Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of art therapy using coloring mandala designs on mental well-being and resilience in major thalassemia patients

Protocol summary

Study aim
Determining the effectiveness of art therapy through mandala coloring on mental well-being and resilience in patients with major thalassemia in the Sistan region in 2025-2026.

Design
The study is a randomized controlled clinical trial that will be conducted in two intervention and control groups in a single-blind on 80 patients with thalassemia major.

Settings and conduct
The research population consists of thalassemia major patients referred to special thalassemia patient centers in Sistan. The samples are randomly divided into two control and intervention groups, and art therapy sessions are conducted in the intervention group. To prevent information leakage, the control group is asked not to ask the intervention group any questions about the project until the end of the intervention, and after the project is completed, the necessary information is provided to them.

Participants/Inclusion and exclusion criteria
1) Confirmed diagnosis of major thalassemia by a specialist. 2) Age between 12 and 35 years 3) Physical health and visual acuity. Exclusion criteria: 1) Having thalassemia intermediate 2) proven mental disorder or ongoing treatment 3)Taking psychiatric medications

Intervention groups
In the intervention group, the intervention will be carried out over ten sessions by a specialist mandala designs. In the intervention group, the art therapy protocol will be as follows: intervention sessions will be 30 to 45 minutes once or twice a week, derived from the Labadi and Ronaghi protocol (2009) and using Albert Hutchinson's book, including teaching a set of coloring different mandala designs, which will be divided into easy, medium, and difficult based on the number of sessions. After these sessions, questionnaires will be completed, and the control group will only receive routine care from the treatment center

Main outcome variables
Mental well-being, resilience

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250627066274N1**
Registration date: **2025-08-30, 1404/06/08**
Registration timing: **registered_while_recruiting**

Last update: **2025-08-30, 1404/06/08**
Update count: **0**

Registration date
2025-08-30, 1404/06/08

Registrant information

Name
ghadir harati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 54 3222 2222

Email address
ghadir0098@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-23, 1404/06/01

Expected recruitment end date
2026-02-20, 1404/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of art therapy using coloring mandala designs on mental well-being and resilience in major thalassemia patients

Public title
The effectiveness of art therapy on mental well-being and resilience in major thalassemia patient

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Confirmed diagnosis of major thalassemia by a specialist Age between 12 and 35 years Minimum literacy in reading and writing No use of any psychological interventions or counseling during the periods when participants are undergoing this intervention Proficiency in the Persian language Consent to participate in the specified courses Physical health and visual acuity

Exclusion criteria:
Having thalassemia intermediate proven mental disorder or ongoing treatment Taking psychiatric medications

Age
From **12 years** old to **35 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization process will involve shuffling cards or envelopes. In this method, a number of cards will be selected by the researcher for the first group, and the same number of cards will be designated for the second group. Then, by merging the cards together (shuffling the cards), one card will be drawn, and its allocation will be recorded. After being drawn, that card will be returned to the pool of remaining cards. The cards will then be merged again, and another card will be drawn. This process will continue until a random sequence is achieved that corresponds to the sample size. To conceal the random allocation, opaque, sealed envelopes containing the random sequence will be used.

Blinding (investigator's opinion)
Single blinded

Blinding description
In order to prevent information leakage, the control group is requested not to ask the intervention group questions about the project until the end of the intervention, and after the completion of the project, the necessary information will be provided to them.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Zabol University of Medical Sciences

Street address
Rajai Street, Research Department of the University

City
Zabol

Province
Sistan-va-Balouchestan

Postal code
9861734184

Approval date
2025-07-15, 1404/04/24

Ethics committee reference number
IR.ZBMU.REC.1404.060

Health conditions studied

1

Description of health condition studied
Major Thalassemia

ICD-10 code
D56.1

ICD-10 code description
Beta thalassemia

Primary outcomes

1

Description
Mental Well-being

Timepoint
Before the intervention and one week after the intervention.

Method of measurement
Keyes and Magyar's Mental Well-Being Questionnaire

2

Description
Resilience

Timepoint
Before the intervention and one week after the intervention.

Method of measurement
Connor-Davidson Resilience Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention sessions will be conducted over ten sessions by an expert familiar with mandala designs (having a university education in psychology, teaching experience, and clinical experience) and a qualified facilitator (master's student, clinical experience). In the intervention group, the art therapy protocol will be as follows: intervention sessions will last 30 to 45 minutes once or twice a week, derived from the Labadi and Ronaghi protocol (2009) and using Albert Hutchinson's book, including teaching a set of coloring different mandala designs, which will be divided into easy, medium, and difficult based on the number of sessions.

Category
Lifestyle

2

Description
Control group: Patients receive the centers' routine care program.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Thalassemia departments of Sistan region

Full name of responsible person
Sara Rashki Ghaleno

Street address
No 16-17 Motahari , Motahari Street, Zabol Town

City
Zabol

Province
Sistan-va-Balouchestan

Postal code
9861663335

Phone
+98 54 3222 5402

Email
info@zbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zabol University of Medical Sciences

Full name of responsible person
Dr. Abdolhossein Miri

Street address
Rejaee street

City
Zabol

Province
Sistan-va-Balouchestan

Postal code
98616615881

Phone
+98 54 3223 0768

Email
Research@zbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Zabol 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
Zabol University of Medical Sciences

Full name of responsible person
Ghadir Harati

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No.11 Ferdowsi St, next to Civil Registry Office, Nursing and midwifery school

City
Zabol

Province
Sistan-va-Balouchestan

Postal code
98616615881

Phone
+98 54 3222 3948

Email
ghadir0098@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zabol University of Medical Sciences

Full name of responsible person
Mahdieh Poodineh moghadam

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
No.11 Ferdowsi St,next to Civil Registry Office,Nursing and midwifery school

City
Zabol

Province
Sistan-va-Balouchestan

Postal code
9861734184

Phone
+98 54 3222 3947

Email
moghadam07@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Zabol University of Medical Sciences

Full name of responsible person
Ghadir Harati

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No.11 Ferdowsi St, next to Civil Registry Office, Nursing and midwifery school,

City
zabol

Province
Sistan-va-Balouchestan

Postal code
9861734184

Phone
+98 54 3222 3948

Email
ghadir0098@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable