

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of group art therapy on stress, depression, anxiety and loneliness of the elderly living in the nursing homes in North Khorasan Province in 2023

Protocol summary

Study aim

Determining the effect of group art therapy on stress, anxiety, depression and feeling of loneliness among the elderly living in nursing homes in selected cities of North Khorasan province in 1402

Design

Available sampling is selected and random assignment of two control and test groups will be done by simple random method in the form of lottery.

Settings and conduct

Before starting the intervention, an informed consent briefing session will be held to obtain and pre-test. Then, the intervention method will be explained for the elderly in the test group. Group art therapy based on painting and music in this research includes 12 sessions (one month) that are held three days a week, and each session lasts for one hour, and this one hour includes three parts: warm-up (10 minutes), program implementation (30 minutes) and summary (20 minutes) will be held. The venue is a room in the care centers for the elderly in selected cities of North Khorasan.

Participants/Inclusion and exclusion criteria

Age over 60 years, not suffering from cognitive disorders or types of dementia, having the ability to participate in the art therapy course and drawing and making handicrafts, the ability to speak and understand Farsi, not suffering from physical, motor disabilities or types of neurological and motor disorders severe enough to interfere with group therapy programs, no known mood disorder.

Intervention groups

Each art therapy session begins with a 10-minute warm-up, then 30 minutes to perform a special and predetermined program of that session, and the last 20 minutes to the presentation of each person's artwork and discussion between members.

Main outcome variables

To measure stress, anxiety, depression from the dass 21 scale, each question is scored from 0 (does not apply to me at all) to 3 (extremely applies to me), and for loneliness from the De Jong Girolid scale with A 5-point Likert scale is used.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240122060767N1**

Registration date: **2024-01-29, 1402/11/09**

Registration timing: **prospective**

Last update: **2024-01-29, 1402/11/09**

Update count: **0**

Registration date

2024-01-29, 1402/11/09

Registrant information

Name

Arezu Mohamadebrahimzade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 983 5569

Email address

arezumohamadebrahimzade@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-03, 1403/01/15

Expected recruitment end date

2024-05-04, 1403/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group art therapy on stress, depression, anxiety and loneliness of the elderly living in the nursing homes in North Khorasan Province in 2023

Public title

The effect of group art therapy on stress, depression, anxiety and loneliness of the elderly living in the nursing homes in North Khorasan Province in 2023

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 60 years Not suffering from cognitive disorders or types of dementia Having the ability to participate in art therapy courses and drawing and making crafts Ability to speak and understand persian Not having physical-motor disabilities or types of neurological and movement disorders (plegia or Parkinson's) severe enough to interfere with group therapy programs Not having a known mood disorder (major depression or anxiety)

Exclusion criteria:

Failure to participate in one or more sessions of group art therapy programs Failure to complete the questionnaire in the post-exam phase Suffering from any debilitating physical and mental illness Hospitalization

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling method In this research, available sampling is selected and random allocation of two control and test groups will be done by simple random method in the form of lottery. After selecting the elderly who meet the entry criteria, each member of the sample was given a specified number, and then to determine the sample members by drawing lots in the presence of a witness, the numbers were put in a box and then the desired number was drawn by lottery. He removed the box containing the number of members who will enter the test group (25 people), then 25 people will be selected as the control group by lot. After the pre-test, the samples that are in the low category in terms of anxiety or stress or depression will be removed and re-sampling will be done to reach the determined sample size.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics Committee of North Khorasan University of Medical Sciences

Street address

Taftazani 10 st, No 14,16

City

Shirvan

Province

North Khorasan

Postal code

9461791986

Approval date

2024-01-22, 1402/11/02

Ethics committee reference number

IR.NKUMS.REC.1402.167

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

Anxiety, stress, depression, loneliness, group art therapy, elderly

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Anxiety

Timepoint

Before the intervention and two weeks after the last intervention session

Method of measurement

Depression, anxiety and stress scale DASS-21

2**Description**

stress

Timepoint

Before the intervention and two weeks after the last

intervention session

Method of measurement

Depression, anxiety and stress scale DASS-21

3

Description

Depression

Timepoint

Before the intervention and two weeks after the last intervention session

Method of measurement

Depression, anxiety and stress scale DASS-21

4

Description

Loneliness

Timepoint

Before the intervention and two weeks after the last intervention session

Method of measurement

De Jong-Girold Loneliness Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, the intervention includes group art therapy. Group art therapy based on painting and music in this research includes 12 sessions (one month) that are held three days a week (Saturday, Monday, Wednesday or Sunday, Tuesday and Thursday), and each session lasts for one hour. It will be held in three parts: warm-up, program implementation and summation. The venue is a room in the care centers for the elderly. Each group will receive a total of twelve intervention sessions. Each art therapy session begins with a 10-minute warm-up. In these 10 minutes, the researcher warms up the members for that meeting by telling a story related to the topic of that meeting and introducing an activity related to the same meeting, and then 30 minutes to implement the special and predetermined program of that meeting and the last 20 minutes to The presentation of each person's artwork and the discussion between the group members are assigned. For each session, a predetermined program is developed, which includes painting with different techniques and with different materials and methods, such as making a tag for one's own name, preparing by using warm-up techniques such as scribble and finding images in between. Draw lines and color them, draw (draw a front view), draw a family member as an animal, draw (an animal he likes to be) as an art activity, draw his own and others' faces, draw a gift he likes to receive and give a gift to his family members, expressing one's thoughts by performing a practical task, creating a book of life with a drawing (various topics such as the first and

most important memory he had from childhood to the present day or the most important event in his life or three wishes who likes to be fulfilled), finger painting by listening to three wordless music (first lively and then sad and finally relaxing), review of previous sessions and integration of achievements presented by the researcher. The last meeting includes summarizing and preparing people to finish the meetings.

Category

Rehabilitation

2

Description

Control group: Control group: For the control group, the normal daily program of nursing homes will be implemented and no art therapy intervention will be done. In order to respect the rights of the elderly and prevent any unpleasant feelings or discrimination, in addition to explaining the conditions of the research, the control group will be assured that after the completion of the research period, if they wish, a similar program will be organized for them.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Selected nursing homes in selected cities of North Khorasan (Bojnord and Shirvan)

Full name of responsible person

Arezu Mohammad Ebrahim zadeh

Street address

Taftazani 10 st, No 14,16

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Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Arezu Mohammad Ebrahim zadeh

Street address

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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

50

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

Arezu Mohammad Ebrahim zadeh

Position

Master's student in geriatric nursing

Latest degree

Master

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

Arezu Mohammad Ebrahim zadeh

Position

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Master

Other areas of specialty/work

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

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Full name of responsible person

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Position

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Latest degree

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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