

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of the effects of active and inactive distraction methods on burn pain severity and anxiety in children.

Protocol summary

Study aim

Comparison of the effect of two active (game)and inactive (music) distraction methods on pain intensity of burning dressing in children 3-6 years old

Design

The clinical trial has two intervention groups (computer game and music) and a control group, with parallel group design and non-randomized allocation. Sample size is 120 kids including 40 person in each group.

Settings and conduct

The intervention will be performed in the waiting room and dressing room of Shahid Motahari Burn Hospital. Only the statistician will not be aware of the type of intervention performed in each group and the data will be given to groups A, B, and C.

Participants/Inclusion and exclusion criteria

Inclusion criteria: burn extent equal to 9-35%; lack of hearing and visual impairment; Non-burn in one hand; No have other pain. Non - inclusion criteria: Burn with electrical, chemical and bitumen things; perineal, head and neck burns; insensibility in the burn area.

Intervention groups

First intervention group: The child will play with the tablet 10 minutes before entering the dressing room until the dressing is completed and his or her pain and anxiety will be measured before and during the dressing change. Second intervention group: The child will listen to his/her favorite music from 10 minutes before entering the dressing room until the dressing is completed and his/her pain and anxiety will be measured before and during the dressing change. Control group: The child will receive no routine care intervention. Both pain and anxiety will be measured before and during dressing change.

Main outcome variables

Pain; Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160119026104N8**
Registration date: **2019-10-22, 1398/07/30**
Registration timing: **retrospective**

Last update: **2019-10-22, 1398/07/30**

Update count: **0**

Registration date

2019-10-22, 1398/07/30

Registrant information

Name

Mahnaz Shoghi

Name of organization / entity

Iran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4687 1192

Email address

shoghi.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-21, 1397/09/30

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of active and inactive distraction methods on burn pain severity and anxiety in

children.

Public title

Effect of distraction methods on burn pain in children

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Burnout size 9-35% do not have other acute or chronic diseases without burning do not have hearing and visual impairment Lack of cognitive impairment Non-burn in one hand to play with game Do not have pain without pain of burning Lack of burn experience in the past

Exclusion criteria:

Burns with electricity, chemicals and bitumen Perineal and head and neck burns Anesthesia is the location of the burn because of its wide depth

Age

From **3 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Analysis will be done without the knowing intervention types in the groups .the Groups will be marked with with A, B,C

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

School of Nursing and Midwifery.,Shahid Yasemi Street., North Kordestan highway., Tehran., Iran

City

Tehran

Province

Tehran

Postal code

۱۹۹۶۷۱۳۸۸۳

Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

IR.IUMS.REC.1397.715

Health conditions studied

1

Description of health condition studied

Pain, Anxiety

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

Pain

Timepoint

Before intervention- During intervention

Method of measurement

visual analog scale

2

Description

Anxiety

Timepoint

Before intervention- During intervention

Method of measurement

Observational Scale of Behavioral Distress

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: listening to favorite music from 10 minutes before entering the dressing room until end of dressing change .

Category

Behavior

2

Description

Second intervention group: playing with tablet games from the 10 minutes before entering the dressing room until the end of dressing change.

Category

Behavior

3

Description

Control group: not receiving any intervention. Only routine care will perform during dressing change .

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari Burn Rescue Hospital

Full name of responsible person

Roghaye Samimi

Street address

Faculty of Nursing and midwifery , Shahid Yasemi Street, Koderstan highway, Tehran, IRAN

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Phone

+98 21 8877 0031

Fax

+98 21 8877 0048

Email

hospital.motahari@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seid Kazam Malakuti

Street address

School of Nursing and Midwifery, Shahid Yasemi Street., North Kordestan Highway., Tehran., IRAN

City

Tehran

Province

Tehran

Postal code

1996713883

Phone

+98 21 4365 1000

Email

PR@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mahnaz Shoghi

Position

Associated professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Shahid yasemi Street, Kordestan highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1996713883

Phone

+98 21 4365 1000

Email

shoghi.m@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mahnaz Shoghi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nursing and Midwifery School, Shahid Yasemi Street., North Kordestan Highway., Tehran., Iran

City

Tehran

Province

Tehran

Postal code

1996713883

Phone

+98 21 4365 1000

Email

shoghi.m@iums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Mahnaz Shoghi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nursing and Midwifery School, Shahid Yasemi Street,
Kordestan Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1996713883

Phone

+98 21 4365 1000

Email

shoghi.m@iums.ac.ir

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

Not applicable

Title and more details about the data/document

In order to keep the participants anonymous, the data will be provided by code to the requestor

When the data will become available and for how long

The end of sampling until six months after article publishing.

To whom data/document is available

Ethical, Reviewer and Editorial committees, Researchers.

Under which criteria data/document could be used

Systematic review and meta-analysis or secondary analysis citation .

From where data/document is obtainable

Mahnaz Shoghi, Email: shoghi.m@iums.ac.ir

What processes are involved for a request to access data/document

After sending a request to academic email, we will send our data files up to one week.

Comments