

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### The Effect of Relaxation Training on the Pain after Surgery in 8-12 year old Children Admitted to the Surgical Units of Shiraz University of Medical Sciences in 1393-94

#### Protocol summary

##### Summary

The aim of this study was to evaluate the effect of relaxation training on the pain after surgery in children admitted to the surgical units of Shiraz University of Medical Sciences in 1393-94. samples included 104 eight to twelve year old children who underwent surgery and were randomly divided into two groups of control ) and intervention Used tools included demographic characteristics questionnaire and a pain rating scale. In addition to routine care, the children in the intervention group were trained by Benson relaxation techniques during two sessions, each session 20 minutes with an interval of 4 hours a day before the operation. The control group received routine care of the unit. The pain score of the child was measured in both groups, before the operation, one hour after intervention and twelve hours after intervention.outcom of study was pain.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016021526572N1**

Registration date: **2016-08-02, 1395/05/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-08-02, 1395/05/12

##### Registrant information

##### Name

Fahimeh Safizadeh

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 4233 3964

##### Email address

stud3071903261@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2015-01-21, 1393/11/01

##### Expected recruitment end date

2015-05-18, 1394/02/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Relaxation Training on the Pain after Surgery in 8-12 year old Children Admitted to the Surgical Units of Shiraz University of Medical Sciences in 1393-94

##### Public title

The effect of relaxation on the pain after surgery

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria included: 8-12 years old children; signing of informed consent by parents; lack of a clear mental retardation and mental health problems in parents and children; child is literate; no history of surgery lack of vision and hearing problems in the child; and Exclusion criteria: the reluctance of parents to continue to collaborate in this research and the presence

of a disease; or an acute problem that prevents the continuation of cooperation of the child were the exclusion criteria

### 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: **104**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### 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

Shiraz University of Medical Sciences

##### Street address

Central building of Shiraz University of Medical Sciences, Zand boulevard.,

##### City

Shiraz

##### Postal code

71348-14336

##### Approval date

2015-02-16, 1393/11/27

##### Ethics committee reference number

ct-9371-7381

## Health conditions studied

### 1

#### Description of health condition studied

pain

#### ICD-10 code

R52.0

#### ICD-10 code description

Acute pain

## Primary outcomes

### 1

#### Description

pain

#### Timepoint

before the intervention, one hour after intervention and twelve hours after intervention

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The children in the intervention group, in addition to routine care which includes analgesics (a dose of 10 mg/kg Apotel and 0.1 mg/kg Petedin) if required, were introduced to the relaxation method that was trained individually during 2 sessions, each session 20 minutes, with an interval of 4 hours a day before surgery along with listening to a CD in which the procedure was explained by the researcher and after each session to ensure the child's learning, 10 minutes for questions and answers was considered. The intervention by the child himself and in the presence of the researcher was conducted for 20 minutes, an hour later from entering the patient to the unit and the pain score of the child was measured before intervention, one hour after intervention and twelve hours after intervention Then its impact was measured on the score of the severity of his pain in three above phases

#### Category

Other

### 2

#### Description

Control group routine care which includes analgesics (a dose of 10 mg/kg Apotel and 0.1 mg/kg Petedin) if required

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Nemazee hospital

##### Full name of responsible person

Nooshin Beheshti poor, Instructor of Pediatric Department(Advisor)

##### Street address

Nemazee square, Zand ave., Shiraz

**City**  
Shiraz

**2**

**Recruitment center**

**Name of recruitment center**  
Mother and Child hospital

**Full name of responsible person**  
Nooshin Bbeheshhti poorh

**Street address**  
First Gulshan Town, Gateway Qur'an

**City**  
Shiraz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**  
Shiraz University of Medical Science

**Full name of responsible person**  
Dr.Seyed Basir Hashemi

**Street address**  
Zand ave.Central Building Shiraz University of Medical Sciences,zand ave

**City**  
Shiraz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shiraz University of Medical Science

**Proportion provided by this source**  
100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**  
Shiraz Univrsity Medical sciences

**Full name of responsible person**  
Nooshin Behshti poor

**Position**  
Instructor of pediatric Department/ nursing graduate

**Other areas of specialty/work**

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Shiraz, Nemazee squire, School of Nursing and Midwifery.

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## **Sharing plan**

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*