

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Investigating the effect of mandala coloring on anxiety of children with cystic fibrosis

#### Protocol summary

##### Study aim

Determining the effect of mandala coloring on the anxiety of children with cystic fibrosis

##### Design

This study is a simple randomized clinical trial. The study samples are 130 children with cystic fibrosis admitted to Mofid. Allocation of samples to intervention and control groups will be random and using a table of random numbers.

##### Settings and conduct

In this research with the context of children's anxiety, first, in both groups, the anxiety of children hospitalized in the pulmonary department of Mofid Hospital is measured with Spielberger's state-trait anxiety questionnaire before the intervention. If the child's anxiety was moderate to severe, in the mandala coloring group, for six consecutive days in the evening for 30 minutes, a mandala design is colored with colored pencil. Then, the child's anxiety is checked in the evening of the sixth day of the intervention and in the control group, only the level of children's anxiety will be examined before routine care and six days after that.

##### Participants/Inclusion and exclusion criteria

Inclusion: 1. The ability to communicate 2. The ability to paint 3. The child does not have a cognitive and hearing disorders, neurological conditions based on the documents Exclusion: 1. Physical and mental inability to draw or paint 2. The existence of cognitive disability and mental illness of the child

##### Intervention groups

In the mandala coloring group, for six consecutive days in the evenings, five different designs of mandala painting and a pack of 12 colored pencils are provided to the child. He/She is asked to choose one of the designs and paints it in 30 minutes and in the evening of the sixth day of the intervention, the level of anxiety will be checked again. In the control group, there will be no intervention and only the level of children's anxiety will be examined before routine care and six days after that.

#### Main outcome variables

anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211004052665N2**

Registration date: **2022-11-20, 1401/08/29**

Registration timing: **prospective**

Last update: **2022-11-20, 1401/08/29**

Update count: **0**

##### Registration date

2022-11-20, 1401/08/29

##### Registrant information

##### Name

Ali Omidi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 0000 0000

##### Email address

aliomidi978@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-11-21, 1401/08/30

##### Expected recruitment end date

2023-02-19, 1401/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of mandala coloring on anxiety of children with cystic fibrosis

**Public title**

The effect of mandala coloring on anxiety of children with cystic fibrosis

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Willingness to participate in the study and written consent Age 6 to 18 years Definitive diagnosis of cystic fibrosis Having the ability to communicate verbally The ability to paint The child does not have a cognitive disorder, language problems, hearing disorders, neurological conditions based on the file documents

**Exclusion criteria:**

Physical and mental inability to draw or paint The existence of cognitive disability and mental illness of the child Leaving the research community (change of ward, death, etc.) Non-cooperation to continue the research

**Age**

From **6 years** old to **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **130**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****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 Institute of Children Health - Shahid Beheshti University of Medical Science

**Street address**

Shariati Street, Mofid Children's Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

8313774691

**Approval date**

2022-10-12, 1401/07/20

**Ethics committee reference number**

IR.SBMU.RICH.REC.1401.026

**Health conditions studied****1****Description of health condition studied****ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Anxiety

**Timepoint**

before intervention and in the evening of the sixth day of intervention

**Method of measurement**

Spielberger State-Trait Anxiety Inventory

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: In the mandala coloring group, after measuring the child's anxiety, for six consecutive days in the evenings, five different designs of mandala painting are provided to the child individually on A4 paper and a pack of 12 colored pencils. And he chooses one of the designs as he likes and paints it in 30 minutes. In the evening of the sixth day of the intervention, the anxiety questionnaire is completed again by the child.

**Category**

N/A

**2****Description**

Control group: In the control group, there is no intervention and the child's anxiety is checked only at the same time intervals in the mandala coloring group.

**Category**

N/A

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Mofid Hospital

**Full name of responsible person**

Ali Omid

**Street address**

No 4, Moghaddam deadlock, South Ramin Ave, East Ferdows Blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1481999586

**Phone**

+98 21 2387 2416

**Email**

aliomidi978@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Mofid Hospital Gastroenterology Research Center

**Full name of responsible person**

Ali Omid

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No 4, Moghaddam deadlock, South Ramin Ave, East Ferdows Blvd

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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**

Mofid Hospital Gastroenterology Research Center

**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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Ali Omid

**Position**

Master of science

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

### Contact

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Ali Omid

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## Person responsible for updating data

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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**

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**

All data can potentially be shared after de-identifying individuals in the article format.

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

The access period starts from 2023

**To whom data/document is available**

Researchers working in academic institutions or research centers

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

Researchers are licensed by the research committee

**From where data/document is obtainable**

After publishing the article, visit the magazine site to get more information write to aliomidi978@yahoo.com

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

Researchers can receive the necessary response after two weeks by sending an e-mail to the person in charge.

**Comments**