Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Compare the effectiveness of virtual reality games and positively communicate in reducing symptoms of stress and pain during dressing change in children hospitalized with burns

Protocol summary

Summary

In a clinical trial study will be done with aim to compare the effectiveness of virtual reality games and positively communicate in reducing symptoms of stress and pain during dressing change in children hospitalized with burns, children separately and without linking together and in different time periods are treated so the blinding will be done just for patients group. receiving their first burn dressing care procedure in this burn center and absence of underlying disease for example: Disabilities is the main inclusion criteria for this study. If a child required intravenous sedation during the procedure refuse participation, or became otherwise unable to communicate during wound care, the child was withdrawn from the study. The study population will be included all children hospitalized with burns wound in Imam Mousa Kazem Hospital. a total of 40 eligible children aged between 6 and 8 years will be selected and randomly will divided into two groups: control group (Positive Communicate) intervention group (Play group). positively communicate technique will be done in both groups but in case group, virtual reality games will be used too and Children will play during dressing change. children's symptoms of stress and pain Intensity as the Main outcomes will be measured before and after burn dressing change procedure and before and after play intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030532886N1**
Registration date: **2017-04-26, 1396/02/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-04-26, 1396/02/06

Registrant information

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2017-02-14, 1395/11/26

Expected recruitment end date

2017-10-18, 1396/07/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effectiveness of virtual reality games and positively communicate in reducing symptoms of stress and pain during dressing change in children hospitalized with burns

Public title

The Effect of Virtual Reality Game’s on Children’s Stress Symptom and Pain Intensity during Burn Wound Care

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: aged 7 to 12 years for children, receiving their first burn dressing care procedure in this burn center (the usual way), no burn with high percentages (severe burns) so that the child does not have to participate in the study (at the discretion of the physician), a lack of underlying disease, for example: Disabilities or Mental disorder, written parental consent to participate in research, older than 18 years for parents and being able to read and understand Persian. Exclusion criteria: a lack of Parental consent during each stage of intervention, If a child required intravenous sedation during the procedure, refuse participation, or became otherwise unable to communicate during wound care, the child was withdrawn from the study.

Age
From **7 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In this study Simple randomization was performed by shuffling cards.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan University of Medical Sciences Ethics Committee

Street address
Isfahan University of Medical Sciences, HezarJerib Ave, Azadi Sq, Isfahan

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8174673461

Approval date
2017-02-14, 1395/11/26

Ethics committee reference number
IR.MUI.REC.1395.3.954

Health conditions studied

1

Description of health condition studied
Burn

ICD-10 code
T29, T31

ICD-10 code description
Burns and corrosions of multiple body regions, Burns classified according to extent of body surface involved

Primary outcomes

1

Description
Stress Symptom

Timepoint
Before Burn Wound Care

Method of measurement
Iranian version of Sharrer, Ryan-Wenger Children’s Stress Symptom Scale

2

Description
Pain Intensity

Timepoint
After Burn Wound Care

Method of measurement
Wong & Backer Scale

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: In the intervention group, in addition to using positive communication techniques when burn dressing change, children will pay to play 30 to 45 minutes before the start of the dressing change with 3D headset Game

Category
Behavior

2

Description
control group: In the control group will be used positive communication techniques during burn dressing change

Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Mousa Kazem Hospital
Full name of responsible person
Ali Noruzi Koushali
Street address
Imam Mousa Kazem Hospital
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan Univresity of Medical Sciences, Vice chancellor for research
Full name of responsible person
Reza Daryabeigi
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Isfahan University of Medical Sciences, HezarJerib Ave, Azadi Sq, Isfahan
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Grant name
Grant code / Reference number
11/5263/د
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan Univresity of Medical Sciences, Vice chancellor for research
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

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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