Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Effect of Vision and Auditory Distractions on Physiologic Indicators and Pain of Dressing change in 6-12 Years Old Children at the Burn Center of Besat Hospital, 1397-98.

Protocol summary

Study aim

Comparison of the Effect of Vision and Auditory Distractions on Physiologic Indicators and Pain of Dressing change in 6-12 Years Old Children at the Burn Center of Besat Hospital.

Design

A total of 120 hospitalized children in the burning ward with available sampling will be selected from patients' files and then by randomized block assignment placed in a 3 groups clinical trial control, auditory distraction and visual distraction.

Settings and conduct

When changing dressing on the basis of self-reported pain scale, pain is noted for each patient by the researcher. 20 minutes before and 10 minutes after dressing, the physiological indexes of the units of study, including heart rate and arterial oxygen saturation, will be measured in each of the three control groups, visual distortion and auditory deviation, and recorded in special sheets. At the moment of changing the dressing, and then at intervals every two minutes until the end of the dressing, the physiological indicators are measured and recorded in special sheets, then the mean will be obtained and reported.

Participants/Inclusion and exclusion criteria

Lack of speech impairment and mental retardation, No burns in the eyes and ears, The level of burn is 35-9% and grade 2 in the body based on the doctor's diagnosis

Intervention groups

play animation In the first intervention group, the audio tracks of the Ministry of Culture and Guidance for children, in the second intervention group, non-intervention in control group

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170117032025N4**
Registration date: **2019-01-27, 1397/11/07**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-27, 1397/11/07**
Update count: **0**

Registration date

2019-01-27, 1397/11/07

Registrant information

Name

Arash Khalili

Name of organization / entity

Hamadan University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0320

Email address

a.khalili@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2019-04-04, 1398/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the Effect of Vision and Auditory Distractions on Physiologic Indicators and Pain of Dressing change in 6-12 Years Old Children at the Burn Center of Besat Hospital, 1397-98.

Public title
the Effect of Vision and Auditory Distractions on Physiologic Indicators and Pain of Dressing change in 6-12 Years

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
The level of burn is 35-9% and grade 2 in the body based on the doctor's diagnosis Age 6-12 Years Old
Exclusion criteria:
burns in the eyes and ears speech impairment and mental retardation

Age
From **6 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Available sampling from patients' files and then randomized block assignment in a 3 groups clinical trial control, auditory distraction and visual distraction.

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
Ethics committee ofhamadan University of Medical Sciences
Street address
Shahid Fahmideh Street
City
Hamadan
Province
Hamadan
Postal code
6561058582

Approval date
2018-11-17, 1397/08/26

Ethics committee reference number
IR.UMSHA.REC.1397.565

Health conditions studied

1

Description of health condition studied
burn

ICD-10 code
T31

ICD-10 code description
Burns classified according to extent of body surface involved

Primary outcomes

1

Description
pain

Timepoint
during change dressing

Method of measurement
oucher

2

Description
Physiologic Indicators

Timepoint
during dressing change

Method of measurement
check list

Secondary outcomes

empty

Intervention groups

1

Description
first Intervention group: Vision Distraction during dressing change with animation play

Category
Treatment - Other

2

Description
Intervention group: Auditory Distractions with music play during dressing change

Category
Treatment - Other

3

Description
Control group: Non intervention
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital, Burnig Ward
Full name of responsible person
Pegah Sharifiyan
Street address
Hamadan Besta Hospital
City
Hamadan
Province
Hamadan
Postal code
6561065810
Phone
+98 81 3252 0683
Email
rsharifian7@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr Saeed Bashiriyan
Street address
Shahid Fahmideh Street
City
Hamadan
Province
Hamadan
Postal code
6561065810
Phone
+98 81 3252 0683
Email
s.bashirian@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Arash Khalili
Position
Faculty Member
Latest degree
Master
Other areas of specialty/work
Pediatric Nursing
Street address
Shahid Fahmideh Bulvard
City
Hamadan
Province
Hamadan
Postal code
6517625432
Phone
+98 81 3838 0535
Email
arash5920@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr Fatemeh Cheraghi
Position
Faculty Member
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Shahid Fahmideh Street
City
Hamadan
Province
Hamadan
Postal code
6561065810
Phone
+98 81 3252 0355
Email
f.cheraghi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Arash Khalili

Position
Faculty Member

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Shahid Fahmideh Street

City
Hamadan

Province
Hamadan

Postal code
6561065810

Phone
+98 81 3252 0355

Email
arash5920@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available