

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of the effect of group and virtual training to mothers on the quality of life of children's with leukemia

Protocol summary

Study aim

Comparison of the effect of group and virtual training to mothers on the quality of life of children's with leukemia

Design

Randomized clinical trial without control group, not blinded, uncontrolled with placebo, single-centered.

Settings and conduct

In this study, 68 mothers of children's with leukemia who were hospitalized in the Amirkabir Hospital in Arak were studied. Participants are randomly divided into first and second intervention groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mental and physical health
Communication abilities Not having specific diseases Not employment as health professionals Access to virtual space and internet Reading and writing skills
Exclusion criteria: Unwillingness to participate in the study

Intervention groups

First intervention group: In the virtual training group, educational content will sent for mothers once a week (for three weeks) using Soroush's messenger as text, photos and videos. Second intervention group: In the group training group, the samples will placed in 3 groups and for each group, once a week (for three weeks), a 1 to 1.5 hour training session will be held at the hospital congress hall.

Main outcome variables

Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190507043511N1**

Registration date: **2019-08-10, 1398/05/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-10, 1398/05/19**

Update count: **0**

Registration date

2019-08-10, 1398/05/19

Registrant information

Name

Mojtaba Abdolhoseinpoor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6595 3927

Email address

hoseinpoormojtaba@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of group and virtual training to mothers on the quality of life of children's with leukemia

Public title

Effect of group and virtual training on quality of life in children's with leukemia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Mental and physical health Communication abilities Not having specific diseases Not employment as health professionals Access to virtual space and internet Reading and writing skills

Exclusion criteria:
Unwillingness to participate in the study

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
At first, the samples were selected using convenience sampling and then randomly using blocked randomization divided into two first and second intervention groups. At first, 6 blocks will constructed (ABAB ABBA, BBAA, BABA, BAAB, and AABB). Then, these blocks are arranged using a random number table, and individuals will assigned to two groups (according to "A" and "B" letters).

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 Arak University of Medical Sciences

Street address
Arak University of Medical Sciences, Basij Sq., Sardasht Region

City
Arak

Province
Markazi

Postal code
3819693345

Approval date
2019-05-19, 1398/02/29

Ethics committee reference number
IR.ARAKMU.REC.1398.063

Health conditions studied

1

Description of health condition studied

Leukemia

ICD-10 code

C95

ICD-10 code description

Leukemia of unspecified cell type

Primary outcomes

1

Description

Quality of life score in children's quality of life questionnaire

Timepoint

Before and one month after educational sessions

Method of measurement

Children's quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: In the virtual training group, educational content will sent for mothers once a week (for three weeks) using Soroush's messenger as text, photos and videos.

Category

Lifestyle

2

Description

Second intervention group: In the group training group, the samples will placed in 3 groups and for each group, once a week (for three weeks), a 1 to 1.5 hour training session will be held at the hospital congress hall.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir Hospital

Full name of responsible person

Alireza Kamali

Street address

Parastar Sq., Shahid Shiroodi St.

City

Arak

Province
Markazi
Postal code
3819693345
Phone
+98 86 3313 4715
Email
info@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
Street address
Arak University of Medical Sciences, Basij Sq.,
Sardasht Region
City
Arak
Province
Markazi
Postal code
3819693345
Phone
+98 86 3417 3505
Email
info@arakmu.ac.ir

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

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
Arak University of Medical Sciences
Full name of responsible person
Mojtaba Abdolhosseinpour
Position
Student
Latest degree
Bachelor
Other areas of specialty/work

Nursery

Street address

Arak University of Medical Sciences, Basij Sq.,
Sardasht Region

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3505

Email

hoseinpoormojtaba@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mojtaba Abdolhosseinpour

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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+98 86 3417 3505

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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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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

Not applicable

Informed Consent Form

Yes - There is 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

Part of the information's, such as main outcome and the demographic information, can be shared.

When the data will become available and for how long

36 months later.

To whom data/document is available

Researchers in academic and scientific institutions.

Under which criteria data/document could be used

Scientific purposes.

From where data/document is obtainable

Mojtaba Abdolhosseinpour

hoseinpoormojtaba@yahoo.com

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

After receiving the email, the information will sent within 2 or 3 working days.

Comments