

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 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

+98 38 3424 6333

##### 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

##### City

Isfahan

##### Province

Isfahan

##### Postal code

88861183

##### Phone

+98 31 3235 0214

##### Email

omid@mui.ac.ir

##### 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

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81746-73261

##### Phone

+98 31 1668 7153

##### Email

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

#### Street address

Shahrekord, Shahrekord University of Medical Sciences, Borujen Nursing Faculty

#### City

Shahrekord

#### Province

Chahar-Mahal-va-Bakhtiari

#### Postal code

8871948747

#### Phone

+98 38 3422 6333

#### Fax

#### Email

zahratahmasebi92@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shahrekord University of Medical Sciences

#### Full name of responsible person

Zahra Tahmasebi

#### Position

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**Fax****Email**

zahratahmasebi92@gmail.com

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

Shahrekord University of Medical Sciences

**Full name of responsible person**

Zahra Tahmasebi

**Position**

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**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Shahrekord, Shahrekord University of Medical Sciences, Borujen Nursing Faculty

**City****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