Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the Effectiveness of Mandala Coloring and Playing with Lego on Children’s Pre-operative Anxiety

Protocol summary

Study aim
Comparison of the effect of mandala coloring and playing with Lego on children’s pre-operative anxiety

Design
This study is a simple randomized clinical trial.The study samples are 105 pre-operative children admitted to Mofid Hospital and Children's Medical Center.The allocation of the children in three intervention and control groups is based on the arrival day,so that in the columns, "Saturday, Sunday", "Monday, Tuesday" and " Wednesday, Thursday" is placed.The mandala group is classified in the "Saturday Sunday", the Lego group is classified as "Monday Tuesday" and the control group is classified in the "Wednesday Thursday" column.This process continues until the sampling is completed.

Settings and conduct
First,in all three groups,the child's anxiety is measured before entering the operating room with Spielberger's anxiety questionnaire.If the child's anxiety is moderate to severe,in the mandala group,a mandala design is colored for 15-20 minutes and in the Lego group,building different shapes with Lego bricks is done.Then, in the two intervention groups, the child's anxiety is checked immediately after the intervention, and in the control group,only the child's anxiety is checked at the same intervals.

Participants/Inclusion and exclusion criteria
Inclusion:Not suffering from separation anxiety,no surgery history,Exclusion:existence of mental illness,need for emergency surgery

Intervention groups
In the mandala coloring group, five different mandala painting designs and a 12 colored pencils pack are provided to the child.He chooses from the designs and paints it in 15-20 minutes.In the Lego group,a box containing different parts is provided to the child and he is asked to make different shapes.In both groups,anxiety will be checked before and immediately after the intervention.In the control group,only the anxiety is checked before the operation.

Main outcome variables
anxiety level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220203053920N1**
Registration date: **2022-07-20, 1401/04/29**
Registration timing: **prospective**

Last update: **2022-07-20, 1401/04/29**
Update count: **0**

Registration date
2022-07-20, 1401/04/29

Registrant information

Name
Reihane Moghimian Shahrbabaki

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8895 9438

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-23, 1401/06/01

Expected recruitment end date
2022-11-22, 1401/09/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effectiveness of Mandala Coloring and Playing with Lego on Children’s Pre-operative Anxiety

Public title

Effectiveness of Mandala Coloring and Playing with Lego on Children’s Pre-operative Anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study and written consent Age 6 to 18 years and both sexes Having the ability to communicate verbally The ability to paint, draw and play with Lego toys The child does not have a cognitive disorder, language problems, hearing disorders, neurological conditions based on the file documents Not suffering from separation anxiety and known phobia Absence of severe pain before the intervention with visual analogue scale (VAS) No history of surgery

Exclusion criteria:

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: **105**

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

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Intersection of Hashemi Rafsanjani Blvd and Valiasr Street, Zahra Hostel

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Province

Tehran

Postal code

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Approval date

2022-01-29, 1400/11/09

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.975

Health conditions studied

1

Description of health condition studied

mandala coloring

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Play with Lego

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety

Timepoint

Before the intervention and immediately after the 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, five different designs of mandala painting are provided to the child separately on A4 paper and a pack of 12 colored pencils. He/She chooses from the designs and paints it in 15-20 minutes, then the anxiety questionnaire is completed again by the child.

Category

N/A

2

Description

Intervention group: In the Lego group, after measuring the child's anxiety, a box containing different parts is provided to the child and the child is asked to make different shapes from the manual or his creativity, then the anxiety questionnaire is completed again by the child.

Category

N/A

3

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 two groups of mandala coloring and Lego.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Mofid hospital

Full name of responsible person
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Children's Medical Center

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Sponsors / Funding sources

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
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Position
Master student of pediatric nursing

Latest degree
Master

Other areas of specialty/work
Nursery

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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 unrecognizable 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
It will be available for everyone

Under which criteria data/document could be used
Researchers are licensed by the research committee

From where data/document is obtainable
After the publication of the article, visit the journal's website for more information write to moghimianreihane1@gmail.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