

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### The effect of yoga exercises on life satisfaction in caregivers of elderly people living at home

#### Protocol summary

##### Study aim

Determining the Impact of Life Satisfaction on Caregivers of Elderly People at Home

##### Design

The clinical trial has a randomized, single-blind control group.

##### Settings and conduct

Intervention at a sports club in the city center.

##### Participants/Inclusion and exclusion criteria

Entry requirements 1. Minimum literacy 2. Assign at least 31 hours of daily care per week for at least 3 months 3. Physical ability to attend yoga classes 4. No history of attending yoga classes 5. Minimum age of participants is 18 years and maximum 50 years Non-arrival conditions 1. Absent more than three sessions of yoga exercises 2. Elderly disease worsens

##### Intervention groups

The intervention group was divided into two groups: 1 and 2, then the intervention was performed in the experimental group for 4 weeks, three times a week for 90 minutes in a downtown sports club in both intervention groups. The training was conducted on different days of the week. To control the ethics of the study, the control group prepared a training booklet on yoga exercises and exercises and presented to the control group after the end of the study.

##### Main outcome variables

Feeling satisfied with life in the care of the elderly

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191106045353N1**

Registration date: **2019-11-14, 1398/08/23**

Registration timing: **retrospective**

Last update: **2019-11-14, 1398/08/23**

Update count: **0**

##### Registration date

2019-11-14, 1398/08/23

##### Registrant information

###### Name

Zahra Kaveh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 4221 1896

###### Email address

zkaveh@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-22, 1397/09/01

##### Expected recruitment end date

2018-12-23, 1397/10/02

##### Actual recruitment start date

2018-11-22, 1397/09/01

##### Actual recruitment end date

2018-12-23, 1397/10/02

##### Trial completion date

2019-01-21, 1397/11/01

##### Scientific title

The effect of yoga exercises on life satisfaction in caregivers of elderly people living at home

##### Public title

The effect of yoga exercises on life satisfaction

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Minimum literacy Assign at least 31 hours of daily care

per week for at least 3 months Physical ability to attend yoga classes No history of attending yoga classes Minimum age 18 and up to 50 year

**Exclusion criteria:**

Absent more than 3 sessions of yoga classes Elderly disease worsens

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **80**

Actual sample size reached: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random allocation was performed using a random number table. To use the random number table, the framework of the statistical community was first specified. The researcher accidentally started moving from one point in the table to the left of the table. The point selection was done by blindfolding and placing the tip of the pen on the table. Envelopes were given to the participants and the relevant codes were inserted into them, and the study participants were sealed. The envelopes were sealed in such a way that the content was not clear and the participants were given an entry order. Due to the double-digit statistical population, participants were given two-digit codes.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Participants, community health center (sampling center) personnel, and individuals who assisted in collecting information about participants were recruited when participants were divided into control and intervention groups. The randomization was unaware .80 envelopes were considered and the relevant codes were inserted and the participants in the study were sealed and the contents were unclear. Participants were given the order of inclusion according to the two-digit statistical population of the two-digit codes given to the participants. . 40 patients in the intervention group and 40 in the control group.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Faculty of Nursing and Midwifery and Faculty of Rehabilitation-Tehran University

**Street address**

Headquarters of the Ministry of Health and Medical Education, between South Flamak and Zarafshan, Iran Sima Ave, Qods Town (West), Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733171

**Approval date**

2018-11-06, 1397/08/15

**Ethics committee reference number**

IR.TUMS.FNM.REC.1397.147

**Health conditions studied**

1

**Description of health condition studied**

Yoga and Feeling satisfied with life in the care of the elderly

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

Feeling satisfied with life in the care of the elderly

**Timepoint**

After intervention and 4 weeks after intervention

**Method of measurement**

Life Satisfaction Questionnaire.Q-LES-Q-SF

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: In this group yoga exercises were performed for 4 weeks, 90 minutes and three times a week by the intervention group.

**Category**

Lifestyle

2

**Description**

Control group: This group does not do any intervention, but in the end of intervention, this group will be given a

yoga pamphlet.

**Category**

Lifestyle

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Mustafa Khomeini Community Health Center of Saveh

**Full name of responsible person**

Rostamkhan

**Street address**

Shariati Ave. Mustafa Khomeini Community Health Center

**City**

Saveh

**Province**

Markazi

**Postal code**

9177899191

**Email**

info@savehuns.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Seyedeh Fatemeh Waheq Rahimparvar

**Street address**

Dr. Mirkhani St. (East Nosrat),Tohid Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733171

**Phone**

+98 21 6694 1669

**Email**

fnm-researchdeputy@tums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Zahra Kaveh

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Saeedi4 Alley,TAleghani9 Ave

**City**

Saveh

**Province**

Markazi

**Postal code**

3918837399

**Phone**

+98 86 4221 1896

**Email**

z.kaveh1373@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Zahra Kaveh

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Saeedi4 Alley,Taleghani 9 Ave

**City**

Saveh

**Province**

Markazi

**Postal code**

3918837399

**Phone**

+98 86 4221 1896

**Email**

z.kave1373@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Zahra Kaveh

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Saeedi4 Alley,Taleghani9 Ave

**City**

Saveh

**Province**

Markazi

**Postal code**

3918837399

**Phone**

+98 86 4221 1896

**Email**

z.kaveh1373@yahoo.com

**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**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Demographic information is available but the names of the participants are not known.

**When the data will become available and for how long**

Start access period after printing results

**To whom data/document is available**

For university and non-university students

**Under which criteria data/document could be used**

No special conditions

**From where data/document is obtainable**

See Researcher. (Zahra Kaveh) z.kaveh1373@yahoo.com

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

The applicant can send an email.

**Comments**