Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of guided mental imagery on the intensity of anxiety and physiological indicators of the family of patient with head trauma hospitalized in the intensive care unit

Protocol summary

Study aim

Determining the effect of guided mental imagery on the intensity of anxiety and physiological indicators of the family of patient with head trauma hospitalized in the intensive care unit

Design

The third phase of a clinical trial with a control group, with parallel groups, which will be conducted after a Pilot study on a number of biological parents of 7-18 year old patients hospitalized in the intensive care unit.

Settings and conduct

This study will be conducted on the biological parents of patients aged 7 to 18 admitted to the intensive care unit of Pakdasht Martyrs hospital.

Participants/Inclusion and exclusion criteria

Biological parents of head trauma patients aged 7 to 18 years who were present at the time of sampling and did not participate in a similar research with guided mental imagery and had no history of drug addiction and were treated with neuropsychiatric drugs are not included in the study and if they do not reluctance to complete the study or the acute condition of the hospitalized child changes and the parents need to be present at his bedside, they will be excluded from the research.

Intervention groups

Intervention group, 12 to 24 hours after their child's hospitalization in the intensive care unit, and after measuring the physiological indicators and anxiety scores, they listened to the audio tape of guided mental imagery through headphones, and immediately after that, for the second time, the physiological indicators and anxiety scores are measured. The control group after the first round of measurements, rests on the bed for the equivalent time of playing the audio tape, and immediately after that, the second round of measurements is performed.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140721018550N12**
Registration date: **2023-04-08, 1402/01/19**
Registration timing: **prospective**

Last update: **2023-04-08, 1402/01/19**
Update count: **0**

Registration date

2023-04-08, 1402/01/19

Registrant information

Name
Nayyereh Raiesdana
Name of organization / entity
Semnan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of guided mental imagery on the intensity of anxiety and physiological indicators of the family of patient with head trauma hospitalized in the intensive care unit

Public title

The effect of guided mental imagery on the intensity of anxiety and physiological indicators of the family of a patient with head trauma

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Simultaneous presence of both biological parents of the patient at the time of sampling Their child's age should be 7 to 18 years No history of participate in similar research with the guided mental imagery No history of drug addiction Not being treated with neuropsychiatric drugs at the time of the study

Exclusion criteria:

The acute change in the condition of the hospitalized and the need for the presence of the parents at his bedside

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each sample in this research includes both the biological father and mother of a person with a head injury

Randomization (investigator's opinion)

Randomized

Randomization description

Parents of head trauma patients hospitalized in the intensive care units of Pakhdasht Martyrs Hospital are included in the study using the available method. Then they are divided into two groups A and B using the Restricted Randomization method with blocks of six. In other words, out of every six parents who enter the study, 3 parents are randomly placed in group A and three parents in group B. The number of possible states of blocks of six is 20. Among these 20 blocks of six, according to the sample size, blocks of six are randomly selected and based on that, patients are assigned to two groups. The randomization method is as follows: (AAABBB, ABAABB, AABBAB,……,BBBAAA) We assign a sampling number. For example: AAABBB→00-04 ABAABB→05-09 AABBAB→10-14 .. BBBAAA→95-99 Which is twenty groups and each group has 5 numbers, which is 5 sampling numbers for each block.

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

Ethics Committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical sciences, Basij Bolverd, Semnan, Iran

City

Semnan

Province

Semnan

Postal code

3513138111

Approval date

2023-03-13, 1401/12/22

Ethics committee reference number

IR.SEMUMS.REC.1401.335

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F09

ICD-10 code description

Unspecified mental disorders due to Known Physiologic Conditions

Primary outcomes

1

Description

Anxiety

Timepoint

Before and after intervention

Method of measurement

Spielberger State-Trait Anxiety Inventory

Secondary outcomes

1

Description
Systolic and diastolic blood pressure
Timepoint
Before and after intervention
Method of measurement
Digital arm spyghmomanometer (OMRON brand)

2

Description
Pulse rate
Timepoint
Before and after intervention
Method of measurement
Pulse oximeter (Choicemed brand, ModelCN56)

3

Description
O2 saturation percentage
Timepoint
Before and after intervention
Method of measurement
Pulse oximeter (Choicemed brand, ModelCN56)

Intervention groups

1

Description
Intervention group: First, blood pressure, pulse and percentage of oxygen saturation are measured from the left arm while lying on the back. Then, Spielberger State-Trait questionnaire will be completed by each parent alone, and immediately after that, the guided imagery audio clip will be played for them through headphones, and immediately after it is finished, blood pressure, pulse and percentage Oxygen saturation will be measured for second time and the Spielberger State questionnaire will be answered by each parent.
Category
Other

2

Description
Control group: Control group: First, blood pressure, pulse and percentage of oxygen saturation are measured from the left arm while lying on the back. Then, Spielberger's State-Trait anxiety questionnaire will be completed by each parent alone, and immediately after that, subjects lying on the back for the time equivalent to applying the intervention for the intervention group, and immediately after that, blood pressure, pulse and percentage Oxygen saturation will be measured for second time and the Spielberger State questionnaire will be answered by each parent.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Pakdasht Martyrs Hospital
Full name of responsible person
Anoushirvan Sadeghi
Street address
Khyber IV street, Khatun abad, 18th kilometer of Khavaran road, Pakdasht, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Majid Mirmohammadkhani
Street address
Deputy of Research and Technology, Semnan University of Medical sciences, Basij Boulevard, Semnan, Iran
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majidmirmohammadkhani@yahoo.com
Web page address
https://SEMUMS.ac.ir
Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan University of Medical Sciences
Proportion provided by this source

10

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

Semnan University of Medical Sciences

Full name of responsible person

Nayyereh Raiesdana

Position

Associate Professor. faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Email

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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

No - There is not 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

Not applicable

Data Dictionary

Not applicable