

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Exploring the Potential of Virtual Reality in Alleviating Pain, Fear, and Anxiety During Needle Insertion in Pediatric Oncology Patients: Clinical Trial Study

Protocol summary

Study aim

The evaluation of how virtual reality (VR) reduces pain, fear, and anxiety in pediatric oncology patients who undergo needle based medical procedure

Design

This clinical trial consists of two parallel groups, an intervention group and a control group, for which blinding procedures are not necessary, given the absence of pharmacological agents affecting their outcomes. Moreover, the study phase does not bear any significance to this investigation. A sample size of 40 patients, with an equal allocation of 20 subjects per group, was selected through randomization protocols implemented via Minitab version 17

Settings and conduct

To examine the potential impact of VR technology on reducing pain, fear, and anxiety in pediatric oncology patients. The intervention group will receive regular medical treatment along with VR, while the control group will only receive customary care. The researchers will measure pain, fear, and anxiety levels before and after treatment through various methods including patient self reporting, researcher observations, and input from parents. Standardized questionnaires such as the Wong Baker FACE and Face Legs Activity Cry and Consolability scales will be used to assess pain management, while the Child Fear Scale and Children's Anxiety Meter State questionnaires will be utilized to evaluate fear and anxiety

Participants/Inclusion and exclusion criteria

Consent obtained from both minors and their legal guardians, while also verifying their lack of visual, auditory, or speech impairments, in addition to the need for needle based medical interventions

Intervention groups

The intervention group of this investigation is slated to undergo the customary needle administered medical

protocol, complemented by immersive VR material

Main outcome variables

The provision of virtual reality technology to aid in the management of pain during treatment among children with cancer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210710051836N2**

Registration date: **2023-05-04, 1402/02/14**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-04, 1402/02/14**

Update count: **0**

Registration date

2023-05-04, 1402/02/14

Registrant information

Name

Hamed Riyahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3246 0284

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-08, 1402/01/19

Expected recruitment end date

2023-09-25, 1402/07/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Exploring the Potential of Virtual Reality in Alleviating Pain, Fear, and Anxiety During Needle Insertion in Pediatric Oncology Patients: Clinical Trial Study

Public title

Investigating the capability of virtual reality to relieve pain, fear, and anxiety experienced by pediatric oncology patients during needle insertion: A clinical trial

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Obtaining the consent of both children and their parents for participation in the study There are no issues with vision There are no problems with hearing There are no issues with speech The necessity of receiving an injection for medical treatment

Exclusion criteria:

Being below the age of three Being over the age of eighteen The child and their parents' lack of desire to participate in the study Having symptoms such as nausea and dehydration Use of sedatives Psychopathy Unstable state of physical or mental health

Age

From **3 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

By utilizing the Minitab-17 software, we acquired an Excel file that contained random numbers for both the control and intervention groups. We then allocated the participants to their respective groups based on these numbers

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**

Kerman university of Medical Sciences and Health Services Deputy of Research

Street address

Deputy of Research, Jahad Street, Kerman Town

City

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Province

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Postal code

7619696869

Approval date

2023-03-15, 1401/12/24

Ethics committee reference number

IR.KMU.REC.1401.442

Health conditions studied**1****Description of health condition studied**

Pediatric Oncology

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain

Timepoint

From the outset of the investigation

Method of measurement

Wong-Baker FACES (WBS) Pain Rating Scale and The Face, Legs, Activity, Cry and Consolability scale (FLACC)

2**Description**

Fear

Timepoint

From the outset of the investigation

Method of measurement

The Child Fear Scale (CFS)

3**Description**

Anxiety

Timepoint

From the outset of the investigation

Method of measurement

The Children's Anxiety Meter-State (CAM-S)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group receiving intervention will commence the customary treatment that necessitates contact with a needle head, alongside virtual reality material in a distinct room from the rest of the kids.

Category

Rehabilitation

2

Description

Control group: The group receiving intervention will commence the customary treatment that necessitates contact with a needle head, without virtual reality material in a distinct room from the rest of the kids.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Pouria Salajeghe

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2

Recruitment center

Name of recruitment center

Office of an oncology specialist

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Davoud Kalantar Neyestanaki

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Houriyeh Ehtemam

Position

Principle Investigator

Latest degree

Bachelor

Other areas of specialty/work

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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)

Undecided - It is not yet known if there will be 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

Not applicable

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