Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 21 4687 1192

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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, Kodestan highway, Tehran, IRAN
City
Tehran
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Phone
+98 21 8877 0031
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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
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Postal code
1996713883
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PR@ums.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
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Other areas of specialty/work
Nursery
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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