

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 file 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

Country

Iran (Islamic Republic of)

Phone

+98 21 4416 5912

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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

Street address

Yas Rehabilitation Center,Sattar Khan St. - Alstom Power , next to guarding

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Fax

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Shahriar Bijani

Street address

Research Vice Presidency Office, Central Building, Shahed University, Opposite Holy Shrine of Imam Khomeini, Khalij Fars Expressway, Tehran, Iran.

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Phone

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Email

research@shahed.ac.ir

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

Full name of responsible person

Parisa Ahamdi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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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

Person responsible for updating data

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Nasrin Alaei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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City

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