

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Investigating the Impact of Mandala Coloring on Anxiety in Patients with COVID-19: A Randomized Clinical Trial

#### Protocol summary

##### Study aim

Determining the effect of mandala staining on the anxiety of patients with COVID-19

##### Design

This research project is a randomized, controlled, double-blind, blind clinical trial with two parallel arms. They are randomly divided into intervention and control groups.

And will be followed up for 6 days.

##### Settings and conduct

The study will be conducted in the wards of hospitalized patients with covid19 in Amir Al-Momenin Hospital. Studying on both sides will be double-blind. The intervention group included patients with Covid 19 who underwent Mandala staining for 6 consecutive days and 30 minutes each day. The control group included patients with Covid 19 who received only routine care.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 15 to 60 years Have mild to moderate anxiety Stability of hemodynamic status  
Exclusion criteria: Lack of willingness to continue participating in the study Patient discharge

##### Intervention groups

Intervention group: In this way, patients complete The State-Trait Anxiety Inventory -Spielberger questionnaire before starting the intervention, and then after 6 consecutive sessions of Mandala staining daily and every 30 minutes, The State-Trait Anxiety Inventory - Spielberger questionnaire is completed again and their anxiety is measured. Control group: In this group, patients do not receive any intervention from the researcher and only receive routine care.

##### Main outcome variables

Anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180519039711N6**

Registration date: **2020-06-29, 1399/04/09**

Registration timing: **prospective**

Last update: **2020-06-29, 1399/04/09**

Update count: **0**

##### Registration date

2020-06-29, 1399/04/09

##### Registrant information

###### Name

Mohamad Golitaleb

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3417 3506

###### Email address

m.golitaleb@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-07-19, 1399/04/29

##### Expected recruitment end date

2020-10-20, 1399/07/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the Impact of Mandala Coloring on Anxiety in Patients with COVID-19: A Randomized Clinical Trial

##### Public title

Effect of mandala staining on anxiety in patients with

COVID-19  
**Purpose**  
Supportive  
**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age 15 to 60 years Have mild to moderate anxiety  
Stability of hemodynamic status  
**Exclusion criteria:**  
Lack of willingness to continue participating in the study  
Patient discharge

**Age**  
From **15 years** old to **60 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Care provider

**Sample size**  
Target sample size: **60**

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

**Randomization description**  
Patients will be randomly divided into intervention and control groups. Sixty patients were randomly assigned to either the intervention or control groups, initially 6 blocks of 10 different T and C letters (which represent the intervention and control groups) (30) from the intervention group and 30 from the control group. People belong to the control group). Then, the blocks were randomly selected to obtain a 60-sided combination of blocks. It opens to tell which group the patient falls into.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Clinical caregivers, data analysts, and patients are not aware of being in the control or intervention group.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

1

**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Arak University of Medical Sciences

**Street address**  
Deputy of Education and Research, Campus University of Medical Sciences site, Basij square, Arak

**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3848176941

**Approval date**  
2020-05-31, 1399/03/11  
**Ethics committee reference number**  
IR.ARAKMU.REC.1399.089

## Health conditions studied

1

**Description of health condition studied**

Covid 19

**ICD-10 code**  
U07.1

**ICD-10 code description**  
COVID-19

## Primary outcomes

1

**Description**

Anxiety

**Timepoint**

At the beginning of the study and 6 days after the intervention

**Method of measurement**

The State-Trait Anxiety Inventory -Spielberger

## Secondary outcomes

empty

## Intervention groups

1

**Description**

Intervention group: The researcher will use Mandala staining to investigate its effect on the anxiety of patients with hospitalized Covid-19. In this way, patients complete The State-Trait Anxiety Inventory -Spielberger questionnaire before starting the intervention, and then after 6 consecutive sessions of Mandala staining daily and every 30 minutes, The State-Trait Anxiety Inventory -Spielberger questionnaire is completed again and their anxiety is measured.

**Category**

N/A

## Recruitment centers

1

**Recruitment center**

**Name of recruitment center**

Amiralmomenin Hospital  
**Full name of responsible person**  
Fatemeh Khademi  
**Street address**  
Basij square. Arak  
**City**  
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**Province**  
Markazi  
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it-amiralmomenin@arakmu.ac.ir  
**Web page address**  
<https://arakmu.ac.ir/amirhos/fa>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Dr. alireza kamali  
**Street address**  
Education and Research Deputy of Arak University of  
Medical Sciences, Basij Square, Arak  
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info@arakmu.ac.ir  
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<http://arakmu.ac.ir/fa>

#### Grant name

Arak University of Medical Sciences

**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**

Yes

#### Title of funding source

Arak 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**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Mohamad Golitaleb  
**Position**  
Instructor  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Mohamad Golitaleb

**Position**

Instructor

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**Web page address**

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## 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**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

Shared data including demographic and disease information, type and method of intervention, information about sleep quality of participants before and after intervention.

**When the data will become available and for how long**

Start the access period 6 months after the results are published.

**To whom data/document is available**

Researchers and people working in nursing education as well as nursing clinical staff.

**Under which criteria data/document could be used**

The data can be used for education, research and clinical nursing. The applicant must be in the nursing field The data applicant only uses data for teaching, research and clinical nursing.

**From where data/document is obtainable**

Mohamad golitaleb, Department of critical care nursing, school of nursing, Arak university of medical sciences E mail: Mohamadgolitaleb@gmail.com  
Tel: +989379366279

**What processes are involved for a request to access data/document**

After ensuring that the data applicant is in the nursing field, we will be immediately responded to the request form by email.

**Comments**