

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Aug 2026

### The Effect of Mandala Coloring on anxiety and hopelessness in children with cancer

#### Protocol summary

##### Study aim

The Effect of Mandala Coloring on anxiety and hopelessness in children suffering cancer

##### Design

Clinical trial with a control group, with parallel groups, a blind strain, randomized on 98 patients. Sealed Envelope software will be used for randomization.

##### Settings and conduct

This study will be conducted in the educational center of Amir Kabir hospital in Arak. After coloring by the intervention group, their hopelessness and anxiety level is measured and recorded. Only the analyzers do not know how the samples are placed in the groups

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study, Having the ability to paint, Age over 8 years to 18 years, Suitable general condition, Pass at least one course of chemotherapy; Exclusion criteria: Suffering from anxiety and obsessive disorders, Existence of acute stressful conditions during the last six months, Genetic disease in child

##### Intervention groups

Intervention group: The demographic information form and the anxiety and hopelessness questionnaire are completed by children in collaboration with the researcher before the intervention in both groups. Coloring will be done only for the intervention group. The method of coloring and participating in the study will be fully explained by the researcher and the children in the intervention group will be asked to start coloring in a private and quiet place. Coloring is done for six sessions, every day of the week, and each session lasts a maximum of 30 minutes. Control group: They do not receive this intervention during this period. After the intervention, the anxiety and hopelessness questionnaire is completed again by children in collaboration with the researcher in both groups.

##### Main outcome variables

Anxiety and hopelessness

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210501051142N8**

Registration date: **2023-01-30, 1401/11/10**

Registration timing: **prospective**

Last update: **2023-01-30, 1401/11/10**

Update count: **0**

##### Registration date

2023-01-30, 1401/11/10

##### Registrant information

##### Name

Aida Arjloo

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3402 0115

##### Email address

golmehrsherafati@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-03-01, 1401/12/10

##### Expected recruitment end date

2023-03-30, 1402/01/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Effect of Mandala Coloring on anxiety and hopelessness in children with cancer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |  | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Public title</b><br>The Effect of Mandala Coloring on anxiety and hopelessness                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  | <b>Other design features</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Purpose</b><br>Supportive                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  | <b>Secondary Ids</b><br>empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Inclusion/Exclusion criteria</b><br><b>Inclusion criteria:</b><br>Willingness to participate in the study<br>Having the ability to paint<br>Age over 8 years to 18 years<br>Suitable general condition<br>Pass at least one course of chemotherapy<br><b>Exclusion criteria:</b><br>Suffering from anxiety and obsessive disorders<br>Existence of acute stressful conditions during the last six months<br>Genetic disease in child                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  | <b>Ethics committees</b><br><br><b>1</b><br><b>Ethics committee</b><br><b>Name of ethics committee</b><br>Ethics committee of Arak university of medical sciences<br><b>Street address</b><br>Arak university of medical sciences, Basij Sq., Sardasht region<br><b>City</b><br>Arak<br><b>Province</b><br>Markazi<br><b>Postal code</b><br>3848176593                                                                                                                                                                       |
| <b>Age</b><br>From <b>8 years</b> old to <b>18 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  | <b>Approval date</b><br>2022-12-11, 1401/09/20                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Gender</b><br>Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  | <b>Ethics committee reference number</b><br>IR.ARAKMU.REC.1401.269                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Phase</b><br>N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Groups that have been masked</b><br><br>• Data analyser                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Sample size</b><br>Target sample size: <b>98</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Randomization (investigator's opinion)</b><br>Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Randomization description</b><br>children are assigned to groups in the order of arrival and based on the randomization sequence that will be generated in advance. This sequence is unpredictable and does not have a specific pattern, and its arrangement is completely random. To assign the samples to two groups, the block randomization method will be used with a block size of 4, so that by using the random number generation software in the block method, the randomization sequence will be produced according to the required sample size for the two groups. First, all the states where two letters A and B can be arranged together in a block of 2 are created, and a block is randomly selected by placing it between the blocks, and from the arrangement pattern in that block for Child allocation is used then this block will be placed in the main container and another block will be selected again. All this will be done with software called Sealed Envelope. With this method, concealment will also be observed. The concept of concealment is to unpredictably assign individuals to groups that the researcher will not be able to predict which group the next person will be in. |  | <b>Health conditions studied</b><br><br><b>1</b><br><b>Description of health condition studied</b><br>Anxiety<br><b>ICD-10 code</b><br>F06.4<br><b>ICD-10 code description</b><br>Anxiety disorder due to known physiological condition                                                                                                                                                                                                                                                                                      |
| <b>Blinding (investigator's opinion)</b><br>Single blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  | <b>Primary outcomes</b><br><br><b>1</b><br><b>Description</b><br>Average anxiety score<br><b>Timepoint</b><br>Coloring will be done for six sessions, every day of the week and each session will last a maximum of 30 minutes.<br><b>Method of measurement</b><br>At the beginning and end of the study, a demographic questionnaire and a anxiety questionnaire are completed by the children with the cooperation of the researcher in both groups and based on this, the level of anxiety of the children is determined. |
| <b>Blinding description</b><br>The data analyzer will not know how the samples are placed in the intervention and control groups. Other people in the study will be aware of this placement.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Placebo</b><br>Not used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Assignment</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  | <b>Secondary outcomes</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

## 1

### Description

frustration

### Timepoint

Coloring will be done for six sessions, every day of the week and each session will last a maximum of 30 minutes.

### Method of measurement

At the beginning and end of the study, the demographic questionnaire and the frustration questionnaire are completed by the children with the cooperation of the researcher in both groups, and based on this, the level of frustration of the children is determined.

## Intervention groups

## 1

### Description

Intervention group: The demographic information form and the anxiety and hopelessness questionnaire are completed by children in collaboration with the researcher before the intervention in both groups. Coloring will be done only for the intervention group. The method of coloring and participating in the study will be fully explained by the researcher and the children in the intervention group are asked to start coloring a mandala design selected from the mandala coloring book by Alberta Hutchinson in a private and quiet place. Coloring is done for six sessions, every day of the week, and each session lasts a maximum of 30 minutes. After the intervention, the anxiety and hopelessness questionnaire is completed again by children in collaboration with the researcher in both groups.

### Category

Other

## 2

### Description

Control group: They do not receive this intervention during this period. After the intervention, the anxiety and hopelessness questionnaire is completed again by children in collaboration with the researcher in both groups.

### Category

Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Amir Kabir Hospital

#### Full name of responsible person

Mahbobeh Sajadi

#### Street address

A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province

#### City

Arak

#### Province

Markazi

#### Postal code

3819693345

#### Phone

+98 918 599 7635

#### Email

golmehrsherafati@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Arak University of Medical Sciences

#### Full name of responsible person

DR Alireza Kamali

#### Street address

University complex of the Great prophet, Basij square, Sardasht.

#### City

Arak

#### Province

Markazi

#### Postal code

3819693345

#### Phone

+98 918 599 7635

#### Email

golmehrsherafati@gmail.com

#### Grant name

#### 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

80

#### 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

Mahbobeh Sajadi

#### Position

Associate professor

#### Latest degree

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

University complex of the Great prophet, Basij square, Sardasht.

**City**

Arak

**Province**

Markazi

**Postal code**

3819693345

**Phone**

009886341735057

**Email**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Mahbobeh Sajadi

**Position**

Associate professor

**Latest degree**

Ph.D.

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**Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Mahbobeh Sajadi

**Position**

Associate professor

**Latest degree**

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**Email**

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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**

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**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

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

Only the part of the data related to the original outcome will be able to be shared.

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

since the spring of 2023

**To whom data/document is available**

Researchers and students in this field

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

In order to reduce the anxiety and despair of children suffering cancer.

**From where data/document is obtainable**

Vice chancellor for education and research, Arak university of medical sciences

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

These documents will be available on the website of Arak university of medical sciences.

**Comments**