

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Comparative investigation of the effect of deep breathing and guided imagery on sleep quality and vital signs in children admitted to the hospital: A Randomized Controlled Trial

#### Protocol summary

##### Study aim

Investigating and comparing effect of guided imagery and deep breathing on vital signs and sleep quality of children hospitalized in the pediatric department

##### Design

A clinical trial with a control group, with parallel groups, single-blind, randomized, on 75 patients and in general, with three groups; randomization with the table of random numbers

##### Settings and conduct

This research is a single-blind clinical trial study on children hospitalized in Imam Ali Hospital in Karaj. Blinding will be done on the researcher filling the questionnaires. hospitalized children will be randomly divided into three groups: control, play therapy, and storytelling.

##### Participants/Inclusion and exclusion criteria

Inclusion: children aged 6 to 12, admitted to the ward for at least 48 hours, staying in the hospital for at least 5 days, diagnosed disease, obtaining informed consent from the child's parents; Exclusion: the presence of cognitive, nervous and learning problems, the child's lack of consciousness, inability to participate in interventions and cancer

##### Intervention groups

In the guided imagery group, images are shaped through standard images and videos, storytelling and imagination, which will take place for 3 days in two shifts of the morning and the evening for 45 to 60 minutes. In the deep breathing group, after the child is properly taught, he/she is asked to do this. Meanwhile, the researcher starts counting with one hand and puts the other hand on the child's diaphragm to ensure the air flow. The control group will receive the usual hospital treatments.

##### Main outcome variables

level of sleep quality and vital signs, adherence rate to

treatment among child

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220704055367N3**

Registration date: **2022-11-04, 1401/08/13**

Registration timing: **prospective**

Last update: **2022-11-04, 1401/08/13**

Update count: **0**

##### Registration date

2022-11-04, 1401/08/13

##### Registrant information

##### Name

Fatemeh Abdi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 86701

##### Email address

fatemeh.abdi87@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-11-24, 1401/09/03

##### Expected recruitment end date

2023-04-14, 1402/01/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparative investigation of the effect of deep breathing and guided imagery on sleep quality and vital signs in children admitted to the hospital: A Randomized Controlled Trial

**Public title**

Comparison of the effect of deep breathing and guided visualization in children

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Aged between 6 to 12 Hospitalization for at least 48 hours Staying in the hospital for at least 5 days A diagnosed disease Obtaining informed consent from the child's parents

**Exclusion criteria:**

The presence of cognitive, neurological or learning problems Having Cancer Child's lack of consciousness

**Age**

From **6 years** old to **12 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **75**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

By using a randomized table, children will be assigned to one of the three groups (guided imagery, deep breathing and control). Assignment Sequences are determined using a computer random number table (www.Random.com), and in order to hide the allocation, the opaque packets are numbered sequentially.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This study is a blinded clinical trial. Therefore, blinding will be implemented in the evaluators who will analyze the study data. For this purpose, the questionnaires that will be completed by the researchers in all three groups, in the form of a contract between the researchers. Also, it will be specified with one of the English letters above it, which questionnaire was completed by the participants of which of the study groups; However, the evaluators of the data analysis will not be aware of the English letter of agreement between the researchers assigned to each group.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Alborz University of Medical Sciences

**Street address**

Ethics committee office, Second floor, Safarian alley, 45 meters to Golshahr

**City**

Karaj

**Province**

Alborz

**Postal code**

3149779453

**Approval date**

2022-10-22, 1401/07/30

**Ethics committee reference number**

IR.ABZUMS.REC.1401.194

**Health conditions studied****1****Description of health condition studied**

Meningitis

**ICD-10 code**

A87

**ICD-10 code description**

Viral meningitis

**2****Description of health condition studied**

Reye's syndrome

**ICD-10 code**

G93.7

**ICD-10 code description**

Reye's syndrome

**Primary outcomes****1****Description**

Sleep Quality Score

**Timepoint**

Before intervention and one week after intervention

**Method of measurement**

Pittsburgh Sleep Quality Index

**2****Description**

Vital signs

**Timepoint**

Before intervention and one week after intervention

#### **Method of measurement**

1-Blood pressure: by sphygmomanometer 2-Temperature: by thermometer 3-Pulse: counted for one full minute 4-Breathing: counted for one full minute.

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group 1: Guided imagery takes place through standard video images, storytelling and imagination. In this way, the mentioned interventions will be played in the form of headphones for children within 18 to 20 minutes each time. This intervention takes place in three days in two shifts of morning and evening. The content of the audio file includes appropriate and pleasant topics combined with soothing music so that the child can visualize it in his/her mind.

##### **Category**

Behavior

#### **2**

##### **Description**

Intervention group 2: After teaching the deep breathing technique in the form of pursed lips breathing, the child is asked to do this. Meanwhile, the researcher places one hand on the child's diaphragm to ensure the presence of air flow and starts counting with the other hand. To perform this procedure, the patient is asked to inhale and exhale in a ratio of 4:6. Patients are taught to inhale through the nose and count from one to four and exhale through the mouth and count from one to six. It will take 10-15 minutes. This intervention takes place in three days in two shifts of morning and evening.

##### **Category**

Behavior

#### **3**

##### **Description**

Control group: Receiving routine intervention of the ward such as receiving drugs, similar to other hospitalized children who will not participate in the study and will not be exposed to deep breathing or guided imagery.

##### **Category**

Treatment - Drugs

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Imam Ali Educational-Medical Center

###### **Full name of responsible person**

Fatemeh Abdi

##### **Street address**

Resalat crossroad

##### **City**

Karaj

##### **Province**

Alborz

##### **Postal code**

3154646695

##### **Phone**

+98 26 3254 6372

##### **Email**

emamali@abzums.ac.ir

##### **Web page address**

<https://emamali.abzums.ac.ir/fa-IR/emamali.abzums.ac/5418/page/%D8%B5%D9%81%D8%AD%D9%87-%D8%A7%D8%B5%D9%84%DB%8C>

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Karaj University of Medical Sciences

###### **Full name of responsible person**

Razieh Lotfi

###### **Street address**

Alborz University of Medical Sciences (ABZUMS), Northern Taleghani boulevard, Taleghani square

###### **City**

Karaj

###### **Province**

Alborz

###### **Postal code**

3149779453

###### **Phone**

+98 26 3419 7000

###### **Email**

info@abzums.ac.ir

##### **Grant name**

##### **Grant code / Reference number**

##### **Is the source of funding the same sponsor organization/entity?**

Yes

##### **Title of funding source**

Karaj 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**

Karaj University of Medical Sciences

**Full name of responsible person**

Fatemeh Abdi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Taleghani Boulevard, Taleghani square, Karaj, Iran

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**Province**

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**Postal code**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

School of nursing, Eshteraki street, Baghestan BLVD,  
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fatemeh.abdi87@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Fatemeh Abdi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Phone**

+98 26 3419 7000

**Fax****Email**

fatemeh.abdi87@yahoo.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**

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**

No - There is not a plan to make this available

**Title and more details about the data/document**

Only part of the data, such as information related to the main outcome and general demographic information can be shared.

**When the data will become available and for how long**

The access period starts 3 months after the results are published

**To whom data/document is available**

Doctors, nurses, midwives, researchers working in universities and medical centers and hospitals, clinical psychologists

**Under which criteria data/document could be used**

In order to use it for scientific purposes and by mentioning the source used and requesting the journal in which the article will be published.

**From where data/document is obtainable**

Communication through e-mail (if possible to share information from a legal and ethical point of view, such as sharing the primary outcome of the study) To receive information, contact the following email address: fatemeh.abdi87@yahoo.com In the case of sending letter with regard to the current study, the following postal address of the corresponding author is available: School of nursing, Eshteraki street, Takhti Park, Baghestan BLVD

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

Finding the responsible author's email, stating the reason, complying with ethical and legal issues; In this

case, a quick response will be given to the requester.

**Comments**