Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of Mandela art therapy on psychological problems of mothers of children with autism spectrum disorder

Protocol summary

Study aim
Determining the Effect of Mandala Art Therapy on Psychological Problems in Mothers of Children with Autism Spectrum Disorder

Design
In this controlled, parallel-group clinical trial, 64 mothers are selected via simple random sampling and then assigned—using block randomization with block sizes of 4 and 6—to either an art therapy intervention group or a control group.

Settings and conduct
The researcher will visit the Welfare Organization to obtain a list of mothers of children with autism spectrum disorder who are served by specialized autism centers in the city of Kashan. Subsequently, mothers eligible for the study will be identified by reviewing the centers' records. After coordinating with the autism centers, the researcher will contact the selected mothers and invite them to the center. During the in-person visit, and following an explanation of the study's objectives and procedures and the obtaining of written informed consent, the participants will complete pre-test questionnaires.

Participants/Inclusion and exclusion criteria
Participants are mothers of children aged 2–12 with ASD, aged 18–60, without physical disabilities preventing use of art materials. Exclusion criteria: missing two intervention sessions, or experiencing severe stressful life events (e.g., bereavement or major family crises) during the intervention that disrupt participation or affect psychological outcomes.

Intervention groups
For the intervention group, the mandala art therapy program has six components (preparation, mandala selection, mindfulness, coloring, reflection, and integration) and is held in groups over four weeks, twice weekly. The control group receives an educational pamphlet on caring for these children based on National Autistic Society guidelines.

Main outcome variables
Psychological problems of mothers

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20130721014086N18**
Registration date: **2026-10-09, 1405/07/17**
Registration timing: **prospective**

Last update: **2026-10-09, 1405/07/17**
Update count: **0**
Registration date
2026-10-09, 1405/07/17

Registrant information
Name
Mohammad Aghajani
Name of organization / entity
Kashan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 31 5554 2001
Email address
aghajani_m@kaums.ac.ir

Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-10-20, 1405/07/28
Expected recruitment end date
2027-01-15, 1405/10/25
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Mandela art therapy on psychological problems of mothers of children with autism spectrum disorder

Public title

The effect of Mandela art therapy on psychological problems

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian nationality Residency in the city of Kashan Having a child receiving care and services at an autism rehabilitation center supervised by the State Welfare Organization Child with ASD aged between 2 and 12 years Having at least one child with a definitive diagnosis of autism spectrum disorder (ASD) based on medical records and the diagnosis of a child and adolescent psychiatrist Maternal age between 18 and 60 years

Exclusion criteria:

Lack of literacy skills required to complete the questionnaires Physical disability affecting the use of painting tools Concurrent participation in any psychological intervention—such as mindfulness or cognitive-behavioral therapies—during the study period. Receipt of art therapy interventions within the past three months. Absence of severe and debilitating physical illnesses (such as active cancer, advanced heart or kidney failure, or severe neurological disorders) that would affect participation in the study or psychological outcomes. Diagnosis of severe psychiatric disorders (such as schizophrenia, bipolar disorder in the acute phase, or substance use disorder) based on medical records and self-reporting. History of hospitalization in psychiatric wards in the past six months based on self-report

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples are made in blocks of four and six using Sealed Envelope Ltd software. 2017 available through www.sealedenvelope.com are assigned to two intervention and control groups.

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 Faculty of Medicine & Faculty of Dentistry- Kashan University of Medic

Street address

Qotb-e Ravandi Boulevard – Pezeshk Boulevard – School of Nursing and Midwifery

City

kashan

Province

Isfehan

Postal code

8715988141

Approval date

2026-09-20, 1405/06/29

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1405.097

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

2

Description of health condition studied

Sleep quality

ICD-10 code

Z72.82

ICD-10 code description

Problems related to sleep

Primary outcomes

1

Description

Depression – Anxiety – Stress

Timepoint

Measurement of depression, anxiety, and stress (DASS-21) at baseline (before the intervention), at the end of the intervention (4 weeks after study initiation), and at follow-up (6 weeks after study initiation).

Method of measurement
Depression, anxiety, and stress will be measured using the 21-item Depression, Anxiety, and Stress Scale (DASS-21)

Secondary outcomes

1

Description
Sleep Quality
Timepoint
Measurement of sleep quality at baseline (before the start of the intervention), at the end of the intervention (4 weeks after the start of the study), and during the follow-up period (6 weeks after the start of the study).
Method of measurement
Assessment of sleep quality using the 19-item Pittsburgh Sleep Quality Index (PSQI) questionnaire.

Intervention groups

1

Description
Intervention group: The intervention is based on Jungian mandala art therapy and follows the Mandala Coloring Therapy (MCT) framework. Each session comprises four main components: introduction and relaxation (10 minutes), mandala coloring (30–40 minutes), guided reflection and group discussion (10–15 minutes), and summary with homework assignment (5–10 minutes). Pre-designed A4 mandalas of gradually increasing complexity are colored using colored pencils, markers, or crayons according to participants' personal preferences; they are encouraged to use three to five colors and to continue coloring from the center toward the outer layers. Following the coloring activity, a guided reflection and group discussion session is facilitated by the researcher to enhance self-awareness, emotion regulation, and personal insight.
Category
Behavior

2

Description
Control group: In the control group, mothers are provided with an educational pamphlet based on the National Autistic Society’s guidelines on caring for children with this disorder.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Specialized Autism Center of Kashan County (Saraye Omid and Ayin-e Mehravarzi)
Full name of responsible person
Dr Mohammad Aghajani
Street address
Qotb-e Ravandi Boulevard, Pezeshk Boulevard, School of Nursing and Midwifery
City
Kashan
Province
Isfehan
Postal code
8715988141
Phone
+98 31 5558 9135
Email
aghajani-m@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr Golamali Hamidi
Street address
Qotb-e Ravandi Boulevard
City
Kashan
Province
Isfehan
Postal code
8715988141
Phone
+98 31 5558 9135
Email
research@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person

Dr Mohammad Aghajani

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Qotb-e Ravandi Boulevard, Pezeshk Boulevard, School of Nursing and Midwifery

City
Kashan

Province
Isfehan

Postal code
8715988141

Phone
+98 31 5558 9135

Email
aghajani-m@kaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Mohammad Aghajani

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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City
Kashan

Province
Isfehan

Postal code
8715988141

Phone
+98 31 5558 9135

Email
aghajani1362@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Mohammad Aghajani

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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aghajani-m@kaums.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
The data will be shared upon request and if necessary through the corresponding author. In general, however, given the sensitive nature of the psychological data (depression, anxiety, stress, and sleep quality) and the specific population under study (mothers of children with autism spectrum disorder), maintaining the confidentiality and trust of participants is of paramount importance, and sharing data—even in de-identified form—may compromise this trust.

Study Protocol
Undecided - It is not yet known if there will be 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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable