Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 34 3246 0284

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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
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7614525150
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2

Recruitment center
Name of recruitment center
Office of an oncology specialist
Full name of responsible person
Pouria Salajeghe
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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
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7619813159
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+98 34 3226 3787
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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
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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