

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparison of the effect of two methods of listening and reading tales on anxiety and sleep onset time in 8-12 year old in hospitalized children with fractures: a randomized controlled clinical trial

Protocol summary

Study aim

Determination and comparison of intra-group and inter-group child's anxiety score and heart rate different measuring times. Determination and comparing the intra-group, inter-group and length of time to fall asleep at different measuring times.

Design

Randomized clinical trial has 3 groups in parallel groups: 1. Intervention group hearing the story; 2. Intervention group hearing the story and reading simultaneously; and 3. the control group

Settings and conduct

The present study is a randomized clinical trial that will be performed on children aged 8 to 12 admitted with fracture of one of the limbs in Tabriz Shohada Hospital in 2018- 2019. In this study, the children were divided into three groups: Listening to the story; read and listen to the story simultaneously; The control group (with out intervention). Interventions are done in the evening and the night of the second day of hospitalization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Parents should satisfy with the child's participation in the study. Children should have age from 8 to 12 years. A family member should exist in the patient bed. a patient who has not sleep disorders and illnesses associated with sleep. The patient should have a fracture in one of the organs. The patient should be a student in the second to the sixth grade The patient should have no hearing or visual impairment. Exclusion criteria: a patient who has multiple trauma a patient who is not fluent in reading and writing. a patient who has anxiety disorders.

Intervention groups

In this study, the children were divided into three groups. 1)The groups who listen to the story and 2) the groups who listen and read the story simultaneously (intervention groups) 3)control group(no intervention).

The intervention is done in the evening and the night of the second day of hospitalization.

Main outcome variables

Anxiety- Sleep Onset Time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180622040189N1**

Registration date: **2018-12-15, 1397/09/24**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-15, 1397/09/24**

Update count: **0**

Registration date

2018-12-15, 1397/09/24

Registrant information

Name

Azam Romouzi Kouche Bagh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-05, 1397/08/14

Expected recruitment end date

2019-05-03, 1398/02/13

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of two methods of listening and reading tales on anxiety and sleep onest time in 8-12 year old in hospitalized children with fractures: a randomized controled clinical trial

Public title
Comparison of the effect of two methods of listening and reading tales on anxiety and sleep onest time

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Not having a history of sleep disorder Not having anxiety disorder
Exclusion criteria:
Unaccompanied patient A patient who has multiple trauma

Age
From **8 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **102**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples are selected using the available method. In the next step, random blocks with 3 sets are assigned to two test groups and one control group. A random sequence is generated using the STATA14 software. Number of blocks 34, size 3. After blocking, patients (individuals) will assign to study groups by main researcher using generated randomized sequential as they will recruit.like this: A: First intervention group B: Second intervention group C: control group First person 1 A 2 B 3 C 1 C 2 A 3 B 1 C 2 B 3 A 1 C 2 B person 102 3 A

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

Regional Ethics College Committee for Biomedical Research, Tabriz University of Medical Sciences

Street address

Golgasht Ave, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2018-07-22, 1397/04/31

Ethics committee reference number

IR.TBZMED.REC.1397.334

Health conditions studied

1

Description of health condition studied

Comparison of the Effect of Two Methods of Listening and Reading Tales on Anxiety and Sleep Onest Time in 8-12 Year Old in Hospitalized Children with Fractures

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety Score in Revised Children's Manifest Anxiety Scale

Timepoint

Completion of the anxiety questionnaire on the first day after pulse control and the second day after intervention

Method of measurement

Revised Children's Manifest Anxiety Scale

2

Description

Time to fall asleep children

Timepoint

The first night after 21:30 and the second night after the intervention

Method of measurement

chronometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group heard the story: on the evening of the second day (day of operation), a heart rate measurement was first performed, then the player's headphones are provided to the child and he listens to the researcher's story book stories for 30 minutes. Then the heart rate is recorded and the RCMAS children's apparent anxiety questionnaire (with the exception of polygraph questions) is completed. In the bedtime of the children, the final visit is done, player's headphones available to the child, and child listens to storytelling for 30 minutes in the presence of a researcher, and the time taken from the beginning of the story will be recorded until the child falls asleep.

Category

Other

2

Description

Intervention group: listening and reading the story text simultaneously. The actions performed in this group are like the first group, with the difference that during this intervention, in addition to listening to story, the group also uses the look at story text at the same time. On the evening of the second day (day of operation), a heart rate measurement was first performed, then the story book is available to the child, and for 30 minutes, in the presence of a researcher, while listening to the same story while using the headphone player, the story book is also viewed and followed by the child, then the heart rate is recorded and the RCMAS children's apparent anxiety questionnaire (with the exception of polygraph questions) is completed. In the bedtime of the children, the final visit is done, the story book is available to the child and for 30 minutes in the presence of a researcher while listening to the same tale while using the headphone player the story book is also viewed and followed by the child, and the time taken from the beginning of the story will be recorded until the child falls asleep.

Category

Other

3

Description

Control group: In this group, the researcher visits the department for two consecutive days (including the day of admission and day of operation) and twice a day (evening and night), but there is no intervention. In the evening of the admission day, the researcher's assistance, the number of pulses is determined and recorded by using the pulse oximeter. Then, children listen to story by the player's headphones for 30 minutes. After that, the heart rate is recorded and the questionnaire is completed. On the evening of the second day (day of operation), the heart rate will be measured. The re-connection takes place at 10 o'clock and the length of sleep time will be measured. On the

second day (day of operation), the heart rate is recorded twice with a half an hour interval and the time to fall asleep is measured and recorded.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Hospital

Full name of responsible person

Leyla Valizadeh

Street address

Nursing & Midwifery Faculty, Shariati Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

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

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Azam Romouzi Kouche Bagh

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available