

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 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)

##### Phone

+98 21 4365 1000

##### Email address

sadeghiavalshahr.h@iums.ac.ir

#### 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 (prolapsed) 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

**Street address**

Faculty of Nursing and Midwifery, Iran University of Medical Sciences, , Rashid Yasmi St., Valiasr St.

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۹۹۶۷۱۳۸۸۳

**Phone**

+98 21 4365 1000

**Fax**

+98 21 8820 1978

**Email**

fnm@iums.ac.ir

**2****Recruitment center****Name of recruitment center**

Faculty of Medical Information and Management, Iran University of Medical Sciences

**Full name of responsible person**

Dr. Soudabe Vatankhah

**Street address**

Faculty of Medical Information and Management, Iran University of Medical Sciences Rashid, Yasemi St. Valiasr St.

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۹۹۶۷۱۳۸۸۳

**Phone**

+98 21 8879 4301

**Fax**

+98 21 8888 3334

**Email**

public.shmis@iums.ac.ir

**3****Recruitment center****Name of recruitment center**

Faculty of Medicine, Iran University of Medical Sciences

**Full name of responsible person**

Dr. Fahimeh soheilpour

**Street address**

Faculty of Medicine, Iran University of Medical Sciences , next to Milad Tower, Hemmat highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 86701

**Fax****Email**

Schoolofmedicine@iums.ac.ir

**4****Recruitment center****Name of recruitment center**

faculty of allied medical sciences, Iran University of Medical Sciences

**Full name of responsible person**

Dr. Ali Neshastehriz

**Street address**

faculty of allied medical sciences, Iran University of Medical Sciences, next to Milad Tower, Hemmat highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 86701

**Email**

info@iums.ac.ir

**5****Recruitment center****Name of recruitment center**

School of Public Health, Iran University of Medical Sciences

**Full name of responsible person**

Dr Mohammadreza Vafa

**Street address**

School of Public Health, Iran University of Medical Sciences, next to Milad Tower, Hemmat highway,

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 86701

**Email**

info@iums.ac.ir

**6****Recruitment center**

**Name of recruitment center**

School of Advanced Technology in Medicine, Iran  
University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Taghi Joghataei

**Street address**

School of Advanced Technology in Medicine, Iran  
University of Medical Sciences, next to Milad Tower,  
Hemmat highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 86701

**Email**

info@iums.ac.ir

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

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Abdolreza Pazouki

**Street address**

Iran University of Medical Sciences, next to Milad  
tower, Hemmat highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 86701

**Email**

info@iums.ac.ir

**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

**Full name of responsible person**

Homa Sadeghi Avval Shahr

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Education

**Street address**

School of Nursing & Midwifery, Rashid Yasemi St.  
Valiasr St

**City**

تهران

**Province**

Tehran

**Postal code**

۱۹۹۶۷۱۳۸۸۳

**Phone**

009843651810

**Fax****Email**

sadeghiavalshahr.h@iums.ac.ir

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

Iran University of Medical Sciences

**Full name of responsible person**

Homa Sadeghi Avval Shahr

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Education

**Street address**

School of Nursing & Midwifery Rashid Yasemi St.  
Valiasr St.

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۹۹۶۷۱۳۸۸۳

**Phone**

+98 21 4365 1810

**Email**

sadeghiavalshahr.h@iums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Homa Sadeghi Avval Shahr

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Education

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**Province**

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**Postal code**

۱۹۹۶۷۱۳۸۸۳

**Phone**

+98 21 4365 1810

**Email**

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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**