Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Jahad. 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 Jahad 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)

Phone

+98 51 5729 2111

Email address

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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sa_1344@hotmail.com
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 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