

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effect of peer education on stress , anxiety and depression in mothers of children with leukemia

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Effect of peer education on stress , anxiety and depression in mothers of children with leukemia

Design

Quasi- experimental with a control group

Settings and conduct

For the intervention group, 4 sessions of 30 to 45 minutes are performed face to face in groups of 3-5 women, the approved educational booklet will be taught to the mothers of the intervention group by their peers. The DASS-21 questionnaire will be completed at the beginning of the study and one, two months later by the mothers of this group. The control group also receives section routines.

Participants/Inclusion and exclusion criteria

No anti-anxiety and depression drugs Persian language proficiency Passed at least 6 months from the diagnosis of a child's illness Absence in the same sessions and classes lack of other stressful events other than childhood during the past 6 month

Intervention groups

For the intervention group, 4 sessions of 30 to 45 minutes are available in groups of 3 to 5 mothers, and a two-way approved by the academic staff on the diagnosis of leukemia, symptoms, treatments, diet, exercise and proper care , stress management methods are provided to the mothers of the intervention group by their peers. The control group also receives section routines.

Main outcome variables

Peer Education

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160119026104N9**

Registration date: **2019-10-26, 1398/08/04**

Last update: **2019-10-26, 1398/08/04**

Update count: **0**

Registration date

2019-10-26, 1398/08/04

Registrant information

Name

Mahnaz Shoghi

Name of organization / entity

Iran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4687 1192

Email address

shoghi.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of peer education on stress , anxiety and depression in mothers of children with leukemia

Public title

Effect of peer on stress , anxiety and depression in mothers of children with leukemia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

No anti-anxiety and depression drugs Persian language proficiency Passed at least 6 months from the diagnosis of a child's illness Absence in the same sessions and classes

Exclusion criteria:

History of psychological illness Other stressful events other than childhood during the past 6 month

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Tehran, Valiasr Ave., higher than Vanak Square, Rashidiassemi Avenue, Iran Nursing Midwifery Faculty

City

Tehran

Province

Tehran

Postal code

1996713883

Approval date

2019-01-20, 1397/10/30

Ethics committee reference number

IR.IUMS.REC.1397.778

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

Z63.7

ICD-10 code description

Other stressful life events affecting family and household

2

Description of health condition studied

Stress

ICD-10 code

Z63.7

ICD-10 code description

Other stressful life events affecting family and household

3

Description of health condition studied

Depression

ICD-10 code

R68.8

ICD-10 code description

Other general symptoms and signs

Primary outcomes

1

Description

Stress

Timepoint

The beginning of the study (before the study began) and one month, two month later

Method of measurement

Questionnaire DASS-21(Depression, Anxiety, Stress Scale 21)

2

Description

Anxiety

Timepoint

The beginning of the study (before the study began) and one month, two month later

Method of measurement

Questionnaire DASS-21(Depression, Anxiety, Stress Scale 21)

3

Description

Depression

Timepoint

The beginning of the study (before the study began) and one month, two month later

Method of measurement

Questionnaire DASS-21 (Depression, Anxiety, Stress Scale 21)

Secondary outcomes

empty

Intervention groups

1

Description

A total of 70 children with cancer who are eligible to participate in the study will be selected using the available method and will be included in the study. After explaining the actions and obtaining the informed consent, in the first stage, "before intervention," the anxiety and stress, depression of the mothers of both intervention groups And control is measured by questionnaire. This intervention with peers run during the childhood admission of children in the hospital during the days when the conditions of the child, mother and child are allowed to run every day, which includes 4 sessions of 30 to 45 minutes in groups of 3-5 people, and a booklet prepared ; was given to the mothers of the intervention group. After the completion of the sessions, DASS-21 questionnaire will be completed after one and two month by the intervention group participants. It should be noted that there is no intervention for the control group and they will be under the usual care of the department. At the end of the study, a booklet will be provided to the control group participants

Category

Other

2

Description

Control group: Approved instruction booklet

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Childrens medical center

Full name of responsible person

Tahereh Mohamadzadeh

Street address

Number 62, Childrens Medical Center, Dr. Qarib street, Keshavarz blvd.

City

Tehran

Province

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Postal code

1511419733

Phone

+98 21 6147 2917

Email

cmc.tums@gmail.com

2

Recruitment center

Name of recruitment center

Hazrat Ali Asghar Hospital

Full name of responsible person

Soroor Sohrabi

Street address

Ali Asghar hospital, Shahid Dasgerdi street

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Province

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Postal code

1919816766

Phone

+98 21 2222 2041

Email

soroor.soh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seid Kazam Malakuti

Street address

School of Nursing and Midwifery, Shahid Yasemi Street., North Kordestan Highway., Tehran., IRA

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1996713883

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+98 21 4365 1000

Email

PR@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

Mahnaz Shoghi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Yasemi Ave., Iran Nursing Midwifery Faculty

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mahnaz Shoghi

Position

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Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Person responsible for updating data

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Full name of responsible person

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Latest degree

Ph.D.

Other areas of specialty/work

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

After Data coding in order to keep the confidentiality of
the participants in the research.

When the data will become available and for how long

The end of sampling till six months after article
publishing.

To whom data/document is available

Ethical, Reviewer and Editorial committees, Researchers.

Under which criteria data/document could be used

Systematic review and meta-analysis or secondary
analysis citation

From where data/document is obtainable

Mahnaz Shoghi, Email: shoghi.m@iums.ac.ir

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

After sending a request to academic email, we will send
our data files up to one week.

Comments