

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Survey the effect of a designed computer game on the quality of life of children undergoing chemotherapy

#### Protocol summary

##### Summary

This study will be done with aim to survey the effect of a designed computer game on the quality of life of children undergoing chemotherapy in Imam Reza hospital of Isfahan in 2015. This is non-blinded clinical trial. The study population will be included all children with cancer undergoing chemotherapy that refer to Seyed Al Shohada hospitals in Isfahan and a total of 64 eligible patients will be selected and randomly will divided into two experimental and control groups. Before intervention the quality of life questionnaire will be provided for children with cancer or their parents in both groups. Then the computer game will be trained and computer game will be provided for the children. They will be asked to do the game with focus and precision for at least 3 hours a week for four consecutive weeks. To ensure the authenticity of doing the game, researchers will call parents by available phone number and they will be asked about the time and duration of a child's play. The control group will not receive special intervention and routine process will be carried out. Then, immediately and one month after the last week of doing the game, the quality of life questionnaire will be provided for both groups again and the two groups will be compared. Inclusion criteria: Age between 8 to 12 years; Undergoing chemotherapy for at least 4 months; The ability to perform computer game Exclusion criteria: A stressful event such as parental divorce, parental death; Change Location

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016102414333N60**

Registration date: **2016-11-20, 1395/08/30**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-11-20, 1395/08/30

##### Registrant information

###### Name

Feizollah Foroughi

###### Name of organization / entity

kermanshah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 1821 4653

###### Email address

fforoughi@kums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Esfahan University of Medical Sciences

##### Expected recruitment start date

2016-11-05, 1395/08/15

##### Expected recruitment end date

2017-03-05, 1395/12/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Survey the effect of a designed computer game on the quality of life of children undergoing chemotherapy

##### Public title

Effect of a designed computer game on quality of life of children undergoing chemotherapy

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Age between 8 to 12 years; Catching a type of cancer; Undergoing chemotherapy for at least 4 months; The ability to perform computer game; Ability to understand and read Persian dialects; No major physical or psychological problem. Exclusion criteria: A stressful event such as parental divorce, parental death, brother or sister death; Change Location during study that affected quality of life, self-esteem and the creation of stress

### **Age**

From **8 years** old to **12 years** old

### **Gender**

Both

### **Phase**

2

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **64**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **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**

Committee Ethics, Esfahan University of Medical Sciences

##### **Street address**

Vice Chancellor for Research Affairs, Esfahan University of Medical Sciences, hezarjarib street

##### **City**

Esfahan

##### **Postal code**

##### **Approval date**

2014-11-17, 1393/08/26

##### **Ethics committee reference number**

lr.mui.rec.1393.3.511

## **Health conditions studied**

### 1

#### **Description of health condition studied**

leukaemia

### **ICD-10 code**

C91

### **ICD-10 code description**

Lymphoid leukaemia

## **Primary outcomes**

### 1

#### **Description**

Quality of life

#### **Timepoint**

The beginning of the study, after study and one month after the end of the study

#### **Method of measurement**

According to Children with Cancer Quality of Life Questionnaire (PedsQL Cancer module version 3.0)

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

The control group will not receive special intervention

#### **Category**

Other

### 2

#### **Description**

The intervention group will do the computer game with focus and precision at least 3 hours a week for four consecutive weeks.

#### **Category**

Behavior

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Syedoshohada Hospital

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

Syedeh Zahra Fazelnia

##### **Street address**

##### **City**

Esfahan

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Vice chancellor for research, Esfahan University of Medical Sciences

**Full name of responsible person**

Dr. Mahdi Nematbakhsh

**Street address**Vice Chancellor for Research Affairs, Esfahan  
University of Medical Sciences, hezarjarib street**City**

Esfahan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**Vice chancellor for research, Esfahan University of  
Medical Sciences**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Sedigheh Talakoub

**Position**

Master of Pediatric and Neonatal Nursing

**Other areas of specialty/work****Street address**School of Nursing & Midwifery, Esfahan University of  
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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Seyedeh Zahra Fazelnia

**Position**

Master of nursing children

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*