

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

Comparison of two methods of music therapy and laughter yoga on depression in the elderly

Protocol summary

Study aim

The purpose of this study was to compare the effect of music therapy with laughter yoga on depression in the elderly referred to health centers in Rafsanjan in 2022.

Design

90 eligible seniors will be divided into 3 groups (two intervention groups and one control group) using a simple random division method using a random number table, and the type of intervention will be determined again by random division on each group.

Settings and conduct

For depressed elderly people referred to Rafsanjan health centers, music intervention is done using headphones at home and laughter yoga intervention is done in groups in the gym.

Participants/Inclusion and exclusion criteria

Earn a score higher than 6 from the GDS questionnaire
No addiction and use of psychiatric drugs
No severe physical or mental problems
No cognitive impairment
No psychological problems in the last 6 months
Reluctance to continue cooperation
Start taking antidepressants
Perform other exercises and interventions that affect depression
Do not do more than 3 sessions of exercises

Intervention groups

The music intervention group will undergo music therapy for 8 weeks and 2 sessions per week for 30 minutes. The Laughter Yoga intervention group will undergo Laughter Yoga intervention for 8 weeks and 2 sessions per week. The control group will be voiced over 8 weeks in the WhatsApp group about the problems that will occur in the aging process and their medical questions and problems will be answered.

Main outcome variables

depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150519022320N25**

Registration date: **2022-02-22, 1400/12/03**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-22, 1400/12/03**

Update count: **0**

Registration date

2022-02-22, 1400/12/03

Registrant information

Name

Tayebbeh Mirzaei

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

Email address

t.mirzaei@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-19, 1400/11/30

Expected recruitment end date

2022-05-20, 1401/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two methods of music therapy and laughter yoga on depression in the elderly

Public title

Comparison of the effect of music therapy and laughter yoga on depression in the elderly

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Being over 60 years old
Lack of severe hearing problems
Ability to use a smartphone
Obtaining a score higher than 6 from the GDS questionnaire
No addiction and use of psychiatric drugs
Not having severe physical and mental problems
Do not suffer from cognitive disorders based on medical diagnosis and being treated
No psychological problems in the last 6 months

Exclusion criteria:

Reluctance to continue cooperation
Start taking antidepressants
Performing exercises and other interventions that affect depression
Do not do more than 3 sessions of exercises

Age

From **60 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

After identifying the depressed elderly according to the inclusion criteria and its listing, they will be divided into 3 groups of 30 people A, B and C by simple random division using a table of random numbers and then the groups will be divided again by simple random division. On each group (2 intervention groups and one control group) it will be determined what intervention will be done on each group

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Rafsanjan University of Medical Sciences

Street address

School of Nursing and Midwifery, Nurse Avenue, Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7718796755

Approval date

2022-02-06, 1400/11/17

Ethics committee reference number

IR.RUMS.REC.1400.235

Health conditions studied**1****Description of health condition studied**

Depression in the elderly

ICD-10 code**ICD-10 code description**

Depression

Primary outcomes**1****Description**

GDS Questionnaire Depression Score

Timepoint

Before, immediately and one month after the intervention

Method of measurement

Geriatric Depression Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The music intervention group will undergo music therapy for 8 weeks and 2 sessions per week for 30 minutes. The type of music to be intervened is a piece prepared with soothing songs with a gentle, happy and relaxing style, and preferably first the priority will be chosen by the taste of the elderly, and finally the final music file will be approved by the tutor and the consultant. This intervention will be done at home and preferably with headphones on pre-determined and agreed days by the researcher and the elderly for 30 minutes to the songs that are uploaded to the WhatsApp group and how to follow it. They were asked to notify the researcher immediately after listening to the music on the pre-arranged day.

Category

Treatment - Other

2

Description

Intervention group: The Laughter Yoga intervention group will also undergo Laughter Yoga intervention for 8 weeks and 2 sessions per week. The laughter yoga intervention group is divided into two groups, men and women, and as a group, the intervention in the gym will be pre-determined and will be performed on the elderly group at a time determined and predetermined by the researcher. During these 8 weeks of intervention, if the corona peak starts again and interrupts the intervention, this intervention will be followed virtually and a training video on how to perform Laughter Yoga in WhatsApp will be sent to them and in WhatsApp the absence of direction. Ensure the implementation of the intervention will be done.

Category

Treatment - Other

3

Description

Control group: The control group will be formed by the WhatsApp group for 8 weeks by the researcher, and the problems that will arise in the aging process will be explained aloud, and their medical questions and problems will be answered.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health service centers in Rafsanjan

Full name of responsible person

Dr.Tayebeh Mirzaei

Street address

Faculty of Nursing, Nurse blvd., Jomhury street,
Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7718174715

Phone

+98 34 3428 0038

Email

T.Mirzaei@rums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr.Reza Vazirinejad

Street address

Emam Ali blvd

City

Rafsanjan

Province

Kerman

Postal code

7718174715

Phone

+98 34 3131 5075

Email

alishamsy@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr.Tayebeh Mirzaei

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing, Nurse blvd., Jomhury street,
Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7718174715

Phone

+98 34 3428 0038

Fax

+98 34 3425 8497

Email

t.mirzaei@rums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr.Tayebe Mirzaei

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing, Nurse blvd., Jomhury street,
Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7718174715

Phone

+98 34 3428 0038

Fax

+98 34 3425 8497

Email

T.Mirzaei@rums.ac.ir

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing, Nurse blvd., Jomhury street,
Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7718796755

Phone

+98 34255900

Fax

+98 34 3425 8497

Email

t.mirzaei@rums.ac.ir

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

Person responsible for updating data

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr.Tayebe Mirzaei

Position

Associate Professor

Latest degree

Ph.D.