Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of visual art therapy on activities of daily living and self-Efficacy in elderly

Protocol summary

Study aim
Determining the effect of visual art on daily activities of life and self-efficacy in the elderly

Design
Sampling will be done in a convenient manner so that after selecting the centers, eligible elderly people from each center will be identified and after obtaining informed consent, they will be assigned to two intervention and control groups using a four-way random block method. In this way, we will have an intervention and control group in each center.

Settings and conduct
The study population will be the elderly in day care centers or health centers in Mashhad. A list of all day care centers or health centers in Mashhad will be prepared and then the centers will be selected based on the level of cooperation.

Participants/Inclusion and exclusion criteria
Criteria for inclusion in the study: Age over 65 Achieving a score of 7 or higher on the AMT cognitive test Having visual, auditory, and upper motor abilities Having the ability to read and write

Intervention groups
Intervention group: The intervention group in this study includes elderly residents of two selected elderly day care centers in Mashhad who were randomly selected to receive the visual art therapy intervention. This group will participate in visual art therapy group sessions twice a week for 8 weeks. The sessions will last 60 to 150 minutes and include various artistic activities such as painting, coloring, drawing, decorating, and craft making. The aim of this intervention is to stimulate and improve the physical functioning, quality of life, and interpersonal communication of the elderly. Also, the sessions are designed in such a way that the elderly share their artwork and express their feelings at the end of each session.

Main outcome variables
Level of daily living activities and self efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250514065734N1**
Registration date: **2025-06-10, 1404/03/20**
Registration timing: **prospective**

Last update: **2025-06-10, 1404/03/20**
Update count: **0**

Registration date
2025-06-10, 1404/03/20

Registrant information

Name
Naser Jamshidi bozorgi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-06, 1404/05/15

Expected recruitment end date
2025-09-21, 1404/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect of visual art therapy on activities of daily living and self-Efficacy in elderly

Public title
The effect of visual art therapy on daily living activities and self-efficacy of the elderly.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 65 years Having visual, auditory, and upper motor abilities Absence of cognitive impairment Having the ability to read and write
Exclusion criteria:
Having a debilitating disease during the study, such as Parkinson's, rheumatoid arthritis, stroke, etc., or possible injuries or fractures The emergence of new medical conditions that make participation risky (e.g., stroke, heart attack, or advanced chronic diseases) Severe and complete lack of dependence according to the Barthel questionnaire Exacerbation of underlying diseases that prevent continued participation Presence of a mental disorder (schizophrenia, severe depression) and severe cognitive disorder (dementia) and undergoing treatment according to the medical record Failure to attend more than one intervention session Loss of contact with the participant, migration of the participant to an area where access is difficult or impossible Death of an elderly person
Age
From **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
60 samples are randomly sequenced in a random block of four using the randomization site (for example: AABB, ABAB, BAAB,.....). In each block, two people are randomly assigned to the intervention group and two people to the control group. After the random sequence is determined, we consider the letters A to be the intervention group and the letters B to be the control group. They are placed in sealed envelopes in sequence and the envelopes are numbered 1 to 60. When sampling, individuals receive the envelope corresponding to their number in the order in which they enter the study. After opening the envelope, individuals are assigned to the control or intervention group according to the letter written.
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 Committees of School of Nursing & Midwifery - Mashhad University of Medical Sciences
Street address
Razavi Khorasan, Mashhad, Azadi Square, East Gate of Ferdowsi University of Mashhad, University Campus, Shahid Dr. Kharazmi Educational Complex
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Approval date
2025-05-20, 1404/02/30
Ethics committee reference number
IR.MUMS.NURSE.REC.1404.031

Health conditions studied

1

Description of health condition studied
elderly
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Level of daily living activities
Timepoint
Before the start of the study and after the end of the study
Method of measurement
Modified Barthel Index

2

Description
Level of self-efficacy
Timepoint
Before the start of the study and after the end of the study
Method of measurement
Self-Efficacy Scale for Everyday Activities

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, the art therapy program will be held over 4 weeks in 8 sessions (60 to 150 minutes). The sessions will be held in a quiet, well-lit environment and in a well-equipped classroom. This intervention is designed based on the MOLACE program and includes creative activities such as painting, drawing, decorating, and craft making. The eighth session will be dedicated to displaying the created artworks. Each session will be divided into four stages: introduction and preparation (5-10 minutes), performing the art activity (30-50 minutes), sharing the work and expressing emotions (20-50 minutes), and ending the session (5-10 minutes). Also, the sessions are designed so that the elderly share their artwork and express their emotions at the end of each session. The art activities in this program are designed to help strengthen the physical and mental dimensions of the elderly on the one hand, and to improve the quality of social communication and the feeling of satisfaction with life in the elderly on the other. The ultimate goal is that through this intervention, seniors will have more positive feelings about their daily lives.

Category

Rehabilitation

2

Description

Control group: Elderly people will receive routine care at the day care center or health center. The day care center for the elderly provides services in the fields of education, rehabilitation, recreation and daily care. In this center, educational classes such as language, music, painting and life skills are held, as well as sports programs such as yoga, stretching, walking. Physiotherapy and psychological counseling services are available. Participation in group activities, celebrations and cultural events, as well as health monitoring, including blood pressure and blood sugar control, are carried out regularly. Healthy nutrition is provided by providing breakfast and lunch, and if necessary, a shuttle service, is another facility of the center. The health center regularly monitors the health status of the elderly by conducting periodic examinations, screening for blood pressure, blood sugar, lipids, vision, hearing, depression and memory. Necessary education about healthy nutrition, age-appropriate physical activity, medication use and disease prevention is also provided to the elderly and their families. Psychological and social counseling to reduce anxiety, loneliness, and depression of the elderly is also provided in the form of individual or group counseling programs. In addition, training of caregivers of the elderly in the family is also considered to provide a safer and healthier environment for the elderly at home. Holding group meetings, light sports programs, and social activities to maintain the morale and interaction of the elderly are other supportive measures of the center.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Yadegar day care

Full name of responsible person

Marjan Mirzaei

Street address

Mashhad, Sajjad Blvd., corner of Sajjad 12 (South Shaghayegh), next to Tashk-e-Bern, No. 25, first floor

City

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Province

Razavi Khorasan

Postal code

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2

Recruitment center

Name of recruitment center

Danehmooz Comprehensive Health Services Center

Full name of responsible person

Dr. Barat Ali Arabnejad

Street address

Danehmooz Boulevard - Around Farhang Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9179793945

Phone

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Email

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3

Recruitment center

Name of recruitment center

Sadaf Comprehensive Health Services Center

Full name of responsible person

Dr. Barat Ali Arabnejad

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Vakil Abad 43- Sadaf 28

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Province

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Email
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4

Recruitment center

Name of recruitment center
Navid Zendig Institute

Full name of responsible person
Dr. Bita Tehranchi

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No. 39,Sekhavati 3, Palestine 36 ,Mashhad

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Razavi Khorasan

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.

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+98 915 821 1508

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bita.tehranchi@gmail.com

5

Recruitment center

Name of recruitment center
Neshat day care

Full name of responsible person
Hamideh Safarian

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Corner of Kalantari, Shahid Kalantari Highway,Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Mohsen Tafaghodi

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Khorasan Razavi, Mashhad, Daneshgah Street - Next to Hoveyzeh Cinema - Qorashi Building - Deputy for Research and Technology

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TafaghodiM@mums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Naser Jamshidi Bozorgi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Razavi Khorasan, Mashhad, Azadi Square, East Gate of Ferdowsi University of Mashhad, University Campus, Shahid Dr. Kharazmi Educational Complex

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jamshidibn4022@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person
Maryam Salehian

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
NaserJamshidi Bozorgi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
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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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is 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

Title and more details about the data/document
Things that explain the results of our intervention and limitations

When the data will become available and for how long
Access period starts 6 months after results are published.

To whom data/document is available
Research

Under which criteria data/document could be used
Scientific research to help the aging society

From where data/document is obtainable
Researchers' email

What processes are involved for a request to access data/document
At least 1 month

Comments