinding, randomized

Settings and conduct

Elderly people referring to Rafsanjan Comprehensive Health Centers will be selected in the first session of training exercises in person and then a DVD of exercises will be provided to people and people will do exercises for 8 weeks, 3 times a week for 30 minutes. The statistician does not know which people are in the intervention or control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: elderly people 60 years and older; no musculoskeletal problems and mental illness. Exclusion criteria: start treatments for depression and anxiety; perform relaxation techniques

Intervention groups

Qi Gong Mental-Physical Exercise involves slow focused movements, coordinated with breathing and cognitive skills. This exercise creates more peace and integration of mind and body. The intervention group will perform exercises for 8 weeks, 3 times a week for 30 minutes and the control group will have their daily activities.

Main outcome variables

Depression; anxiety; stress and daily activities

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150519022320N24**
Registration date: **2020-10-17, 1399/07/26**

Registration timing: **prospective**

Last update: **2020-10-17, 1399/07/26**

Update count: **0**

Registration date

2020-10-17, 1399/07/26

Registrant information

Name

Tayebeh Mirzaei

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of Qigong on depression, anxiety, stress and activity of daily living in elderly referring to comprehensive health center in Rafsanjan 2020

Public title

Investigation the effect of Qigong on depression, anxiety, stress and activity of daily living in elderly referring to comprehensive health center in Rafsanjan 2020

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Elderly people over 60 years Ability to use a smartphone
No depression, anxiety, stress disorder when undergoing medication from 3 months before the study
No disability
Interested in participating in research
No Parkinson's and Alzheimer's disease
Do not engage in any kind of relaxation technique
No sports ban
No drug abuse
Lack of musculoskeletal problems

Exclusion criteria:

Reluctance to continue collaborating in this study
Do not do exercises for 3 sessions or more
Performing relaxation techniques such as massage therapy or acupuncture
Diseases such as myocardial infarction, stroke, late stages of cancer, organ transplantation
Initiated taking antidepressants, anxiety, stress drugs

Age

From **60 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

According to the simple randomization, elderly were divided into two group 35 person, the intervention group and the control group. Elderly will divided into two groups of 35 people, A and B, based on a table of random numbers, and finally, groups A and B will divided into intervention and control groups based on the lottery.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Individuals will be divided into two groups of intervention and control, and the intervention group will perform Qi Gong exercise, then will be studied and compared the effect of Qi Gong exercise on the level of depression, anxiety, stress and activity of daily living between the two groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Rafsanjan University of Medical Sciences

Street address

School of Nursing and Midwifery, Nurse Avenue, Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7718796755

Approval date

2020-10-04, 1399/07/13

Ethics committee reference number

IR.RUMS.REC.1399.159

Health conditions studied

1

Description of health condition studied

Depression in elderly

ICD-10 code

F32.9

ICD-10 code description

Depression

2

Description of health condition studied

Anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Depression

Timepoint

Before, one month and 2 months after intervention

Method of measurement

DASS21 questionnaire

2

Description

Anxiety

Timepoint

Before, one month and 2 months after intervention

Method of measurement

DASS21 questionnaire

3

Description

Stress

Timepoint

Before, one month and 2 months after intervention
Method of measurement
DASS21 questionnaire

4

Description

Activity of daily living

Timepoint

Before, one month and 2 months after intervention

Method of measurement

ADL& IADL questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first session will be given to the necessary training for the companies in the presence of the instructor, and then the training exercises DVD will be provided to you. The members of the intervention group are added to the Watts group and a photo of the exercises in the group is sent to the individuals. Others are asked to do the exercises 3 times a week for 30 minutes to 8 weeks. Then follow up the phone to do the exercises

Category

Treatment - Other

2

Description

Control group: : The first session, which will be held at a predetermined time and date in accordance with health protocols and will be completed by individuals after attracting the participants' opinion on researching the relevant questionnaires.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health service centers in Rafsanjan

Full name of responsible person

Dr. Tayebah mirzaei

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Jomhory street, Parastar blv

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

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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

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

Dr.Tayyebah Mirzaei

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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