

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of combined Drawig and storytelling techniques on anxiety and fatigue of children with cancer undergoing chemotherapy

Protocol summary

Study aim

Determining the effect of the combined method of painting and storytelling on the anxiety and fatigue of children with cancer undergoing chemotherapy

Design

Semi-experimental design with two groups before-after

Settings and conduct

The study setting is Tehran. After obtaining permission from the ethics committee of Iran University of Medical Sciences, the researcher will enter the research setting between 12 am to 6 pm and select eligible child who meet the inclusion criteria for the study. Before the intervention, the procedure is explained to the child and parents, and written consent is given. Then the pre-test questionnaires are given to both control and intervention groups. In the intervention group, after the pre-test, the researcher with the clinical psychologist (research consultant) went to the play room located in the pediatrics' ward and provided the environment for the children to attend by placing enough tables and chairs in the room. And the room is disinfected. Then, in each treatment session, 3-4 children are invited to the play room according to the space of the room, and the combined five-day program begins. On the sixth day, the post-test is done by filling in the questionnaires.

Participants/Inclusion and exclusion criteria

Inclusion criteria : • Age between 6 and 12 years • Receiving two or more courses of chemotherapy • At least 24 hours since the child's admission • child's mastery of the Persian language • hospitalization in the ward for 7 days
Eclusion criteria: • Discharge of the child from the hospital • Unwillingness to continue participating in the study • A major distressing life event other than a child's illness, such as a parent's divorce in the past six months

Intervention groups

Combined program of storytelling and painting

Main outcome variables

Anxiety: fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230202057303N2**

Registration date: **2023-05-10, 1402/02/20**

Registration timing: **prospective**

Last update: **2023-05-10, 1402/02/20**

Update count: **0**

Registration date

2023-05-10, 1402/02/20

Registrant information

Name

Mona Alinejad naenie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4365 1180

Email address

mona_alinejad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of combined Drawig and storytelling techniques on anxiety and fatigue of children with cancer undergoing chemotherapy		Province Tehran Postal code ۱۴۳۹۶۱۴۵۳۵
Public title The effect of combined Drawig and storytelling techniques on anxiety and fatigue of children with cancer		Approval date 2023-04-08, 1402/01/19
Purpose Supportive		Ethics committee reference number IR.IUMS.REC.1401.624
Inclusion/Exclusion criteria Inclusion criteria: Age is between 6 and 12 years Receiving two or more chemotherapy courses At least 24 hours have passed since the child was admitted to the ward Child's mastery of the Persian language Admission to the ward for 7 days Exclusion criteria: Discharge of the child from the hospital during the intervention period Major distressing life event other than the child's illness such as parental divorce, parental death, moving in the past six months Unwillingness to continue participating in the study Implementation of a specific therapeutic procedure during the intervention for the patient Being in the final phase of the disease		Health conditions studied 1 Description of health condition studied Anxiety ICD-10 code anxiety ICD-10 code description The essential feature is recurrent attacks of severe anxiety (panic), which are not restricted to any particular situation or set of circumstances and are therefore unpredictable. As with other anxiety disorders, the dominant symptoms include sudden onset
Age From 6 years old to 12 years old		Primary outcomes 1 Description Anxiety -Fatigue Timepoint 2 times -Before and After the intervention Method of measurement Spence Children’s Anxiety Scale - Childhood Fatigue Scale
Gender Both		
Phase 3		
Groups that have been masked No information		
Sample size Target sample size: 96		Secondary outcomes empty
Randomization (investigator's opinion) Not randomized		
Randomization description Blinding (investigator's opinion) Not blinded		
Blinding description Placebo Not used		
Assignment Parallel		Intervention groups 1 Description Intervention group: storytelling Category N/A
Other design features		
Secondary Ids empty		2 Description Control group:Drawing Category N/A
Ethics committees 1 Ethics committee Name of ethics committee Research Ethics Committee's Iran university of medical sciences Street address School of Nursing and Midwifery, Rashid Yasami St, Vali- e Asr St, Tehran, Iran City Tehran		
		Recruitment centers 1 Recruitment center Name of recruitment center

Hazrat Rasol Akram hospital

Full name of responsible person

Mona Alinejad-Naeini

Street address

Hazrat Rasool Akram Hospital, corner of Mansouri St.,
Niayesh St., Sattar Khan St., Tehran

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Recruitment center

Name of recruitment center

Hazrat Ali Asghar Medical Education Center

Full name of responsible person

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Tehran, Modares highway (north), after Mirdamad,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice President of Iran University of Medical
Sciences

Full name of responsible person

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School of Nursing and Midwifery, Rashid Yasami St,
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Vice President of Iran University of Medical
Sciences

Proportion provided by this source

50

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

Iran University of Medical Sciences

Full name of responsible person

Mona Alinejad naiene

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the fact that this study is conducted on children with cancer, there is no decision to publish it

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available