Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

The effect of coloring mandalas on depression, anxiety and stress in elderly people referred to daily rehabilitation center for the elderly in Tehran.

Protocol summary

Study aim
Determining the effect of mandala coloring on depression, anxiety, stress of the elderly referring to daily rehabilitation center for the elderly in Tehran.

Design
Study group: According to inclusion criteria elderly persons were selected by non randomize method(n= 40)

Settings and conduct
At the Yas daily rehabilitation center for elderly in Tehran, the study was conducted in eight sessions; each session lasted approximately 20 minutes. These sessions were held for 4 consecutive weeks, two days a week, at 11 Am. In each session, a white mandala design was given to each of the elderly person. In each session, participants painted Mandela's design with 6 colors of colored pencils. The first session was explained about the work method, before the intervention, depression, anxiety and stress scale was completed. Also, after the last intervention session (Mandela drawing coloring) depression, anxiety and stress scale was completed. In order to complete the scale before and after the intervention, the researcher read each statement of the depression, anxiety and stress scale for any participant and entered the answer in scale.

Participants/Inclusion and exclusion criteria
1-At least the age 60 years old 2-Obtaining the score 7 and above in abbreviated mental test score(AMTs) 3-Not having a mental or physical disability based on the information in the filet 4 -Having visual, hearing and movement ability 5-Elderly consent to participate in research 6-Obtaining the 8 and above in the anxiety subscale of the DASS-21 test

Intervention groups
Intervention group: performing coloring of mandela's designs - one group

Main outcome variables
Improving the mental health of the elderly

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220512054828N1**
Registration date: **2022-10-07, 1401/07/15**
Registration timing: **retrospective**

Last update: **2022-10-07, 1401/07/15**
Update count: **0**

Registration date
2022-10-07, 1401/07/15

Registrant information

Name
Parisa Ahmadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01

Expected recruitment end date
2021-11-22, 1400/09/01

Actual recruitment start date
2021-10-23, 1400/08/01

Actual recruitment end date
2021-11-22, 1400/09/01

Trial completion date
2022-03-17, 1400/12/26

Scientific title
The effect of coloring mandalas on depression, anxiety and stress in elderly people referred to daily rehabilitation center for the elderly in Tehran.

Public title
The effect of coloring mandalas on depression, anxiety and stress in elderly people referred to daily rehabilitation center for the elderly in Tehran.

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age at least 60 years Obtaining Score 7 or higher in Abbreviated mental test score(AMTs) Having visual, hearing and movement ability Elderly consent to participate in research Obtaining score 8 and above of anxiety subscale in test DASS-21

Exclusion criteria:
Having a mental or physical disability based on the information in the file

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**
Actual sample size reached: **40**

Randomization (investigator's opinion)
N/A

Randomization description

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 Shahed university

Street address
Khalije fars highway, Shahed university

City
Tehran

Province
Tehran

Postal code
3319118651

Approval date
2021-04-27, 1400/02/07

Ethics committee reference number
IR.SHAHED.REC.1400.004

Health conditions studied

1

Description of health condition studied
Depression

ICD-10 code
Z13.3

ICD-10 code description
Special screening examination for mental and behavioral disorders

2

Description of health condition studied
Anxiety

ICD-10 code
F41.1

ICD-10 code description
Generalized anxiety disorder

3

Description of health condition studied
Stress

ICD-10 code
F23.9

ICD-10 code description
Acute and transient psychotic disorder, unspecified

Primary outcomes

1

Description
Comparison of the score of depression, anxiety and stress (according to DASS-21) before intervention and after the last intervention session

Timepoint
Immediately before and after the last intervention session

Method of measurement
Depression Anxiety and Stress Scale 21 (DASS-21)

Secondary outcomes

empty

Intervention groups

1

Description
One group with before and after method. Intervention: mandala design coloring. According to the purpose of the research, a sample of 40 people who are eligible to enter

the study are selected. During the intervention, people are given mandala designs (which have been approved by expert professors). In this way: The number of sessions includes eight sessions (two sessions each week) in which the participants have 20 minutes of time to paint. Each senior is assigned a box of six colors and a mandala design. At first, the cognitive status of the participants is studied with the Abbreviated Mental Test (AMT). If the cognitive status score was higher than 7, the participants were evaluated with the mental health measurement scale (The Depression, Anxiety and Stress Scale - 21 Items (DASS-21).If the anxiety subscale score of the participants was 8 or higher, they were included in the study. In the next step, the demographic questionnaire is also completed by the researcher face-to-face. The format of the sessions is as follows: First session: First part: introduction of the therapist, familiarization with the rules of the session, introduction of mandala and presentation of coloring tools, paper patterned with mandala design to each of the participants. The second part: coloring the raw mandala sample on an A4 sheet of paper freely for twenty minutes using 6 colored pencils (in red, blue, yellow, purple, green and orange colors) that are available to each member. has it. Sessions 2 to 7: coloring a raw mandala sample for 20 minutes. Session 8, part one: coloring a raw mandala sample for 20 minutes. The second part of DASS-21 post-examination.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Yas Daily Rehabilitation Center for the Elderly
Full name of responsible person
Marzieh Shirazikhah
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Yas Rehabilitation Center,Sattar Khan St. - Alstom Power , next to guarding
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
the researcher
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Shahed University
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Parisa Ahamdi
Position
student
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is 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
Essay, thesis

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
Health researchers

Under which criteria data/document could be used
-

From where data/document is obtainable
researcher

What processes are involved for a request to access data/document
Sending e-mail documents showing activity in the field of health

Comments