Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)
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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

Street address
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

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Name of organization / entity

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Full name of responsible person
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Position
Instructor

Latest degree
Master

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Nursery

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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