

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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during the procedure refuse participation, or became otherwise unable to communicate during wound care, the child was withdrawn from the study.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

Name

Ali Noruzi Koushali

Name of organization / entity

Isfahan University of Medical Sciences

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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

City

Isfahan

Postal code

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

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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
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Isfahan

Grant name

Grant code / Reference number

11/5263/3

**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

Contact

Name of organization / entity

Isfahan University of Medical Sciences

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Ali Noruzi Koushali

Position

Masters

Other areas of specialty/work

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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