Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 pencilsthen,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 Omidi
Street address
No 4, Moghaddam deadlock, South Ramin Ave, East Ferdows Blvd
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mofid Hospital Gastroenterology Research Center
Full name of responsible person
Ali Omidi
Street address
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 Omidi
Position
Master of science
Latest degree
Master
Other areas of specialty/work
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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 can receive the necessary response after two weeks by sending an e-mail to the person in charge.
Comments