

# 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

##### Email address

h.ehtemam@kmu.ac.ir

##### 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**

Kerman

**Province**

Kerman

**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

##### Street address

Imam Highway

##### City

Kerman

##### Province

Kerman

##### Postal code

7614525150

##### Phone

+98 34 3132 8358

##### Email

h.ehtemam@gmail.com

### 2

#### Recruitment center

##### Name of recruitment center

Office of an oncology specialist

##### Full name of responsible person

Pouria Salajeghe

##### Street address

Azadegan Blvd

##### City

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##### Province

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##### Postal code

7619696869

#### Phone

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#### Email

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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

##### Street address

Research Deputy, Jahad Blvd

##### City

Kerman

##### Province

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##### Postal code

7619813159

##### Phone

+98 34 3226 3787

##### Email

h.ehtemam@gmail.com

#### 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

Others

##### Street address

Haft Bagh Alavi

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences

**Full name of responsible person**  
Houriyeh Ehtemam  
**Position**  
Principle Investigator  
**Latest degree**  
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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