Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigation of Audio-Visual Distraction Influence on Reduction of Catheterization Pain among School-Aged Children

Protocol summary

Study aim

This study was designed and conducted with the aim of assessing the impact of audiovisual distraction on reducing pain induced by catheterization in school-aged children.

Design

This research was conducted as a randomized controlled clinical trial experimental study (with control group).

Settings and conduct

This study was conducted on school-age children attending a hospital for admission. The tools employed in the research were divided into two parts. The first consisted of a questionnaire related to demographic information including gender, age, ethnicity, birth rating and the duration of catheterization; the second part was an Oucher face pain intensity scale. To check the reliability of the tool, an inter-rater coefficient (Kappa 0.8) was employed; for checking the validity of the intervention, a Tom and Jerry-labelled CD product type (comedy) and a target audience (children and adolescents) were employed. The animated CD was played through three-dimensional glasses and once finished, the children were asked about the amount of pain they had experienced; catheterization duration was also recorded. All of the above steps, except for playing the animation CD, were also performed for the control group.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Iranian children of school age, lack of vision problems (astigmatism, lens and glasses), lack of previous hospitalization and Catheterization. Exclusion Criteria: Children who were agitated, toxic, unconscious, suffering from diabetes and peripheral nerve disorder conditions, or who had another special status (mental retardation) were excluded from the study.

Intervention groups

In order to control pain, audiovisual distortion was utilized using three-dimensional glasses with auditory and visual disturbances. No intervention was performed in the control group.

Main outcome variables

Control and reduce the intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100802004490N4**
Registration date: **2018-12-01, 1397/09/10**
Registration timing: **retrospective**

Last update: **2018-12-01, 1397/09/10**
Update count: **0**

Registration date

2018-12-01, 1397/09/10

Registrant information

Name

Mohadese Babaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8865 5366

Email address

hadisbabaie@yahoo.com

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

2015-03-21, 1394/01/01

Actual recruitment end date
2015-06-22, 1394/04/01
Trial completion date
2015-07-23, 1394/05/01

Scientific title
Investigation of Audio-Visual Distraction Influence on Reduction of Catheterization Pain among School-Aged Children

Public title
Effect of audio-visual distraction on Pain
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Iranian children aged between six and 14 years old Not having a history of hospitalization and catheterization not receiving painkillers prior to catheterization
Exclusion criteria:
agitated, toxic and unconscious children vision problems (astigmatism, lens and glasses) Children suffering from diabetes and peripheral nerve disorder conditions children with another special status (mental retardation)
Age
From **6 years** old to **14 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Actual sample size reached: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
A list of children with inclusion criteria was prepared and randomly selected and assigned to intervention and control groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Tehran, Velenjak street
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2015-04-21, 1394/02/01
Ethics committee reference number
SBMU2.TEC.1394.2

Health conditions studied

1

Description of health condition studied
pain management
ICD-10 code
Z51.9
ICD-10 code description
Medical care, unspecified

Primary outcomes

1

Description
The effect of audio-visual distraction on the reduction of pain intensity in children
Timepoint
10 minutes after intervention
Method of measurement
Oucher face pain intensity scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Audiovisual distraction using 3-D glass equipped by audio-video player to display cartoon for children in Intervention group
Category
Other

2

Description
Control group: no intervention was made.
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Qods hospital

Full name of responsible person
Mohadese Babaie

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Valiasr Avenue, Niayesh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Ziai

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Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mohadese Babaie

Position
Ph.D candidate

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Only part of the data on pain control information can be shared.
When the data will become available and for how long
Available 6 months after printing results.
To whom data/document is available
Data will be available to researchers working in academic and academic institutions.
Under which criteria data/document could be used
Only as a source for comparing the progress of the study are allowed.
From where data/document is obtainable
Mohadese Babaie hadisbabaie88@yahoo.com
What processes are involved for a request to access data/document
After checking the email
Comments