

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effect of virtual reality on pain and anxiety of circumcision in children over 5 years of age

Protocol summary

Study aim

The effect of virtual reality on circumcision pain and anxiety in children over 5 years

Design

. In this clinical trial, 40 children referred for circumcision were randomly divided into experimental and control groups. The pain and anxiety questionnaires for both groups were completed by trained researcher in three times 30 minutes before surgery, at the beginning of operation and at the end of circumcision. In the intervention group, the circumcision educational film, which included circumcision and post-circumcision care, was broadcast preoperatively. During the circumcision, a cartoon animation was broadcast from the beginning to the end of the circumcision to distract the children in the intervention group. The control group did not take any action. The intervention group consisted of 40 children referred for circumcision in the two experimental and control groups. The experimental group received virtual reality images while the control group received only routine care.

Settings and conduct

The study site was the urology clinic of Gonabad University Jihad. The intervention group received a training film and a cartoon animation. The control group did not take any action.

Participants/Inclusion and exclusion criteria

Inclusion criteria were children over 5 years old who referred to the Jihad Clinic of Urology for circumcision surgery.

Intervention groups

The intervention group consisted of 40 children referred for circumcision in two groups of 20 interventions and 20 controls. The intervention group received virtual reality images while the control group received only routine care.

Main outcome variables

pain and anxiety in children

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190419043323N1**

Registration date: **2020-01-11, 1398/10/21**

Registration timing: **retrospective**

Last update: **2020-01-11, 1398/10/21**

Update count: **0**

Registration date

2020-01-11, 1398/10/21

Registrant information

Name

Reza Hassannia

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 5729 2111

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r.hassannia@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-06, 1397/12/15

Expected recruitment end date

2019-04-09, 1398/01/20

Actual recruitment start date

2019-03-06, 1397/12/15

Actual recruitment end date

2019-04-09, 1398/01/20

Trial completion date

2019-04-09, 1398/01/20

Scientific title

Effect of virtual reality on pain and anxiety of circumcision in children over 5 years of age	
Public title	Effect of virtual reality on pain and anxiety
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Children Referred to the Urology Clinic of Gonabad University Jihad for Circumcision Surgery Complete the informed consent form to participate in the research Age over 5 years Not having a history of personality anxiety (interviewing parents) No history of surgery (interview with parents) Has no history of hearing or visual impairments (interview with parents) Lack of hypospadiasis or epipadiasis Lack of clotting problems Exclusion criteria: The child or parent's unwillingness to continue participating in the study for any reason Developing extreme anxiety during the study Abnormal bleeding during surgery
Age	From 5 years old
Gender	Male
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 40 Actual sample size reached: 40
Randomization (investigator's opinion)	Randomized
Randomization description	Purposeful and accessible sampling was used and the samples were randomly with permuted block randomization (Four blocks) divided into two groups of control and intervention. The method of assigning samples to the groups is a randomized block design with four blocks. The letter A for the intervention group and the letter B for the control group are considered. Then write all the permutation combinations of the letters A, A, B, and B, which are six different combinations (AABB for digit 1, ABBA for digit 2 ...), then we select a digit from the digits 1 to 6. For example, if digit 2 is selected, its concept is that the first person in the intervention group is the next two in the control group and the fourth in the intervention group. Continue this until the sample size reaches to the quorum.
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 of Gonabad University of Medical Sciences

Street address

Research & Technology Dept, Gonabad University of Medical Sciences, Asian Roads, Gonabad, Khorasan Razavi

City

gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2019-02-10, 1397/11/21

Ethics committee reference number

IR.GMU.REC.1397.114

Health conditions studied

1

Description of health condition studied

Circumcision surgery

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

pain

Timepoint

30 minutes before circumcision, The moment the circumcision begins, End of circumcision

Method of measurement

OUCHER pain questionnaire

2

Description

anxiety

Timepoint

30 minutes before circumcision, The moment the circumcision begins, End of circumcision

Method of measurement

observational scale of behavioral distress – revised

Secondary outcomes

1

Description

pain

Timepoint

30 minutes before circumcision, The moment the circumcision begins, End of circumcision

Method of measurement

Oucher Pain Questionnaire

2

Description

anxiety

Timepoint

30 minutes before circumcision, The moment the circumcision begins, End of circumcision

Method of measurement

observational scale of behavioral distress - revised

Intervention groups

1

Description

Intervention group: Virtual reality technology. In the intervention group, using a virtual reality headset (Remax-RT-V03 audio-visual glasses with internal memory) the circumcision educational film, which included circumcision and post-circumcision care for 4 minutes 35 seconds, was broadcast preoperatively. During the circumcision, a similar cartoon animation was broadcast from the beginning to the end of the circumcision for approximately 20 minutes to distract the children in the intervention group.

Category

Treatment - Devices

2

Description

Control group: Routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Urology Clinic of Gonabad University Jahad

Full name of responsible person

moosa sajjadi

Street address

Research & Technology Dept, Gonabad University of Medical Sciences, Asian Roads

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sajjadi1975@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Seyed Ali Sajjadi

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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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

moosa sajjadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

Moosa sajjadi

Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

Potential data can be shared only after identification

When the data will become available and for how long

Get started one month after the results are published.

To whom data/document is available

Researchers working in academia and academic

Under which criteria data/document could be used

The data are sent by official request through academic or organizational emails of the researchers after confirmation and identification of the sender.

From where data/document is obtainable

Dr. Moosa Sajjadi

What processes are involved for a request to access data/document

The data are sent by official request through academic or organizational emails of the researchers after confirmation and identification of the sender.

Comments