

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effect of guided imagery on anxiety of children candidate for tonsillectomy

Protocol summary

Study aim

The effect of guided imagery on anxiety of children candidate for tonsillectomy

Design

Randomized controlled clinical trial, without placebo. Random number table will be used for randomization.

Settings and conduct

This study will be performed in Amir-Kabir Hospital in Arak on children who are candidates for tonsillectomy. Participants are randomly divided into intervention and control groups. Allocation concealment was not performed in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 7 to 12 years; lack of previous experience of surgery; no psychological disorders; no hearing disorders; reading and writing skill of mothers. Exclusion criteria: reluctance of parents and children to participate in the study

Intervention groups

Intervention group: samples of the intervention group listen to an audio file using handsfree for 15 minutes, one hour before surgery. The contents of the audio file contain appropriate and pleasant topics that are combined with soothing music for the child to visualize in his/her mind. Control group: The control group did not receive any intervention during this time.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211008052701N1**

Registration date: **2021-11-07, 1400/08/16**

Registration timing: **prospective**

Last update: **2021-11-07, 1400/08/16**

Update count: **0**

Registration date

2021-11-07, 1400/08/16

Registrant information

Name

Mahdieh Ajerloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3445 9312

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mmahdieaajerloo1994@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of guided imagery on anxiety of children candidate for tonsillectomy

Public title

The effect of guided imagery on anxiety of children candidate for tonsil surgery

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 7 to 12 years Lack of previous experience of surgery No psychological disorders No hearing disorders Reading and writing skill of mothers

Exclusion criteria:

Reluctance of parents and children to participate in the study

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **7001**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples individually divided into intervention and control groups using simple random allocation method and a random number table.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Basij Sq., Sardasht Region

City

Arak

Province

Markazi

Postal code

3848176593

Approval date

2021-06-23, 1400/04/02

Ethics committee reference number

IR.ARAKMU.REC.1400.056

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Anxiety score in facial anxiety assessment tool

Timepoint

Before and immediately after the intervention

Method of measurement

Facial anxiety assessment tool

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Samples of the intervention group listen to an audio file using handsfree for 15 minutes one hour before surgery. The contents of the audio file contain appropriate and pleasant topics that are combined with soothing music for the child to visualize in his mind.

Category

Prevention

2

Description

Control group: The control group did not receive any intervention during this time.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir-Kabir Hospital

Full name of responsible person

Ehsan Rahimi

Street address

Parastar Sq., Rah-Ahan Sq., Shahid Shiroodi St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Mahdieh Ajerloo
Position
Nurse
Latest degree
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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

It is provided unrecognizably at the request of individuals.

When the data will become available and for how long

The access period will start after the results are printed.

To whom data/document is available

Researchers at other Universities are allowed access.

Under which criteria data/document could be used

Documentation is provided in order to know how the work is done and to critique it.

From where data/document is obtainable

Sharareh Khosravi Email: khosravi@arakmu.ac.ir

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

After stating the purpose of accessing the information, the requested items will be sent via email.

Comments