Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Mandala Coloring on Antenatal Anxiety in Women Referring to Al-Zahra Educational, Medical and Research Center of Rasht: A Randomized Placebo-Controlled Clinical Trial

Protocol summary

Study aim

To reduce pregnancy-related anxiety

Design

Randomization: Eligible pregnant women attending the prenatal clinic will be consecutively sampled. After pretest and informed consent, participants will be allocated 1:1 to experimental or control groups using block randomization with block sizes of four and six. Allocation sequences will be generated from possible block combinations (e.g., AABB, ABAB, ABBA, BAAB, BABA, BBAA) to maintain balance between groups. The intervention and control groups run in parallel. There is no blinding. It is randomized.

Settings and conduct

This study will be conducted at the prenatal care clinic of Al-Zahra Educational, Therapeutic, and Research Center in Rasht. For the intervention group, six mandala designs and colored pencils will be provided, and participants will be asked to focus on coloring—completing one design per day for six consecutive days—for at least 30 minutes each session in a quiet environment. The control group will color simple shapes, and both groups will receive routine prenatal care. Post-tests will be administered to both groups immediately after the six-day period and again one month later.

Participants/Inclusion and exclusion criteria

In: Signed consent Out: Acute crisis or suicidal ideation

Intervention groups

Intervention: mandala coloring (one design/day, 6 consecutive days, ≥30 min/session, quiet setting). Control: simple-shape coloring. Both: routine prenatal care. Post-tests: after 6 days and 1 month.

Main outcome variables

Pregnancy-related anxiety,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20261010071368N1**
Registration date: **2026-11-05, 1405/08/14**
Registration timing: **prospective**

Last update: **2026-11-05, 1405/08/14**
Update count: **0**

Registration date

2026-11-05, 1405/08/14

Registrant information

Name

fatemeh Rezaei kermajanei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 910 382 5318

Email address

fatemeh.rezaei0523@gmail.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-11-16, 1405/08/25

Expected recruitment end date

2027-02-12, 1405/11/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of Mandala Coloring on Antenatal Anxiety in Women Referring to Al-Zahra Educational, Medical and Research Center of Rasht: A Randomized Placebo-Controlled Clinical Trial

Public title
The Effect of Mandala Coloring on Antenatal Anxiety in Women Referring to Al-Zahra Educational, Medical and Research Center of Rasht: A Randomized Placebo-Controlled Clinical Trial

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
- Willingness to participate in the study and sign a written informed consent form; - Iranian citizenship; - Ability to communicate and speak in Persian;- Basic literacy (ability to read and write); - Gestational age of 28 to 32 weeks based on the first day of the last menstrual period and/or a valid ultrasound (third trimester); - Singleton, low-risk pregnancy as documented in prenatal care records and confirmed by a physician or midwife; - No history of spontaneous abortion, induced abortion, or stillbirth - Absence of underlying medical conditions or known pregnancy complications at study entry (including pre-gestational diabetes, chronic hypertension, pre-eclampsia, heart disease, or known fetal anomalies); - No history of severe psychiatric disorders (such as psychotic disorders or bipolar disorder); - Not currently taking psychiatric medications, antidepressants, or anti-anxiety drugs at study entry; - No history of delivering an infant with a disability or congenital anomaly; - Access to a smartphone and the ability to use a messaging app to receive educational materials, submit photos of completed coloring pages, and participate in study follow-ups.

Exclusion criteria:
Severe visual impairment or color blindness Severe motor disability in hands Acute psychiatric crisis or suicidal ideation Severe hearing or speech impairment

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization Method Consecutive sampling will be conducted among eligible pregnant women visiting the prenatal care clinic. Following the completion of the pre-test and obtaining informed consent, participants will be assigned to either the experimental or control group at a 1:1 ratio using block randomization with varying block sizes of four and six. The allocation sequence will be generated using all possible block combinations (e.g., AABB, ABAB, ABBA, BAAB, BABA, and BBAA) to maintain a balanced number of participants across the two groups throughout the study. Random Allocation Sequence Generation Method The random sequence will be generated using the Sealed Envelope™ online system. This system will create the allocation list based on block sizes of four and six and a 1:1 allocation ratio, utilizing a random number generation algorithm. Allocation Concealment Method To prevent selection bias, the allocation sequence will be generated by an individual independent of the sampling and data collection processes. Each participant's allocation assignment will be placed inside a sequentially numbered, opaque, and sealed envelope (SNOSE). Following the confirmation of eligibility criteria, obtaining informed consent, and the completion of pre-test questionnaires, the researcher will open the envelope corresponding to the next participant to reveal the assigned group. Consequently, prior to the opening of the envelope, neither the researcher responsible for participant recruitment nor the participants themselves will be aware of the assigned group.

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
Ethics Committee of Guilan University of Medical Sciences

Street address
Rasht – Shahid Beheshti Highway – Daneshju Street

City
Rasht

Province
Guilan

Postal code
41469-39814

Approval date
2026-10-10, 1405/07/18

Ethics committee reference number
IR.GUMS.REC.1405.329

Health conditions studied

1

Description of health condition studied
Pregnancy-related anxiety

ICD-10 code
F41.9
ICD-10 code description
Anxiety disorder, unspecified

Primary outcomes

1

Description
Pregnancy-related anxiety,
Timepoint
Before, immediately after, and one month after the intervention
Method of measurement
Pregnancy-Related Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For the intervention group, six mandala designs and colored pencils are provided, and participants are asked to focus on coloring in a quiet environment for six consecutive days completing one design per day for at least 30 minutes each time.
Category
N/A

2

Description
Control group: The control group involves coloring simple shapes distinct from a mandala structure at a rate of one design per day for six days.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Educational, Therapeutic, and Research Center, Rasht
Full name of responsible person
Fatemeh Rezaei Kermajanei
Street address
Al-Zahra (SA) Educational and Treatment Center, opposite Shahid Ozodi Stadium, Namjoo Street, Rasht, Gilan.
City
Rasht
Province
Guilan
Postal code
41446-54839
Phone
+98 13 3336 9324
Email
azzahra@gums.ac.ir
Web page address
https://azzahra.gums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Seyed Ali Alavi
Street address
Daneshju Street, Shahid Beheshti Highway, Rasht
City
rasht
Province
Guilan
Postal code
41469-39814
Phone
+98 13 3255 3202
Email
z_bostani@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Fatemeh Rezaei Kermajanei
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address

Daneshju Street, Shahid Beheshti Highway, Rasht

City
Rasht

Province
Guilan

Postal code
41469-39814

Phone
+98 918 137 0523

Email
fatemeh.rezaei0523@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Fatemeh Rezaei Kermajanei

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Rasht – Shahid Beheshti Highway – Daneshju Street

City
Rasht

Province
Guilan

Postal code
41469-39814

Phone
+98 918 137 0523

Email
fatemeh.rezaei0523@gmail.com

Web page address
https://nmr.gums.ac.ir/

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Fatemeh Rezaei Kermajanei

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Daneshju Street, Shahid Beheshti Highway, Rasht

City
Rasht

Province
Guilan

Postal code
41469-39814

Phone
+98 918 137 0523

Email
fatemeh.rezaei0523@gmail.com

Web page address
https://nmr.gums.ac.ir/

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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
De-identified individual participant data (IPD) and the related data dictionary from the randomized clinical trial. The shared data include demographic variables, intervention assignment, primary and secondary outcomes, and safety variables. All direct identifiers will be removed before sharing.

When the data will become available and for how long
Access will begin 6 months after publication of the main results and will remain available for 5 years.

To whom data/document is available
Qualified researchers from academic, non-profit, and governmental institutions, as well as researchers from industry, may request access.

Under which criteria data/document could be used
Data may be used for secondary research, validation of results, or meta-analysis. Use is conditional on approval of a research proposal, ethics committee approval, and a signed data-use agreement. Commercial use is not permitted without prior written consent.

From where data/document is obtainable
Requests should be sent to the Data Access Committee at Guilan university of medical sciences

What processes are involved for a request to access data/document
1. Applicant submits a research proposal and data-use agreement. 2. The Data Access Committee reviews the request within 4 weeks. 3. If approved, the applicant signs the data-use agreement and provides ethics approval. 4. Data are transferred securely within 2 weeks after all documents are complete. Total time: approximately 6–8 weeks.

Comments