# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Investigating the effects of Mandala coloring on anxiety in patients with ulcerative colitis

## Protocol summary

**Study aim**
Studying the effects of Mandela coloring on anxiety in patients with ulcerative colitis

**Design**
A randomized, parallel-group clinical trial was conducted on 46 patients with ulcerative colitis; simple randomization was performed in a 1:1 ratio using a random number table

**Settings and conduct**
Patients are selected by faculty members at the Sari Gastroenterology and Liver Research Center. The patients' anxiety levels are measured using the Hospital Anxiety and Depression Scale questionnaire. Anxious individuals are divided into two intervention and control groups using a random number table. The intervention group colors the Mandala on a page daily for 6 days, and then the patients' anxiety levels are measured after 6 days.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Patients with ulcerative colitis aged 18 to 60 years with a minimum score of 7 based on the Hospital Anxiety and Depression Scale questionnaire who are in clinical remission, with written consent. Exclusion criteria: Severe psychiatric illness, Psychological instability, Chronic debilitating disease, taking psychiatric medications, taking supplements that reduce anxiety

**Intervention groups**
The intervention group, in addition to their usual care, will do mandala coloring for 30 minutes a day for 6 consecutive days during their free time. Initially, each patient will receive a pack of six colored pencils (yellow, blue, green, red, purple, and brown) and 6 sheets of printed mandala designs. The control group will consist of patients who will receive only usual care.

**Main outcome variables**
Anxiety score based on the anxiety subscale of the Hospital Anxiety and Depression Scale questionnaire

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20250727066647N1**
Registration date: **2026-07-07, 1405/04/16**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-07, 1405/04/16**
Update count: **0**

**Registration date**
2026-07-07, 1405/04/16

**Registrant information**

**Name**
Mahboobe Ebrahimi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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

**Funding source**

**Expected recruitment start date**
2026-05-22, 1405/03/01

**Expected recruitment end date**
2026-10-23, 1405/08/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**

Investigating the effects of Mandala coloring on anxiety in patients with ulcerative colitis

**Public title**
the effects of Mandala coloring on anxiety
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients in remission phase of ulcerative colitis Between 18 and 60 years old Willingness to participate in the study and provide written consent. Minimum score of 7 on the Hospital Anxiety and Depression Scale questionnaire
**Exclusion criteria:**
Having severe psychological illnesses taking psychiatric medications taking supplements that reduce anxiety Psychological instability (such as bereavement/loss of a loved one) Chronic debilitating disease (such as cancer/diabetes with advanced complications)
**Age**
From **18 years** old to **60 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **46**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Randomization method: Simple randomization. Each patient is assigned to one of the two groups with equal probability, independently of the allocation of other patients. Unit of randomization: Individual (each patient is the unit of randomization). Randomization strata: Stratified randomization was not used. Randomization tool: Random sequence generation software (Random Allocation Software) for generating the sequence and opaque, sealed, consecutively numbered envelopes for allocation and concealment. Sequence generation: The random sequence is generated before the start of the study by a person independent of the research team (who has no role in screening or assessing patients), using Random Allocation Software, with a 1:1 allocation ratio for 46 patients. Allocation concealment: Based on the generated sequence, the same independent person prepares 46 opaque, sealed, and consecutively numbered envelopes, each containing the name of the allocated group. After confirming eligibility and obtaining written consent, the researcher opens the next envelope in the order patients enroll and assigns each patient to the intervention or control group according to its content. The person who generated the sequence has no involvement in patient enrollment or assignment in order to maintain allocation concealment.
**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**
Ethic committee of Imam hospital-Mazandaran University of Medical Science
**Street address**
Imam Khomeini Hospital., Amir Mazandarani Street
**City**
Sari
**Province**
Mazandaran
**Postal code**
۳۳۱۳۱ -۴۸۱۶۶
**Approval date**
2025-07-21, 1404/04/30
**Ethics committee reference number**
IR.MAZUMS.IMAMHOSPITAL.REC.1404.035

## Health conditions studied

### 1

**Description of health condition studied**
Anxiety levels in ulcerative colitis patients
**ICD-10 code**
F41.9
**ICD-10 code description**
Anxiety disorder, unspecified

## Primary outcomes

### 1

**Description**
Anxiety score based on the anxiety subscale of the Hospital Anxiety and Depression Scale
**Timepoint**
Before the intervention begins and after the intervention ends
**Method of measurement**
Hospital Anxiety and Depression Scale (HADS)

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Patients in the remission phase of ulcerative colitis who, in addition to their usual medical care, perform mandala coloring for 30 minutes a day for 6 consecutive days during their free time. A mandala (from the Sanskrit word meaning "circle") is a geometric, circular, and symmetrical pattern that radiates from a center outward and is used in art therapy as a tool for focusing the mind and reducing tension. Initially, each patient receives a pack of six colored pencils (yellow, blue, green, red, purple, and brown) and 6 sheets of printed mandala designs. The designs are standard circular and symmetrical patterns of moderate complexity, with a different design provided each day. Patients are instructed to sit in a calm environment and complete each design within 30 minutes, with focus and without any restriction on color choice or coloring order. The aim of this activity is to direct the patient's attention toward a simple, repetitive artistic task to promote mental calmness and reduce anxiety. The researcher follows up on the completion of the coloring daily via phone call or text message.

**Category**
Other

**2**

**Description**
Control group: Ulcerative colitis patients in remission who receive only standard treatments.

**Category**
Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
GUT and liver research center

**Full name of responsible person**
Fateme Mohamadnejad

**Street address**
Amirmazandarani street., Emam Khomeini hospital

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Mazandaran University of Medical Sciences

**Full name of responsible person**
Ahmadali Enayati

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**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Mazandaran 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**
Mazandaran University of Medical Sciences

**Full name of responsible person**
Mahboobe Ebrahimi

**Position**
assistant professor

**Latest degree**
Subspecialist

**Other areas of specialty/work**
Internal Medicine

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## Person responsible for updating data

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## 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**
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