

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

City

Karaj

Province

Alborz

Postal code

3146883811

Phone

+98 26 3419 7000

Fax**Email**

fatemeh.abdi87@yahoo.com

Person responsible for scientific 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

Midwifery

Street address

School of nursing, Eshteraki street, Baghestan BLVD,
Karaj, Iran

City

Karaj

Province

Alborz

Postal code

3146883811

Phone

+98 26 3433 6007

Email

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

Street address

Taleghani Boulevard, Taleghani square, Karaj, Iran

City

Karaj

Province

Alborz

Postal code

3146883811

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