Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigatig the effect of mandala coloring on the anxiety of children candidates for tonsillectomy

Protocol summary

Study aim
General purpose: to determine the effect of mandala coloring on anxiety caused by tonsillectomy
Design
This study will be conducted as a clinical trial, with a control group and an intervention group, without blinding, simple randomization, on 60 patients through convenient sampling methods.
Settings and conduct
This study will be conducted on 60 patients referred for tonsillectomy surgery to Imam Khomeini Hospital (RA) in Khomein city. In the intervention group, the samples will be colored for 30-45 minutes using 10 colors of colored pencils to color the raw mandala sample. After completing the coloring, the Spence questionnaire will be filled again by the participants.
Participants/Inclusion and exclusion criteria
Inclusion criteria Age 8 to 15 Satisfaction of the patient and the patient's parents Obtaining a score higher than 84% in the Spence anxiety test and exclusion criteria Lack of cooperation of the patient and parents patient restlessness
Intervention groups
After completing the Spence questionnaire, in the intervention group, the samples will be asked to paint a raw mandala (25 x 17 dimensions) using 10 colored pencils for 30-45 minutes; No special action will be taken in the control group
Main outcome variables
Reducing anxiety caused by tonsillectomy

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221102056383N2**
Registration date: **2025-09-01, 1404/06/10**
Registration timing: **retrospective**
Last update: **2025-09-01, 1404/06/10**
Update count: **0**
Registration date
2025-09-01, 1404/06/10

Registrant information
Name
zeynab beheshti
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-08-21, 1403/05/31
Expected recruitment end date
2025-02-18, 1403/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigatig the effect of mandala coloring on the anxiety of children candidates for tonsillectomy

Public title
Determining the effect of mandala coloring on the anxiety
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:

Age between 8 and 15 years Consent of the patient and the patient’s parents Score higher than 84% on the Spence Anxiety Test

Exclusion criteria:

Suffering from severe psychiatric disorders Severe visual or motor impairments that interfere with the ability to perform coloring activities Inability to establish basic verbal communication with the therapist or researcher Use of anxiolytic or other stable psychiatric medications within the past three months

Age

From **8 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling was carried out using convenience sampling and purposive sampling based on the study’s inclusion criteria. Subsequently, the participants were assigned into intervention and control groups through a simple randomization method. For the simple randomization procedure, 60 rows of numbers were entered into SPSS software (version 27). Then, using the commands Data, Select Cases, Random sample of cases, the software was instructed to randomly select 50% of the cases. The selected 50% were assigned to the intervention group, while the remaining 50% (unselected cases) were considered as the control group. During patient enrollment, and in accordance with the randomization process performed by the software, the sequence of allocation was as follows: the first three admitted patients were assigned to the intervention group, the next four patients to the control group, the following two patients to the intervention group, the next four patients to the control group, one patient to the intervention group, the next patient to the control group, the subsequent patient to the intervention group, the next patient to the control group, the following six patients to the intervention group, two patients to the control group, and so forth until the 60th patient (the last patient recruited according to the calculated sample size) was allocated.

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 Ethics Committees of Islamic Azad University- Aligudarz branch

Street address

Islamic Azad University, Aligoudarz Branch, Daneshgah Square

City

Aligudarz

Province

Lorestan

Postal code

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Approval date

2024-07-10, 1403/04/20

Ethics committee reference number

IR.IAU.AGZ.REC.1403.002

Health conditions studied

1

Description of health condition studied

Anxiety caused by tonsillectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Average anxiety score

Timepoint

Before and after the intervention, mandala coloring

Method of measurement

At the beginning of the study, a demographic questionnaire and Spence questionnaire were completed, and after the mandala coloring was completed, the Spence questionnaire was completed again, and based on this, the patients' anxiety level was determined.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The samples are asked to color a raw mandala sample measuring 25×17 for 30-45 minutes using 10 colored pencils. It should be noted that in this study, 5 designs are used, and the participants will choose one of them according to their taste. After the intervention, the Spence Child Anxiety Scale will be

completed by the participants in the intervention group.

Category
Other

2

Description
Control group: No intervention was performed in this group and they will simply complete the questionnaire.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatima Al-Zahra Educational and Medical Center, Khomein City

Full name of responsible person
Zeynab Beheshti

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Fatemeh Zahra Hospital, Khomein Bypass Road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
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Islamic Azad University, Khomein Branch, University Town, Daneshgah Boulevard, Shohada-ye Daneshjoo Boulevard

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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
Islamic Azad University

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
Islamic Azad University, Khomein Branch

Full name of responsible person
Zeynab Beheshti

Position
Science Committee, Instructorr

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
Undecided - It is not yet known if there will be 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
Yes - There is 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 de-identified data relevant to the primary outcomes of the study will be shared upon request.
When the data will become available and for how long
Data will be available starting 6 months after the publication of the study results.
To whom data/document is available
Qualified researchers and postgraduate students in the related field
Under which criteria data/document could be used
For academic and clinical research purposes aimed at improving healthcare outcomes and reducing anxiety in the studied population, under appropriate ethical approval.
From where data/document is obtainable
To the principal investigator at Islamic Azad University, Khomein Branch
What processes are involved for a request to access data/document
If someone requests the data or documentation of the study, they must send a written request via email to the principal investigator. Upon review and approval by the research team, and if necessary, after obtaining approval from the Ethics Committee, the de-identified data will be shared with the requester. This process may take between 2 to 4 weeks.
Comments