

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 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

Street address

Valiasr Avenue, Niayesh

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Email

hadisbabaie88@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Ziai

Street address

Shahid Beheshti University of Medical Sciences,
Velenjak street, Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Email

Hadisbabaie88@yahoo.com

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

Street address

Tehran, Velenjak street, Shahid Beheshti University of
Medical Sciences

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

00

Fax**Email**

hadisbabaie88@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Azam Shirinabadi Farahani

Position

PhD, Lecturer

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nursing & Midwifery School, Shahid Beheshti
University of Medical Sciences, Niayesh street, Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Fax**Email**

farahani1381@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohadese Babaie

Position

PhD Candidate

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Valiasr Avenue, Niayesh, Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Fax**Email**

hadisbabaie88@yahoo.com

Web page address**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