

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

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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

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Building of education retirees association, Basij crossroad, Bojnurd.

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

Bojnourd 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

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

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Full name of responsible person

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Position

Instructor

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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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