Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of story therapy on anxiety of children with cancer undergoing chemotherapy

Protocol summary

Study aim
Determining the effect of story therapy on anxiety in children with cancer undergoing chemotherapy

Design
A single-blind randomized clinical trial study using block randomization. Randomization was done using the software of www.sealedenvelope.com website.

Settings and conduct
This study was conducted in the hematology and oncology ward of Ali Asghar Children's Hospital in Tehran. Patients were randomly assigned to intervention and control groups. Intervention group patients, participated in story therapy classes for 8 weeks. The rate of anxiety was measured using the Revised Children's Manifest Anxiety Scale (RCMAS) before the intervention and 8 weeks after the intervention by the subjects or their parents. The outcome assessor in this study was blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Parent's consent to participate in the study Children aged 6 to 18, Children with cancer (Types of cancer) undergoing chemotherapy Exclusion criteria: Lack of physical and mental ability of the patient to participate in storytelling sessions, Patients with history of other congenital anomalies and a history of psychological diseases,Taking anti-anxiety drugs

Intervention groups
In the intervention group, patients participated in story therapy classes (10 sessions and each session for 1:30 hours) weekly and in the control group, patients did not participate in any story reading class or other psychological treatments to reduce anxiety.

Main outcome variables
Anxiety Rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230923059493N1**
Registration date: **2023-12-26, 1402/10/05**
Registration timing: **retrospective**

Last update: **2023-12-26, 1402/10/05**
Update count: **0**

Registration date
2023-12-26, 1402/10/05

Registrant information

Name
Afsaneh Ehtesham

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2260 7152

Email address
afsanehehtesham@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-30, 1401/11/10

Expected recruitment end date
2023-05-31, 1402/03/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of story therapy on anxiety of children with cancer undergoing chemotherapy

Public title

The effect of story therapy on anxiety of children with cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Parent's consent to participate in the study Children aged 6 to 18 Children with cancer (Types of cancer) undergoing chemotherapy

Exclusion criteria:

Lack of physical and mental ability of the patient to participate in storytelling sessions Patients with history of other congenital anomalies and a history of psychological diseases Taking anti-anxiety drugs

Age

From **6 years** old to **19 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the Block Randomization method was used using block size of four. The website https://www.sealedenvelope.com was used to generate randomized sequences. For the concealment, each patient was assigned a unique code through this website. The randomized list and unique codes were provided to a researcher who was not involved in the intervention, and he determined which group each patient would be placed in.

Blinding (investigator's opinion)

Single blinded

Blinding description

Physician blinding: In this study, the outcome assessor was blinded. The outcome score was calculated using a questionnaire. The researcher who gave the questionnaire to the subjects and calculated the outcome score did not know which of the groups each of the studied subjects was placed in.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine - Iran University of Medical Sciences

Street address

Iran university of medical science, Next to Milad Tower, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2023-01-21, 1401/11/01

Ethics committee reference number

IR.IUMS.FMD.REC.1401.532

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Anxiety rate

Timepoint

Before the intervention and 10 sessions after the intervention

Method of measurement

Revised Children's Manifest Anxiety Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, patients participated in a weekly storytelling class, , for 10 weeks (1.30 hours per session). The story telling program included 11 stories with different educational goals, including deep breathing and respiratory relaxation, self-acceptance, teaching various emotions and problem solving, understanding feelings of worry and how to deal with it, separation anxiety from the primary caregivers, understanding different experiences in hospital, understanding chemotherapy and its side effects, self-

confidence, self-efficacy, individual capabilities, Accepting people's differences (physical weaknesses), understanding anger and anger management, Social skills & friendships.

Category

Behavior

2

Description

Control group: In this group, the patients did not participate in any storytelling class or other psychological treatments to reduce anxiety.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Asghar children's Hospital

Full name of responsible person

Neda Ashayeri

Street address

Ali Asghar Children's Hospital, Zafar St, Modares Hwy

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2304 6253

Email

ashayeri.n@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Reza Falak

Street address

Iran University of Medical Sciences, next to the Milad Tower, Hemat Hwy

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2503

Email

falak.r@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Afsaneh Ehtesham

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

No. 4,Sheikhi Ave.,Emamzadeh Ave.,Shariati Ave

City

Tehran

Province

Tehran

Postal code

1916883583

Phone

+98 41 3724 6585

Email

afsanehehtesham@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Afsaneh Ehtesham

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

No.4, Sheiki Alley., Emmamzade Ave., Shariati St.

City

Tehran

Province

Tehran
Postal code
1916883583
Phone
+98 21 2260 7152
Fax
Email
afsanehehtesham@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Afsaneh Ehtesham
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
No 4, Sheiki Alley, Emmamzade St, Shariati St.
City
Tehran
Province
Tehran
Postal code
1916883583
Phone
+98 21 2260 7152
Fax
Email
afsanehehtesham@gmail.com

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
No - There is not a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
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