# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## The Effect of Coloring Mandala on Existential Anxiety, Feeling Loneliness, and Spiritual Health of the Elderly

## Protocol summary

**Study aim**
Determining the effect of mandala coloring on existential anxiety, loneliness, and spiritual health of the elderly living in nursing homes

**Design**
Randomized clinical trial

**Settings and conduct**
The current study is a randomized clinical trial study that will be conducted at the Shahrekord University of Medical Sciences in 1403. The sample will be done by simple randomization from 3 nursing homes in Shahrekord and Borujen, and participants will be randomly assigned to two test and control groups. The intervention involves the implementation of the mandala painting method over 4 weeks. Before and after the intervention, demographic and health information questionnaires, Good existential anxiety questionnaire, UCLA Loneliness Scale and spiritual health scale will be collected.

**Participants/Inclusion and exclusion criteria**
Being at least 60 years old- Participant's consent to participate in the research- - People who are accommodated in a nursing home (separate from their family) - Not memory impairment or Alzheimer's disease according to the hospice doctor's diagnosis and the information in the file-

**Intervention groups**
The researcher gives detailed verbal explanations to the elderly in the intervention group about the intervention method. Then, each elderly person is given a box of 6 colored pencils (red, orange, yellow, green, blue, and purple) and the subjects during 4 consecutive weeks, in 2 sessions per week (Saturday and Tuesday every week), mandala designs in the dimensions of A4 paper (21.0 cm x 29.7 cm) provided by the researcher in each session from simple to complex for 20 minutes from the periphery to the center of the circle for. After the pretest, the control group will receive only routine care from the nursing home staff.

**Main outcome variables**
Existential anxiety, loneliness and spiritual health

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20240806062674N1**
Registration date: **2024-08-26, 1403/06/05**
Registration timing: **prospective**

Last update: **2024-08-26, 1403/06/05**
Update count: **0**

**Registration date**
2024-08-26, 1403/06/05

**Registrant information**

**Name**
Farshad Heidari

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 38 3333 0061

**Email address**
heidari.f@skums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2024-10-22, 1403/08/01

**Expected recruitment end date**
2025-10-23, 1404/08/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**

empty

**Scientific title**
The Effect of Coloring Mandala on Existential Anxiety, Feeling Loneliness, and Spiritual Health of the Elderly

**Public title**
The effect of coloring on anxiety, loneliness and spiritual health

**Purpose**
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
- Being at least 60 years old- Participant's consent to participate in the research- - People who are accommodated in a nursing home (separate from their family) - Not having a mental or physical disability based on the file information (the elderly person has the necessary visual, hearing and movement ability)- Not memory impairment or Alzheimer's disease according to the hospice doctor's diagnosis and the information in the file- Not having acute mental disorders based on the diagnosis of the hospital doctor and file information- Non-participation in other treatment courses at the same time- Not receiving psychiatric drugs for more than two weeks before the start of the intervention based on the report of the elderly and file information- At least 3 months have passed since the elderly person was in the nursing home- Not using temporary leave for more than one week during the study period

**Exclusion criteria:**
- Withdrawal of participants from continuing cooperation- Death of a participant during the study period- Absence from the intervention for more than two sessions- Occurrence of any kind of serious physical and mental illness leading to hospitalization of the elderly.- Taking medication for the nerves and psyche during the implementation of the intervention- Non-participation of the elderly in the assessments before or after the intervention

**Age**
From **60 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **72**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Blocking of two pairs: The researcher wrote down the different conditions of the two groups (4 conditions in total: 1 control, test 2 test, control 3 test, test 4 control, control) on 5 cards each in a sealed envelope These envelopes are placed in a box and the researcher does not know which group the studied units belong to before selecting the card By taking one of the envelopes out of the box, the researcher determines which group the two elderly people participating in the study will belong to. This process continues until all 5 cards have been removed from the box. Then the cards are put back into the box and the random selection of cards is repeated.

**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 Shahrekord University of Medical Sciences

**Street address**
Kashani Blvd

**City**
Shahrekord

**Province**
Chahar-Mahal-va-Bakhtiari

**Postal code**
۸۸۱۵۷۱۳۴۷۱

**Approval date**
2024-07-09, 1403/04/19

**Ethics committee reference number**
IR.SKUMS.REC.1403.052

## Health conditions studied

### 1

**Description of health condition studied**
Elderly

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Existential Anxiety

**Timepoint**
Before the start of the intervention - after the end of the intervention

**Method of measurement**
Good Existential Anxiety Scale (EAS)

### 2

**Description**
Feeling Loneliness

**Timepoint**
Before the start of the intervention - after the end of the intervention
**Method of measurement**
UCLA Loneliness Scale

**3**

**Description**
Spiritual Health
**Timepoint**
Before the start of the intervention - after the end of the intervention
**Method of measurement**
Spiritual Health Scale (SWBS)

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: After an online search on http://www.free-mandalas.net, the researcher selects pre-drawn mandala designs that are suitable for the elderly population. Mandalas are not so complicated but still interesting and have clear, bold lines that are easy to see and can be easily colored by older people. The intervention will be done on each of the participants in the test group individually in the consultation room of the elderly care center. The researcher gives the older people in the intervention group detailed verbal explanations about the method for carrying out the intervention. Then, each elderly person will be given a box of 6 colored pencils (red, orange, yellow, green, blue, and purple) and the subjects paint mandala designs in the dimensions of A4 paper (21.0 cm x 29.7 cm) provided by the researcher in each session from simple to complex for 20 minutes from the periphery to the center of the circle for 4 consecutive weeks in 2 sessions per week (Saturdays and Tuesdays). The individual motifs are colored freely and according to the personal ideas of the participants. Immediately after coloring the last mandala design in the eighth session, the scales of existential anxiety, loneliness, and spiritual health are evaluated by the participants.
**Category**
Rehabilitation

**2**

**Description**
Control group: After the pre-test, the control group will only receive routine care from the nursing home staff. In this group, the researcher will answer the subjects' questions about their state of health and the training they have received from the care staff. In this group, a post-test will be conducted after 4 weeks. The post-tests for the test and control groups will be carried out on different days. To comply with ethical considerations, the research method will be explained to the participants in the control group at the end so that they can also use this method if they wish.
**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Shahrekord nursing home
**Full name of responsible person**
Marzieh Borjian
**Street address**
بلوار امام علی،خ هاشم مبینی،خ امام قلی جعفر زاده،
**City**
Shahrekord
**Province**
Chahar-Mahal-va-Bakhtiari
**Postal code**
8813733333
**Phone**
+98 38 3227 5686
**Email**
m.borjian@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shahre-kord University of Medical Sciences
**Full name of responsible person**
Dr Omrani
**Street address**
Shahrekord University of Medical Sciences, Kashani Blvd., Shahrekord, Iran
**City**
Shahrekord
**Province**
Chahar-Mahal-va-Bakhtiari
**Postal code**
۸۸۱۵۷۱۳۴۷۱
**Phone**
+98 38 3333 0061
**Email**
m.borjian@yahoo.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shahre-kord 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**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Marzieh Borjian

**Position**

Educator

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Shahrekord University of Medical Sciences, Kashani Blvd., Shahrekord, Iran

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

۸۸۱۵۷۱۳۴۷۱

**Phone**

+98 38 3333 0061

**Email**

m.borjian@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Marzieh Borjian

**Position**

Educator

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Shahrekord University of Medical Sciences, Kashani Blvd., Shahrekord, Iran

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

۸۸۱۵۷۱۳۴۷۱

**Phone**

+98 38 3333 0061

**Email**

m.borjian@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Farshad Heidari

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Shahrekord University of Medical Sciences, Kashani Blvd., Shahrekord, Iran

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

۸۸۱۵۷۱۳۴۷۱

**Phone**

+98 38 3333 0061

**Email**

Heidari.f@skums.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available