Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of laughter yoga on General health and happiness of postmenopausal women

Protocol summary

Study aim
Determining the effect of laughter yoga on the general health and happiness of postmenopausal women

Design
A Quasi-experimental clinical trial, with a control group, without blinding, with allocation of two centers for the two groups, on 62 postmenopausal women.

Settings and conduct
The intervention group will participate in eight 45-minute sessions twice a week of laughter yoga exercises held in the Faculty of Nursing, Midwifery and Management of Iran University of Medical Sciences, Tehran, by the researcher and under the supervision of an international laughter yoga coach. The control group in the central campus of Iran University of Medical Sciences will only receive the illustrated pamphlet of Laughter Yoga prepared by the researcher.

Participants/Inclusion and exclusion criteria
Inclusion criteria: menopausal women 65 years old and younger. Exclusion criteria: having acute physical diseases, 3rd and 4th degree hernia, hemorrhoids, heart disease, epilepsy, severe back pain, 4th degree uterine prolapse, use of hormone replacement therapy, history of mental illness or history of stressful events in three in the last month, the experience of participating in laughter yoga, music therapy, meditation and relaxation classes, taking neuropsychiatric and sedative drugs.

Intervention groups
Intervention group: participation in 8 sessions of 45 minutes, twice a week Control group: receiving the illustrated booklet of Laughter Yoga prepared by the researcher

Main outcome variables
General health, happiness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230225057525N1**
Registration date: **2023-04-17, 1402/01/28**
Registration timing: **prospective**

Last update: **2023-04-17, 1402/01/28**
Update count: **0**

Registration date
2023-04-17, 1402/01/28

Registrant information

Name
Homa Sadeghi Avvalshahr

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-21, 1402/02/01

Expected recruitment end date
2023-06-22, 1402/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of laughter yoga on General health and happiness of postmenopausal women

Public title

The effect of laughter yoga on health and happiness

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Menopausal women 65 years old and younger

Exclusion criteria:

Having diseases such as: hernia, hemorrhoids (grade 3 and 4 based on the question of the symptoms of the disease) Suffering from heart problems or chest pain, epilepsy, severe back pain, uterine prolapse (procidentia based on the person's statements and asking about the symptoms of the disease) Use of hormone replacement therapy Having a history of mental illness based on the person's statements Having experience participating in laughter yoga classes Taking neuropsychological and sedative drugs based on the person's statements Having experience participating in music therapy, dance, meditation or relaxation classes

Age

To **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Next to Milad Tower, Hemat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2022-11-15, 1401/08/24

Ethics committee reference number

IR.IUMS.REC.1401.640

Health conditions studied

1

Description of health condition studied

General health, happiness

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

General health:: According to the definition of the World Health Organization(1998), health is a state of complete physical, mental and social health, not just the absence of disease or infirmity .

Timepoint

Before the start of the intervention, after the end of the intervention and one month later

Method of measurement

General health will be measured using 28-Item General Health Questionnaire.

2

Description

Happiness: According to Diener's definition (2002), happiness is the evaluation that a person makes of himself and his life. This evaluation can have a cognitive aspect, such as judgments about life satisfaction, or an emotional aspect that includes the mood and emotions that appear in response to life events. Therefore, happiness consists of the following components, which are: satisfaction with life, positive and pleasant moods and emotions, the absence of negative emotions and feelings, and other factors such as optimism, self-esteem, and a sense of prosperity are involved in it.

Timepoint

Before the start of the intervention, after the end of the intervention and one month later

Method of measurement

Happiness will be measured using the Oxford Happiness Questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Participating in the practice sessions of the laughter yoga program, which includes eight 45-minute sessions twice a week.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Nursing and Midwifery, Iran University of Medical Sciences
Full name of responsible person
Dr. Hamid Peyravi
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2

Recruitment center
Name of recruitment center
Faculty of Medical Information and Management, Iran University of Medical Sciences
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3

Recruitment center
Name of recruitment center
Faculty of Medicine, Iran University of Medical Sciences
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4

Recruitment center
Name of recruitment center
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5

Recruitment center
Name of recruitment center
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6

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

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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
Iran 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
Iran University of Medical Sciences
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Homa Sadeghi Avval Shahr
Position
Assistant Professor
Latest degree
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Person responsible for updating data

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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
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
Title and more details about the data/document
All potential data can be shared after de-identifying individuals
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Submit an official application form from the workplace
From where data/document is obtainable
E-mail address of the researcher: sadeghiavalshahr.h@iums.ac.ir
What processes are involved for a request to access data/document
Sending the official request approved by the directorate of the educational or research institution via academic email to the researcher's email, verifying the applicant's information, sending the requested information after anonymizing the information.
Comments