Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of virtual reality-based games and cartoon watching on anxiety, fear, and pain in children with acute lymphoblastic leukemia during chemotherapy

Protocol summary

Study aim

Comparison of the effect of playing and watching cartoons through virtual reality on anxiety, fear, and pain in children with acute lymphoblastic leukemia during chemotherapy in pediatric oncology departments of medical centers affiliated with Hamadan University of Medical Sciences

Design

A clinical trial with two intervention groups and one control group, Without blinding, randomized, on 93 children. Randomization is performed using a block design.

Settings and conduct

The study is being conducted at the Oncology Center of Ekbatan Hospital affiliated with Hamadan University of Medical Sciences. Playing virtual reality games and watching cartoons with virtual reality glasses is performed from 10 minutes before the start of chemotherapy until the end of it (approximately 1 hour). In the control group, playing games and watching cartoons with virtual reality is not performed. Pain intensity, fear, and anxiety will be recorded.

Participants/Inclusion and exclusion criteria

Acute lymphoblastic leukemia, first course of chemotherapy, no gastrointestinal diseases, no speech, vision, or hearing impairments, and no intellectual disability, under treatment with vincristine. Exclusion criteria: unwillingness to continue participation in the study.

Intervention groups

Virtual Reality Gaming Group: A 3D game appropriate to the child's gender and interests is selected, starting 10 minutes before chemotherapy and continuing throughout it (approximately one hour).Virtual Reality Cartoon Viewing Group: A 3D cartoon appropriate to the child's gender and interests is selected, starting 10 minutes before chemotherapy and continuing throughout it (approximately one hour).Control Group: Receives no virtual reality intervention, and the intensity of pain, fear, and anxiety is recorded 10 minutes before, during, and immediately after chemotherapy.

Main outcome variables

The intensity of pain, fear, and anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190703044082N13**
Registration date: **2025-10-10, 1404/07/18**
Registration timing: **registered_while_recruiting**

Last update: **2025-10-10, 1404/07/18**
Update count: **0**

Registration date

2025-10-10, 1404/07/18

Registrant information

Name

Fateme Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-23, 1404/07/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of virtual reality-based games and cartoon watching on anxiety, fear, and pain in children with acute lymphoblastic leukemia during chemotherapy

Public title

Comparison of the effect of virtual reality-based games and cartoon watching on anxiety, fear, and pain in children with acute lymphoblastic leukemia during chemotherapy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Acute lymphoblastic leukemia Age 6 to 12 years First course of chemotherapy No speech, vision, or hearing disorders, or mental retardation No neurological deficits affecting pain perception based on medical records In stage one (Induction Phase) or stage two (Consolidation Phase) of cancer Under treatment with L-asparaginase Willingness to participate in the study Non-dominant arm line is fixed.

Exclusion criteria:

Reluctance to continue the study process Development of poisoning from chemotherapy drugs Occurrence of emergency situations such as cardiopulmonary resuscitation or seizure, etc Not playing games or watching with virtual reality glasses for more than 10 minutes

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

For random allocation into three groups (playing with virtual reality, watching cartoons with virtual reality, and control), a block randomization method with blocks of 6 will be used. This method involves creating 20 blocks of 6 units each (60 combinations), with each block including two participants for each group. The three letters A (playing with virtual reality), B (watching cartoons with virtual reality), and C (control) are written on pieces of paper and placed in an envelope. The random order of drawing the letters determines the groups, for example, A for playing with virtual reality, B for watching cartoons with virtual reality, and C for control. Then, 20 blocks of six-letter combinations such as AABBCC and ABCABC are written on paper and placed in an envelope. The blocks are selected randomly with replacement. Children are assigned to groups based on the order of the selected blocks.

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

Research ethics committee of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical sciences, Khajeh Rashid Blvd

City

Hamadan

Province

Hamadan

Postal code

6817838698

Approval date

2025-09-22, 1404/06/31

Ethics committee reference number

IR.UMSHA.REC.1404.492

Health conditions studied

1

Description of health condition studied

cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain intensity

Timepoint

Before starting chemotherapy, during chemotherapy, and after completing chemotherapy

Method of measurement

Oucher Pain Scale

2

Description
Fear
Timepoint
Before starting chemotherapy, during chemotherapy, and after completing chemotherapy
Method of measurement
Children's Fear Scale

3

Description
Anxiety
Timepoint
Before starting chemotherapy, during chemotherapy, and after completing chemotherapy
Method of measurement
Visual-Facial-Anxiety-Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In group A (virtual reality game): First, a 3D game suitable for the child's gender and interests is selected. Then, the game is started using virtual reality glasses 10 minutes before the start of chemotherapy and continues throughout the chemotherapy session (approximately one hour). Pain intensity, fear, and anxiety will be assessed 10 minutes before chemotherapy, during chemotherapy, and immediately after chemotherapy.
Category
Treatment - Other

2

Description
Intervention group: Intervention group: In group B (watching cartoons with virtual reality): First, a 3D cartoon suitable for the child's gender and interests is selected. Then, watching the cartoon using virtual reality glasses begins 10 minutes before the start of chemotherapy and continues throughout the chemotherapy session (approximately one hour). The intensity of pain, fear, and anxiety will be assessed 10 minutes before chemotherapy, during, and immediately after chemotherapy.
Category
Treatment - Other

3

Description
Control group: In group C (control): No virtual reality-based intervention is received. However, children can use routine activities such as playing or watching movies with their parents' mobile phones, but these activities will be without virtual reality technology. The intensity of pain, fear, and anxiety will be assessed 10 minutes before chemotherapy, during, and immediately after chemotherapy.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ekbatan Hospital affiliated to Hamadan University of Medical Sciences
Full name of responsible person
Fateme Mohammadi
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Hamadan University of Medical sciences, Khajeh Rashid Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Alireza Soltanian
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Hamadan 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
Hamedan University of Medical Sciences

Full name of responsible person
Fateme Mohammadi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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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
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