

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### The effect of motor games on the development motor skills and depression in hospitalized children

#### Protocol summary

##### Study aim

The effect of play on depression and motor development of sick children

##### Design

The clinical trial has two intervention and control groups. Based on the scope of the research, 30 children aged 3 to 6 years, girls and boys with leukemia, lymphoma, sarcoma, etc. admitted to the oncology ward were purposefully selected and randomly divided into two Intervention and control groups are included. The research design is quasi-experimental with pre-test and post-test.

##### Settings and conduct

children who have a case of hospitalization in Afzalipour Hospital, Kerman and have the conditions to enter the study will be selected and randomly divided into experimental and control groups. Both groups will take pre-tests, including the Broninex Ozertsky test and the CDS Depression. Then intervention group will be affected by the motor games for 8 weeks (2 or 3 sessions a week, 60 minutes). At the end of the intervention sessions, post-test (Ozertsky test and CDS Depression Scale) will be taken from both groups

##### Participants/Inclusion and exclusion criteria

Entry requirements: Based on medical records normal IQ, The duration of hospitalization is more than a few weeks. Age range is 3 to 6 years No entry conditions: They will not be able to attend play therapy sessions, Have a medical ban on sports and games, parental dissatisfaction

##### Intervention groups

Intervention group: pre-test will be taken. After the pre-test, the group will be affected by the motor games for 8 weeks (2 sessions per week, 60 minutes). At the end of the intervention sessions, a post-test will be taken. Control group: pre-test will be taken. After the pre-test, no intervention is performed, and after 8 weeks, the post-test, will be taken.

##### Main outcome variables

Communication with the child; Trust in the child Accept instructions in the child; Fear in the child; Child motor development

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210318050739N1**

Registration date: **2021-04-23, 1400/02/03**

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

Last update: **2021-04-23, 1400/02/03**

Update count: **0**

##### Registration date

2021-04-23, 1400/02/03

##### Registrant information

##### Name

Hamide Moeini nejad

##### Name of organization / entity

The university of Semnan

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3332 5631

##### Email address

h-moeine@semnan.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-21, 1400/02/01

##### Expected recruitment end date

2021-07-23, 1400/05/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of motor games on the development motor skills and depression in hospitalized children

**Public title**

The effect of motor games on the development of fundamental motor skills and depression

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Evidence of cancer Age range 3-6 year Based on a medical record with normal IQ Same level of motor skills Homogeneous in terms of height and weight

**Exclusion criteria:**

Children who have been hospitalized for less than a week They are not allowed to participate in play therapy sessions They have a medical ban on sports and games

**Age**

From **3 years** old to **6 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **200**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Sample purposefully selected, And as a simple random selection, Due to the homogeneity of the samples, the lottery method is used. People's names are written on paper and put inside the box. Than the papers are taken out one by one, Until the desired sample, which is about 30 people, is completed.

**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**

Ethics committee of Semnan University of Medical

Sciences

**Street address**

Semnan University of Medical Sciences, Basij Blvd

**City**

Semnan

**Province**

Semnan

**Postal code**

3514799442

**Approval date**

2021-03-17, 1399/12/27

**Ethics committee reference number**

IR.SEMUMS.REC.1399.347

**Health conditions studied****1****Description of health condition studied**

Children with various types of cancer(Leukemia, Lymphoma, Sarcoma, etc

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

The score a person gets on the Bruininks- Oseretsky test

**Timepoint**

Perform pre-test Bruininks- Oseretsky) Before starting the intervention and post-test depending on the length of hospitalization of children About three months after the pre-test

**Method of measurement**

Test Bruininks-Oseretsky , purposeful motor games from the game book for the all round development of the child Brian Barrett

**2****Description**

Depression score in the Depression Assesment Questionnaire Cds (Fisher Child Depression Scale)

**Timepoint**

Perform pre-test(Fisher and Lang) Before starting the intervention and post-test depending on the length of hospitalization of children About three months after the pre-test

**Method of measurement**

Fisher and Lang Children's Depression Test; purposeful motor games from the game book for the all round development of the child Brian Barrett

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group: After pre-testing (Bruininks Oseretsky & Child Depression scale) the intervention group for 8 weeks, two or three sessions a week, 60 minutes are affected by the intervention (motor games) from the book, Games for the whole child, Brian Barrett. After the intervention (motor games) so the test will be taken (Bruininks Oseretsky & Child Depression scale, Fisher and Lang)

### Category

Rehabilitation

## 2

### Description

Control group: pre-testing (Bruininks-Oseretsky & Child Depression Scale) is taken. The control group does not undergo any intervention and at the end of the post-test will be taken (Bruininks-Oseretsky & Child Depression Scale)

### Category

Rehabilitation

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Afzalipour Hospital

#### Full name of responsible person

Mohammed Hussain Mehr Al Hasane

#### Street address

Near Bahonar University, Imam Khomeini Hwy

#### City

Kerman

#### Province

Kerman

#### Postal code

7616913911

#### Phone

+98 34 3132 8000

#### Fax

#### Email

paafzali@kmu.ac.ir

#### Web page address

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

The University of Semnan

#### Full name of responsible person

Seifollah Sadodin

#### Street address

Campus No,1 , In front of Soka Park

#### City

Semnan

#### Province

Semnan

#### Postal code

35131-19111

#### Phone

+98 23 3365 4138

#### Fax

+98 23 3365 4136

#### Email

s\_sadodin@semnan.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

The University of Semnan

#### 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

The University of Semnan

#### Full name of responsible person

Hamide Moeini Nejad

#### Position

Student

#### Latest degree

Master

#### Other areas of specialty/work

Motor Behavior- Motor Development

#### Street address

No.37, 36 Goldast Av, Goldast st, Kerman

#### City

Kerman

#### Province

Kerman

#### Postal code

7617634978

#### Phone

+98 34 3321 5368

#### Email

Moeinihm4084@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

The University of Semnan

#### Full name of responsible person

Hamide Moeini nejad

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Motor Behavior-Motor Development

**Street address**

No.37,Goldasht36, Goldasht st, Kerman

**City**

Kerman

**Province**

Kerman

**Postal code**

7617634978

**Phone**

+98 34 3321 5368

**Fax**

**Email**

Moeinihm4084@gmail.com

7617634978

**Phone**

+98 34 3321 5368

**Fax**

**Email**

Moeinihm4084@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data is potentially shareable after unidentifying individuals

**When the data will become available and for how long**

From the year 2021

**To whom data/document is available**

All applicants are allowed to access the data

**Under which criteria data/document could be used**

According to the terms and conditions of Semnan University, the data can be used

**From where data/document is obtainable**

Refer to semnan University. postal code: 3531-19111, Phone: 00982331530000, Fax: 00982333321005

**What processes are involved for a request to access data/document**

From the beginning of November, 2021, After defending the dissertation

**Comments**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

The University of Semnan

**Full name of responsible person**

Hamide Moeini Nejad

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Motor Behavior-Motor Development

**Street address**

No.37,Goldasht36, Goldasht st, kerman

**City**

Kerman

**Province**

Kerman

**Postal code**