

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of expressive writing on anxiety in children with cancer undergoing chemotherapy

Protocol summary

Study aim

The effect of expressive writing on anxiety in 9 to 15 year old children with cancer undergoing chemotherapy

Design

The clinical trial consisted of one intervention group, one control group, single-blind and randomized on 88 children with cancer aged 9 to 15 years. Children are assigned to groups based on a randomization sequence and first in first out that will be generated in advance, which is unpredictable and has no certain pattern. To assign samples to 2 groups, the block randomization method with the size of 2 and 4 blocks using block random number generator software will be used. All this will be done with software called Matlab.

Settings and conduct

This study will be performed in Amirkabir Hospital in Arak. The personal information questionnaire is completed through an interview. The Spence children's anxiety scale is also completed for both groups. Writing is 3 times and each time for at least 15 minutes and without limit in the number of sentences. After the intervention, the Spence scale is completed again, and the results are compared with the pre-test and control groups. Only data analyzers will not know how the samples are placed in the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Have a minimum literacy, Suitable general condition, Pass at least one course of chemotherapy
Exclusion criteria: Existence of acute stressful conditions during the last six months, Genetic disease in children

Intervention groups

Intervention group: Participants in the intervention group are asked to write about their deepest feelings about the disease, the treatments performed for their disease. Writing is 3 times and each time for at least 15 minutes without limitation in the number of sentences. Control group: This group receives only routine therapeutic care. In this group there is no intervention.

Main outcome variables

Intensity of anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210501051142N2**

Registration date: **2021-12-01, 1400/09/10**

Registration timing: **prospective**

Last update: **2021-12-01, 1400/09/10**

Update count: **0**

Registration date

2021-12-01, 1400/09/10

Registrant information

Name

Aida Arjloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3402 0115

Email address

golmehrsherafati@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of expressive writing on anxiety in children with cancer undergoing chemotherapy

Public title

The effect of expressive writing on anxiety in children with cancer undergoing chemotherapy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Definitive diagnosis of any cancer by a specialist doctor
Diagnosis of anxiety with a higher score of 35 using the Spence questionnaire
Children hospitalized and have a record in a medical center
Have a minimum literacy
Suitable general condition to the extent that she/he is able to participate in the study
Pass at least one course of chemotherapy

Exclusion criteria:

Existence of acute stressful conditions during the last six months
History of psychotropic and drug use during the last six months
Genetic disease in children

Age

From **9 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Children are assigned to one intervention groups and one control group based on the randomization sequence that will be generated in advance, which is unpredictable and its arrangement is completely random. To allocate the samples, the block randomization method with the size of 2 and 4 blocks will be used, so that by using the software for generating random numbers in the block method, a randomization sequence will be generated according to the sample size required for the two groups. First, all the modes in which the 2 letters A, B can be put together in blocks of 2 and 4 are generated, then a block is randomly selected by placing it among the blocks and the layout pattern in that block will be used to allocate children. Finally this block will be placed in the main container and another block will be selected again. Blocks of 2 and 4 will all be in the same container. All this will be done with software called Matlab . With this method, concealment will also be observed. The concept of concealment is to unpredictably assign individuals to groups that the researcher will not be able to predict which group the next person will be in.

Blinding (investigator's opinion)

Single blinded

Blinding description

The outcome assessor will not know how the samples are placed in the intervention and control groups. Other people in the study will be aware of this placement.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Arak university of medical sciences

Street address

Arak university of medical sciences, Basij Sq., Sardasht region

City

Arak

Province

Markazi

Postal code

3848176593

Approval date

2021-09-19, 1400/06/28

Ethics committee reference number

IR.ARAKMU.REC.1400.158

Health conditions studied**1****Description of health condition studied**

Anxiety

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Anxiety rate

Timepoint

Anxiety of each patient is measured before the intervention and immediately after the intervention, 1 month and 3 months after the intervention.

Method of measurement

Anxiety is measured by the Spence Children's Anxiety Scale.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants write in a private and quiet place, regardless of the grammar, about their deepest feelings and thoughts about the illness and the treatments performed for their illness. The time and date of writing the expressive writing are written at the top of the handwriting sheet. Writing is 3 times, each time for at least 15 minutes and no limit on the number of sentences and 1 expressive writing is written per week on the day of chemotherapy. The intervention will last for 3 weeks for each patient.

Category

Other

2

Description

Control group: In this group, no intervention is performed, the control group receives only routine therapeutic care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Mahbobeh Sajadi

Street address

A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province

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3819693345

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+98 86 3943 4364

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golmehrsherafati@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

DR Alireza Kamali

Street address

University complex of the Great prophet, Basij square, Sardasht.

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Email

golmehrsherafati@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak University of Medical Sciences

Proportion provided by this source

80

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

Arak University of Medical Sciences

Full name of responsible person

Mahbobeh Sajadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

University complex of the Great prophet, Basij square, Sardasht.

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Phone

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Email

golmehrsherafati@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only the part of the data related to the original outcome will be able to be shared.

When the data will become available and for how long

since the spring of 2022

To whom data/document is available

Researchers and students in this field

Under which criteria data/document could be used

To reduce anxiety in children during chemotherapy and in order to develop a comprehensive program aimed at the psychological healing of children with cancer and with interventions such as those related to the anxiety of children with cancer or studies related to the factors affecting the mood of children with cancer, researchers can use the results of this study in these areas.

From where data/document is obtainable

Vice chancellor for education and research, Arak university of medical sciences

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

These documents will be available on the website of Arak university of medical sciences.

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

Arak University of Medical Sciences

Full name of responsible person

Mahbobeh Sajadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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