

# 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

###### Email address

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.

**City**

Arak

**Province**

Markazi

**Postal code**

3848176593

**Phone**

+98 86 3313 0040

**Email**  
info@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Alireza Kamali  
**Street address**  
Basij Sq., Sardasht Region  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3848176341  
**Phone**  
+98 86 3417 3639  
**Email**  
research@arakmu.ac.ir  
**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**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Basij Sq., Sardasht Region  
**City**  
Arak  
**Province**  
Markazi

**Postal code**  
3816991561  
**Phone**  
+98 86 3445 9312  
**Email**  
mmahdieaajerloo1994@yahoo.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Sharareh Khosravi  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Basij Sq., Sardasht Region  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3848176341  
**Phone**  
+98 86 3417 3505  
**Email**  
research@arakmu.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Mahdieh Ajerloo  
**Position**  
Nurse  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Basij Sq., Sardasht Region  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3848176341  
**Phone**  
+98 86 3445 9312  
**Email**  
mmahdieaajerloo1994@gmail.com

## 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**