

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of painting on fatigue in children with cancer undergoing chemotherapy admitted to Seyedalshohada hospital in Isfahan

Protocol summary

Study aim

The present study was a clinical trial in 65 children 7-12 years old with cancer undergoing chemotherapy

Design

In this research, 65 children with cancer undergoing chemotherapy. samples were selected and randomly divided in to experimental (n=32) and control groups (n=33).

Settings and conduct

The study is a clinical trial in 65 children with cancer undergoing chemotherapy was admitted to Seyedoshohada hospitals in Isfahan. The data collection tool used was the Pediatric Quality of Life Inventory™ Multidimensional Fatigue Scale. In the experimental group, intervention was performed. After the intervention, the Questionnaire was completed again in both groups.

Participants/Inclusion and exclusion criteria

The Inclusion criteria: being in the age group of 7 to 12 years, having one type of cancer, being at least in the third stage of chemotherapy, having the ability to paint, lack of physical and mental retardation. The exclusion criteria: unwillingness of the children and their families to continue to cooperate, children's lack of ability to cooperate while studying, absence from 2 or more sessions of paintings, facing acute stress.

Intervention groups

the children who were in the intervention group participated in 6 group sessions of open watercolor painting lasting 25 minutes in the painting room. After 25 minutes, all children completed their paintings and explained their paintings to the researchers and other children. All the provided care in the control group was the same as the intervention group with the difference that the painting sessions were not held in this group.

Main outcome variables

fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170806035528N1**

Registration date: **2018-01-21, 1396/11/01**

Registration timing: **retrospective**

Last update: **2018-01-21, 1396/11/01**

Update count: **0**

Registration date

2018-01-21, 1396/11/01

Registrant information

Name

Zahra Tahmasebi

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

tahmasebi.z@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

School of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan

Expected recruitment start date

2015-08-19, 1394/05/28

Expected recruitment end date

2015-11-01, 1394/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of painting on fatigue in children with cancer undergoing chemotherapy admitted to Seyedalshohada hospital in Isfahan

Public title
The effect of Painting on fatigue in Children

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
the age group of 7 to 12 years (due to the ability to paint and respond to the questionnaire) having one type of cancer being at least in the third stage of chemotherapy having the ability to paint and lack of physical and mental retardation lack of physical problems and anxiety disorders lack of use of psychotropic drugs or antidepressants.
Exclusion criteria:
unwillingness of the children and their families to continue to cooperate, children's lack of ability to cooperate while studying, absence from 2 or more sessions of paintings, facing acute stress such as divorce of parents, death of parents or siblings, and changing of living location. children's lack of ability to cooperate while studying absence from 2 or more sessions of paintings facing acute stress such as divorce of parents, death of parents or siblings and changing of living location

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: **65**

Randomization (investigator's opinion)
Randomized

Randomization description
random allocation (by draw)

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
Vice chancellor of research and technology, Isfahan University of Medical Sciences
Street address
Isfahan, hezar jarib Street, Isfahan University of Medical Sciences, University headquarters ,Building No. 4, Vice chancellor of research and technology
City
Isfahan
Province
Isfahan
Postal code
311081775
Approval date
2015-08-16, 1394/05/25
Ethics committee reference number
IR.MUI.REC.1394.3.413

Health conditions studied

1

Description of health condition studied
cancer
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Fatigue
Timepoint
Before the intervention.after the intervention
Method of measurement
Pediatric Quality of Life Inventory™ Multidimensional Fatigue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Before starting the study, completed the questionnaire verbally. Then, the children who were in the intervention group participated in 6 group sessions of open watercolor painting lasting 25 minutes in the painting room. After 25 minut, all children completed their paintings and explained their paintings to the researchers and other children. Immediately after the intervention, the questionnaires were completed again.
Category
Other

2

Description

control group: Before starting the study, completed the questionnaire verbally. All the provided care in the control group was the same as the intervention group with the difference that the painting sessions were not held in this group, but the children sometimes painted in their rooms. Immediately after the intervention, the questionnaires were completed again

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital of Hazrat Sayyid al-Shohada (AS) Isfahan

Full name of responsible person

Dr. Memarzadeh

Street address

Hospital of Hazrat Sayyid al-Shohada (AS) Isfahan

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences, Vice-Chancellor of Research, Faculty of Nursing and Midwifer

Full name of responsible person

Dr. Kazemi

Street address

Isfahan, Hezar Jarib Street, Isfahan University of Medical Sciences, Vice-Chancellor of Research, Faculty of Nursing and Midwifery

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Isfahan

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81746-73261

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research@nm.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Sciences, Vice-Chancellor of Research, Faculty of Nursing and Midwifer

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

Shahrekord University of Medical Sciences

Full name of responsible person

Zahra Tahmasebi

Position

Masters of Pediatric Nursing- Coach Training

Latest degree

Master

Other areas of specialty/work

Nursery

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Web page address**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

Not applicable

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

Person responsible for updating data**Contact****Name of organization / entity**

Shahrekord University of Medical Sciences

Full name of responsible person

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Position

Masters of Pediatric Nursing- Coach Training

Latest degree

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