Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Art therapy on quality of life in elderly women : A randomized controlled trial

Protocol summary

Study aim
Determining the effect of Art therapy on quality of life in elderly women

Design
Clinical trial with intervention and control group with parallel groups, two-way randomized blind, phase 76 patients, Online random allocation.

Settings and conduct
The study population will be elderly women referring to comprehensive health centers in East Gilan who meet the inclusion criteria. First, the samples that meet the criteria for entering the study will be selected using the available sampling method, and if they wish to participate in the study of the quality of life scale of the elderly Lipad, 76 people will be selected as a sample and randomly in the group and or will be controlled. Art therapy will be applied to the experimental group in 4 sessions of 90 minutes. During this period, no art therapy services will be provided for the control group. At the end of the fourth session, the quality of life intervention questionnaire will be completed by the participants in the intervention group and simultaneously by the control group. 8 weeks after the end of the intervention, the quality of life questionnaire will be completed again by both groups.

Participants/Inclusion and exclusion criteria
Elderly women 60 years old and over 60 years old, Willingness to participate in research, Being literate in reading and writing.

Intervention groups
For the intervention group, 4 sessions of 90 minutes (one session per week for one month) of art therapy will be held. During this time, no art therapy services will be provided to the control group.

Main outcome variables
Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220401054380N1**
Registration date: **2025-02-11, 1403/11/23**
Registration timing: **prospective**

Last update: **2025-02-11, 1403/11/23**
Update count: **0**

Registration date
2025-02-11, 1403/11/23

Registrant information

Name
Fatemeh Najafzadehshavaki

Name of organization / entity
The East Guilan School of Nursing and Midwifery

Country
Iran (Islamic Republic of)

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+98 13 4262 0549

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-02-19, 1403/12/01

Expected recruitment end date
2025-06-22, 1404/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Art therapy on quality of life in elderly women : A randomized controlled trial

Public title
The effect of Art therapy on quality of life in elderly women : A randomized controlled trial

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Elderly women 60 years old and over 60 years old Willingness to participate in research Being literate in reading and writing

Exclusion criteria:

Age
From **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on the daily visits of the elderly, they are called to the center and if they meet the inclusion criteria, they will be included in the study. Based on four random blocks, the sequence of which will be obtained through the online random allocation software, into two groups A (art therapy) (and group B) random allocation control. According to the sample size in two groups (n = 76) (19), there will be four random blocks in the random allocation sequence. The list of blocks sequence is placed in the envelope in the package. After the permission from the research vice-chancellor, it is read daily during the implementation of the study.

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
Ethics committee of Guilan University of Medical Sciences

Street address
Ibn Sina Street, Faculty of Nursing, Midwifery and Para medicine, East Guilan

City
Langrud

Province
Guilan

Postal code
4477166595

Approval date
2024-11-13, 1403/08/23

Ethics committee reference number
IR.GUMS.REC.1403.364

Health conditions studied

1

Description of health condition studied
quality of life

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Quality of life score in LEIPAD quality of life questionnaire

Timepoint
At the beginning of the study (before the start of the intervention) and immediately after the end of the intervention and 8 weeks after the end of the intervention

Method of measurement
LEIPAD quality of life questionnaire

Secondary outcomes

1

Description
Quality of life score in LEIPAD quality of life questionnaire

Timepoint
At the beginning of the study (before the start of the intervention) and immediately after the end of the intervention and 8 weeks after the end of the intervention

Method of measurement
LEIPAD quality of life questionnaire

Intervention groups

1

Description
Intervention group: In each art therapy session, the intervention group supervises the implementation of each participant by explaining the working method in that session. The contents of the sessions are implemented through the use of different arts in a way that promotes relaxation and introspection and mental

imagery of a situation. In which the person is located and to create a connection of emotions in people. In the welcome session, the sessions are conducted by the trainer. The warm-up exercise is to create relaxation and prepare people to enter the main exercise (each session). This initial exercise is planned by creating visualization for people for the main exercise that is aimed at describing the beginning of each situation or its solutions. Then, the practice of each session is done according to the content of that session by using accessible and low-cost art tools in a way that can put the person in the current mental state. After each exercise, people are asked to express their feelings and then The instructor will help each person to understand his art product. At the end of each session, the participants will take their artwork home. At the end of each session, they will practice relaxation using music and mental imagery to be in a pleasant atmosphere. It is done along with breathing exercises. On average, the warm-up, relaxation and guided imagery phase will take 7-10 minutes; The stage of artistic output will last 60 minutes and the stage of verbal development will take 15 to 20 minutes. Table 1. Content, purpose and time of art therapy sessions. Construction of the current situation of the exercise: relaxation, listening to silent music and relaxation, the purpose of introducing and getting to know the people of the group, self-expression, time: 10 minutes, the second session, warming up the color spot, exercise: the main full-length picture, painting the worst fears and threatening situations, relaxation exercise, closing the eyes and imagining A calming place, the purpose of expressing anger, fear: time 90 minutes, the third session, warm exercise: making contrasting colors, lines and shapes, exercise: main envelope and: face painting box, make yourself a symbol of your talents or capabilities by drawing or collage drawing a circle of support and relaxation table, relaxation exercise, looking at the mirror and self-love, a valuable goal, ability, support, time 90 minutes, the fourth session, warm-up exercise, making your own symbol with clay, the main exercise of making seasons with clay, making a nest tree, a bird, and a storm-stricken tree, writing a letter to God and a letter to his wife, practicing calming breathing and gratitude music: purpose, vision, solution, hope and future, time 90 minutes.

Category

Rehabilitation

2

Description

Control group: During this period, no art therapy services will be provided for the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Center No. 2 of Rudsar city

Full name of responsible person

Mohammad Zamani

Street address

Heshmat Hospital, Revolution st

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Guilan

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4193713111

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+98 13 4261 3551

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2

Recruitment center

Name of recruitment center

Comprehensive Health Center No. 3 of Rudsar city

Full name of responsible person

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3

Recruitment center

Name of recruitment center

Comprehensive Health Center No. 3 of Lahijan city

Full name of responsible person

Seyed ali zaker nagibi

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4

Recruitment center

Name of recruitment center

Comprehensive Health Center of Lialistan

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohammadreza Naghipour
Street address
Namjo St, Shahid Siyadati St, in front of 17 Shahrivar Hospital
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4144666949
Phone
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research@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Fatemeh Najafzadeh Shavaki
Position
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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is 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

All researchers in academic and scientific institutions will be able to use and analyze the data and results of the study for their future research.

From where data/document is obtainable

The receive data, refer to the email address below: najafzade.fateme.7726@gmail.com

What processes are involved for a request to access data/document

The applicant must send a valid certificate for his employment in academic and scientific institutions to the relevant email, and if the information is valid, the data will be emailed to him within a maximum of one month.

Comments