

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

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7616913911

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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

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Semnan

Postal code

35131-19111

Phone

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Fax

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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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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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

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No.37,Goldasht36, Goldasht st, kerman

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