

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of painting by peers on happiness in school-aged children with cancer

Protocol summary

Study aim

Determining the effect of drawing peers on the happiness of children with cancer at school ages

Design

Two arm parallel group trial with outcome assessment and Blocked Randomization

Settings and conduct

The study is don at the medical center hospital(blood ward and clinic) on school age children suffering of cancer.that performed free painting session in response to the drawing of healthy schoolmates at 5 session.

Participants/Inclusion and exclusion criteria

Interior Criteria: A child with Age range 7 to 11 years. Be able to understand and answer the questions. Not having a disability to draw a painting Exterior Criteria: Children who do not paint more than twice and Baby's death

Intervention groups

For children in both control and intervention groups ,the Happiness Questionnaire is completed before and after the intervention(painting) and then the painting project(5 painting steps with approx one week interval) is don for the intervention group.At each session ,the first one was shown by the researcher to the drawing of healthy counterparts who have been given a free subject for sick children and she asks them to draw their painting with a favorite theme now.In the end ,the questionnaires will be completed for both groups.

Main outcome variables

The happiness of children with cancer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150928024239N4**

Registration date: **2018-05-28, 1397/03/07**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-28, 1397/03/07**

Update count: **0**

Registration date

2018-05-28, 1397/03/07

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66927171

Email address

zareikh@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-07-06, 1397/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of painting by peers on happiness in school-aged children with cancer

Public title

The effect of painting by peers on happiness in school-aged children with cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age period :7 - 11 year Ability for painting Be able to

understand and answer the questions in Persian language

Exclusion criteria:

child death Children who do not paint more than two sessions

Age

From **7 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization have done according balance blocked randomization with four groups in each block.

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 Tehran University of Medical Sciences

Street address

Tehran, tohid square, school of nursing&midwifery

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۷۱

Approval date

2017-09-21, 1396/06/30

Ethics committee reference number

IR.TUMS.FMN.REC.1396,3441

Health conditions studied

1

Description of health condition studied

Children's Happiness

ICD-10 code

c80.1

ICD-10 code description

Malignant (primary) neoplasm, unspecified

Primary outcomes

1

Description

Happiness score in the Children Happiness Scale-Roger Morgan

Timepoint

The Children Happiness Scale-Roger Morgan Questionnaire gets complete in the intervention and control groups before and after the intervention by children.

Method of measurement

The Children Happiness Scale-Roger Morgan Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group is the intervention group including hospitalized children who are seven to eleven years old admitted with cancer in the Children's Medical Center Hospital. They divided based on inclusion and exclusion criteria into intervention and control groups. Intervention consists of five free subject painting sessions on the intervention group. Initially, they are shown painting that have drawn by healthy peers for children with cancer. Then the researcher requests them to draw a painting counterpart in response. Painting sessions are held five times with one-week interval approx, so it takes about 40 days to complete an intervention for each trial. Paper, crayons, pencil and color marker are provided. In the end, the paintings are collected by the researcher. The second group, the control group, is the same as the intervention group, but no intervention by the researcher is performed on them. They take routine care. Happiness assessments were done two times through the Happiness Questionnaire by both of the control and intervention groups, before the first intervention and again after the last intervention.

Category

Behavior

2

Description

The control group is the same as the intervention group, but they do not received any intervention by the researcher. They just received routine intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical Center

Full name of responsible person

Somayeh Palvan

Street address

Tehran, Keshavarz Boulevard, Doctor Gharib Avenue, next to Imam Khomeini Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Maryam Modares

Street address

Tehran, Tohid square, School of Nursing & Midwifery

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Grant name

Tehran University of Medical Sciences

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences

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**

Tehran University of Medical Sciences

Full name of responsible person

Khadijeh Zarei

Position

Instructor, Faculty's Member of Nursing and Midwifery, Tehran University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Tehran, Tohid Square, School of Nursing & Midwifery

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Khadijeh Zarei

Position

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Latest degree

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

Tehran University of Medical Sciences

Full name of responsible person

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Latest degree

Bachelor

Other areas of specialty/work

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only a portion of the data which is the main outcome information could be shared.

When the data will become available and for how long

A clinical study will report six months after the publication of the results.

To whom data/document is available

Professors, and students who have permission from me and my professors. به چه منظور و تحت چه شرایطی داده/مستند قابل استفاده است .

Under which criteria data/document could be used

Not applicable to the public.

From where data/document is obtainable

zareikh@tums.ac.ir s.palvan@gmail.com And the Library of the Faculty of Medicine, which is the basis of the thesis.

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

No documented documents except the thesis recorded in the University Library of the Faculty of Medical Sciences are currently available.

Comments

Only those written in the thesis are available, in which the thesis is also available at the Faculty Library.