

# 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)

##### Phone

+98 81 4567 8904

##### Email address

f-mohammadi@umsha.ac.ir

##### 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 AABBC 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

##### **Street address**

Hamadan University of Medical sciences, Khajeh Rashid Blvd

##### **City**

Hamadan

##### **Province**

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##### **Postal code**

6517838698

##### **Phone**

+98 81 3334 5634

##### **Email**

F-mohammadi@umsha.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Hamedan University of Medical Sciences

##### **Full name of responsible person**

Alireza Soltanian

##### **Street address**

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##### **Email**

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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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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Fateme Mohammadi

**Position**

Assistant Professor

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Ph.D.

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data**

**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**

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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