Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Girold 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

City

Shirvan

Province

North Khorasan

Postal code

9461791986

Phone

+98 915 983 5569

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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Taftazani 10 st, No 14,16
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Person responsible for scientific inquiries

Contact

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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