Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of play-based occupational therapy on symptoms and participation in activities of daily living of hospitalized children with cancer receiving chemotherapy

Protocol summary

Summary

Objectives: To investigate of the effect of play-based occupational therapy on activity of daily living and therapy related symptoms of hospitalized children receiving chemotherapy. Design: 25 children (7-12 years) with cancer receiving chemotherapy in Aliasghar hospital allocated randomized in 2 groups. Setting: Intervention group received 8 sessions (30 minutes) of play-based occupational therapy. Participants: 7-12 years children with cancer receiving inpatient chemotherapy, and parent with literacy ability (pesian). Main outcome measures: Acitivity of daily living & therapy related symptoms as main outcome measures, pain, fatigue & anxiety as secondary outcome measures.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080829260N1**
Registration date: **2016-09-12, 1395/06/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-09-12, 1395/06/22

Registrant information

Name

Afsson Hassani Mehraban

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 22227124

Email address

mehraban.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of play-based occupational therapy on symptoms and participation in activities of daily living of hospitalized children with cancer receiving chemotherapy

Public title

The effect of play-based occupational therapy on symptoms and participation in activities of daily living of hospitalized children with cancer receiving chemotherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Childhood cancer diagnosis; receiving at least one inpatient chemotherapy period; 4 scores in pain (faces pain scale) and fatigue (visual fatigue scale) scales or 3 in anxiety (faces anxiety scale) scale; parents with literature abilities (persian) Exclusion criteria: Any change in chemotherapy protocol; denying participation

up to 2 sessions; other medical conditions

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics commitee of Iran University of Medical Sciences

Street address

Hemmat highway

City

Tehran

Postal code

-

Approval date

2017-03-05, 1395/12/15

Ethics committee reference number

ir.iums.rec.1395.9211525210

Health conditions studied

1

Description of health condition studied

Neoplasms

ICD-10 code

C00-C75

ICD-10 code description

Malignant neoplasms, stated or presumed to be primary, of specified sites, except of lymphoid, haematopoietic and related tissue

Primary outcomes

1

Description

Therapy related symptoms

Timepoint

1. pretreatment 2. after phase 1 treatment (session 4) 3. after discharge (session 8)

Method of measurement

Therapy Related Symptom Checklist (TRSC)

2

Description

Participation in activity of daily living

Timepoint

1. pretreatment 2. after phase 1 treatment (session 4) 3. after discharge (session 8)

Method of measurement

Iranian Children Participation Questionnaire (ICPQ)

Secondary outcomes

1

Description

pain

Timepoint

pre and post each therapy session

Method of measurement

faces pain scale

2

Description

fatigue

Timepoint

pre and post each therapy session

Method of measurement

visual fatigue scale

3

Description

anxiety

Timepoint

pre and post each therapy session

Method of measurement

faces anxiety scale

Intervention groups

1

Description

Intervention group: 8 sessions of individualized play-

based occupational therapy (45 minutes).

Category

Rehabilitation

2

Description

Control group: Occupational therapy routine interventions (sensorimotor) if needed

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Aliasghar hospital

Full name of responsible person

Ahmad Mohammadi

Street address

Aliasghar hospital

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Iran univesiry of medical sciences

Full name of responsible person

Dr. Seyed Ali Javad Moosavi

Street address

Hemmat highway

City

Tehran

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 of Iran univesiry 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

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Ahmad Mohammadi

Position

Master of Science

Other areas of specialty/work

Street address

Rehabilitation faculty, Maadar square

City

Tehran

Postal code

Phone

+222 27124

Fax

Email

aram_mohammadi25@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Afsoon Hassani Mehraban

Position

PhD

Other areas of specialty/work

Street address

Rehabilitation faculty, Maadar square

City

Tehran

Postal code

Phone

+222 27124

Fax

Email

mehraban.a@iums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Ahmad Mohammadi

Position

Master of Science

Other areas of specialty/work

Street address

Rehabilitation faculty, Maadar square

City

Tehran

Postal code

Phone

+212 2227124

Fax

Email

aram_mohammadi25@yahoo.com

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