

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Comparison of the effect of using virtual reality and Standard Care on pain intensity, anxiety and satisfaction of emergency patients during suturing

Protocol summary

Study aim

Determining the effect of using virtual reality and standard care on pain intensity, anxiety and satisfaction of emergency patients during suturing

Design

In this study, 90 people will be randomly divided into two groups, including the group that uses virtual reality and the group receiving standard care

Settings and conduct

90 patients referred to the emergency department of Imam-Reza Hospital in Birjand who are eligible to enter the study will be selected and randomly divided into two groups. For the intervention group, in addition to standard care, relaxing images and music will be played by the virtual reality headset from one minute before the suturing procedure to 10 seconds after the end of the procedure, and the control group will receive only the standard care provided by the hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patient satisfaction; age 18 to 60 years old; a wound need to be sutured according to the doctor prescription; the wound is on the trunk or limbs; no fractures or other accompanying injuries; the wound or tear should only include the skin layer; no injury to fascia, muscle and underlying tissues at the site of rupture; the size of the injury should be about 5 to 10 cm, The patient has visual health; the patient has hearing health; the patient should not be addicted to drugs; patients do not suffer from dementia or Alzheimer's; patients do not get motion sickness and stroke; patients do not have seizures and epilepsy; having the ability to speak and communicate. Exclusion criteria: reluctance to cooperate or participate in the study; the site of the wound or laceration is on the head, face or neck; phobias of the forest and other images used in virtual reality.

Intervention groups

Two groups: Virtual reality use group; standard care recipient group.

Main outcome variables

Pain intensity and anxiety; satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200807048331N2**

Registration date: **2020-12-30, 1399/10/10**

Registration timing: **prospective**

Last update: **2020-12-30, 1399/10/10**

Update count: **0**

Registration date

2020-12-30, 1399/10/10

Registrant information

Name

Ali Sheikhalishahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 35 3722 0539

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-04, 1399/10/15

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of using virtual reality and Standard Care on pain intensity, anxiety and satisfaction of emergency patients during suturing

Public title
The Effect of Virtual Reality on Pain, Anxiety and Satisfaction

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patient satisfaction Age 18 to 60 years old A wound or laceration needs to be sutured according to the doctor's prescription. The wound is on the trunk or limbs No fractures or other accompanying injuries The wound or tear should only include the skin layer. No injury to fascia, muscle and underlying tissues at the site of rupture (according to the doctor) The size of the injury should be about 5 to 10 cm. The patient has visual health. The patient has hearing health. The patient should not be addicted to drugs. Patients do not suffer from dementia or Alzheimer's Patients do not get motion sickness and stroke Patients do not have seizures and epilepsy Having the ability to speak and communicate
Exclusion criteria:
Reluctance to cooperate or participate in the study The site of the wound or laceration is on the head, face or neck Phobias of the forest and other images used in virtual reality

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the simple random allocation method, a coin is tossed so that the head side is equivalent to the intervention group and the tail side is equivalent to the control group. This launch is for the first person and the type of group will be determined for it. Then for other people, it continues as one among the type of group and based on the sample size, this allocation continues, and thus, the type of group for each person will be determined randomly.

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 Birjand University of Medical Sciences

Street address

Deputy of research and technology, Birjand University of Medical Sciences, Ghafari Street

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2020-12-21, 1399/10/01

Ethics committee reference number

IR.BUMS.REC.1399.396

Health conditions studied

1

Description of health condition studied

Open wound of ankle, foot and toes

ICD-10 code

S91

ICD-10 code description

Open wound of ankle, foot and toes

2

Description of health condition studied

Open wound of knee and lower leg

ICD-10 code

S81

ICD-10 code description

Open wound of knee and lower leg

3

Description of health condition studied

Open wound of hip and thigh

ICD-10 code

S71

ICD-10 code description

Open wound of hip and thigh

4

Description of health condition studied

Open wound of wrist, hand and fingers

ICD-10 code

S61

ICD-10 code description

Open wound of wrist, hand and fingers

5

Description of health condition studied

Open wound of elbow and forearm

ICD-10 code

S51

ICD-10 code description

Open wound of elbow and forearm

6

Description of health condition studied

Open wound of shoulder and upper arm

ICD-10 code

S41

ICD-10 code description

Open wound of shoulder and upper arm

7

Description of health condition studied

Open wound of abdomen, lower back, pelvis

ICD-10 code

S31

ICD-10 code description

Open wound of abdomen, lower back, pelvis and external genitals

8

Description of health condition studied

Open wound of thorax

ICD-10 code

S21

ICD-10 code description

Open wound of thorax

Primary outcomes

1

Description

Pain Intensity

Timepoint

Before the intervention, during the intervention and after the end of the intervention

Method of measurement

Visual Analogue Scale

2

Description

Anxiety

Timepoint

Before the intervention, during the intervention and after the end of the intervention

Method of measurement

Anxiety Linear Scale

3

Description

Satisfaction

Timepoint

After the end of the intervention

Method of measurement

Satisfaction linear scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, in addition to routine care, a virtual reality headset will be used from one minute before the start of the procedure to 10 seconds after the end of the procedure. In this way, the headset will fit the patient on the head, so that the eyes are covered with camera lenses and the ears with audio players. The researcher will explain to the patient how to work with this system before using the virtual reality headset.

Category

Other

2

Description

Control group: The control group will not receive any of the above interventions and will only benefit from the routine and standard care applied in the emergency department of Imam Reza Hospital in Birjand, which includes only local anesthesia with 2% lidocaine. Be.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam-Reza hospital

Full name of responsible person

Mohammadreza Ghasemian

Street address

Imam-Reza hospital, Taleghani Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Ali Sheikhalishahi

Position

M.Sc student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Manizhe Nasirizade

Position

Instructor

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Master

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Ali Sheikhalishahi

Position

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Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not 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

Yes - There is 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

Information on the main outcome will be available

When the data will become available and for how long

Access starts the results are published

To whom data/document is available

Researchers

Under which criteria data/document could be used

.

From where data/document is obtainable

alisheikhalishahi95@gmail.com

m.nassirizadeh@yahoo.com

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

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Comments