

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

Street address
Shiraz, Nemazee squire, School of Nursing and Midwifery.

City

Shiraz

Postal code
13119-71936

Phone
+98 71 3647 4254

Fax

Email
Sdighmontasri@yahoo.com
Fahimesafizade67@gmail.com

Web page address
Nurs-Midwif.sums.ac

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Nooshin Beeshtipoor

Position
Instructot of Pediatrics Department/ nursing graduate

Other areas of specialty/work

Street address
Shiraz, Nemazee squire, School of Nursing and Midwifery

City
Shiraz

Postal code
13119-71936

Phone
+98 71 3647 4254

Fax

Email
Fahimesafizad67@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Nooshin Beheshtipoor

Position
Instructor of pediatric department, nursing graduate

Other areas of specialty/work

Street address
Hazrat Fatemeh School of Nursing and Midwifery, Nemazee squire, Shiraz

City
Shiraz

Postal code

Phone
00

Fax

Email
Fahimsafizad67@gmail.com

Web page address

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