

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Effectiveness of laughter yoga on anxiety and depression in women aged 50 to 70

#### Protocol summary

##### Study aim

The effectiveness of laughter yoga on depression and anxiety in women 50 To 70 years old

##### Design

A single-blind randomized controlled clinical trial will be conducted on 60 women aged 50-70 years old, member of the Association of Education Retirees in two intervention and control groups. The subjects will be randomly allocated in the intervention and control groups, using random numbers.

##### Settings and conduct

Intervention will be done in the gym by doing yoga exercises. Control group will receive no intervention. Depression and anxiety will be evaluated by co-researcher who is blind to grouping, using the Beck Depression and Anxiety Inventory.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Being the member of the Association of Retirees for Education; Age between 50 and 70 years; Depression scores above 10 based on the Beck's Depression Inventory; Anxiety score above 8 based on Beck's Anxiety Inventory; Ability to do the exercises based on Laughter yoga instructor confirmation; Being independent in activities of daily living; Ability to communicate; Non-Inclusion Criteria: Suffering from major depressive disorder or generalized anxiety disorder base on psychiatrist diagnosis; Using other complementary therapies.

##### Intervention groups

In the intervention group, women aged 50-70 years will do laughter yoga exercises in the gym for eight weeks, two sessions in a week, 90 minutes per session, under the supervision of certificated laughter yoga instructor. Control Group receives no intervention.

##### Main outcome variables

Depression and anxiety scores by Beck Beck Questionnaire, at the beginning of the study And the fourth and eighth weeks

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180523039804N1**

Registration date: **2018-08-06, 1397/05/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-08-06, 1397/05/15**

Update count: **0**

##### Registration date

2018-08-06, 1397/05/15

##### Registrant information

##### Name

hassan mokarrami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 58 3231 3623

##### Email address

h.mokarrami@nkums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-06-22, 1397/04/01

##### Expected recruitment end date

2018-12-22, 1397/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of laughter yoga on anxiety and depression in women aged 50 to 70

### Public title

Anxiety and depression in women aged 50 to 70

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age 50 to 70 Being independent in activities of daily living Ability to communicate (awareness of time, place, and people)

#### Exclusion criteria:

Use of other supportive and complementary therapies Having Major Depression and Generalized Anxiety Disorder Having problems and physical illnesses having scores of less than 10 and 8 respectively for Beck's Depression Inventory and Beck's Anxiety Inventory suffering from acute illnesses

### Age

From **50 years** old to **70 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomly allocating of the elderly to the intervention and control groups, using random numbers

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

In this study, it is not possible to blind subjects due to the nature of the intervention; and instead, to reduce bias, the co-researcher as assessor will be blind. But, there is no choice for the situation in which only the "assessor" is blind.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of north khorasan University of Medical Sciences

##### Street address

Central building of north khorasan University of

Medical Sciences, Dolat Blvd., Bojnurd

#### City

Bojnurd

#### Province

North Khorasan

#### Postal code

74877-94149

#### Approval date

2018-05-15, 1397/02/25

#### Ethics committee reference number

IR.nkums.REC.1397.011

## Health conditions studied

### 1

#### Description of health condition studied

Depression

#### ICD-10 code

F32.9

#### ICD-10 code description

Depressive episode, unspecified

### 2

#### Description of health condition studied

Anxiety

#### ICD-10 code

F41.9

#### ICD-10 code description

Anxiety disorder, unspecified

## Primary outcomes

### 1

#### Description

Depression

#### Timepoint

Study onset, week 4, and week 8

#### Method of measurement

Beck's depression inventory

### 2

#### Description

Anxiety

#### Timepoint

Study onset, week 4, and week 8

#### Method of measurement

Beck's Anxiety Inventory

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In the intervention group, after training, participants will

be asked to implement laughter yoga protocol for 8 weeks, 2 sessions in a week, and 90 minutes each session; and the level of their depression and anxiety will be measured using Beck Depression Inventory, and Beck Anxiety Inventory at the study onset, and end of the fourth and eighth weeks. Control group, will receive no intervention.

**Category**

Other

**2****Description**

Control group: Receives no intervention.

**Category**

Other

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

Bojnurd Education Retirees Association

**Full name of responsible person**

Behzad Mohammad zadeh

**Street address**

Building of education retirees association, Basij crossroad, Bojnurd.

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<http://nurse.nkums.ac.ir>

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

Bojnourd University of Medical Sciences

**Full name of responsible person**

Dr. Kaveh Hojjat

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Central building of north khorasan university of Medical Sciences, Dolat Blvd.

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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**

Bojnourd 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**

Bojnourd University of Medical Sciences

**Full name of responsible person**

Hassan mokarrami

**Position**

Graduate student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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Bojnurd school of nursing and midwifery, Shahriar St.

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

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**Full name of responsible person**

Mohammad Reza Armat

**Position**

Instructor

**Latest degree**

Master

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

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Bojnourd University of Medical Sciences

**Full name of responsible person**

Hassan Mokarrami

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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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