

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The Effect of Resilience Training on Psychological Well-being and Affects of Parents with Leukemia Children's

Protocol summary

Study aim

The effect of resilience training on psychological well-being and affects of parents with leukemia children's

Design

Randomized control trial with parallel groups, double-blind (outcome assessment and data analysis)

Settings and conduct

In this study, 62 parents of children with leukemia referred to Amir Kabir Hospital in Arak will be participated. Participants are randomly divided into intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 25 to 50 years old Not being diagnosed psychiatric disorders Passing for at least 3 months of diagnosis of leukemia Exclusion criteria: Unwilling of parents to participate in the study Detection of parental psychiatric disorders during study

Intervention groups

Intervention group: The intervention group samples will be trained in 9 sessions of 1 hour. The meetings will be held daily. The content of training sessions has been developed by a clinical psychologist. Control group; Control group samples do not receive intervention during this period.

Main outcome variables

Psychological well-being; affects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161223031522N9**

Registration date: **2019-01-22, 1397/11/02**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-22, 1397/11/02**

Update count: **0**

Registration date

2019-01-22, 1397/11/02

Registrant information

Name

Vahid Naseri Salahshour

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3505

Email address

v.naserisalahshour@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-21, 1397/09/30

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Resilience Training on Psychological Well-being and Affects of Parents with Leukemia Children's

Public title

The Effect of Resilience Training on Psychological Well-being and Affects of Parents with Leukemia Children's

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

25 to 50 years old Not being diagnosed psychiatric

disorders Passing for at least 3 months of diagnosis of leukemia

Exclusion criteria:
Unwilling of parents to participate in the study Detection of parental psychiatric disorders during study

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples individually divided into two intervention and control groups using simple random allocation method and using the random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

The outcome evaluator and data analyzer do not know about allocation of people to intervention and control groups.

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

Basij Sq., Sardasht Region

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2018-11-04, 1397/08/13

Ethics committee reference number

IR.ARAKMU.REC.1397.197

Health conditions studied

1

Description of health condition studied

Leukemia

ICD-10 code

C95

ICD-10 code description

Leukaemia of unspecified cell type

Primary outcomes

1

Description

Score of psychological well-being of the scale of Ryff

Timepoint

Before the study and 9 days after the intervention

Method of measurement

Ryff score of psychological well-being

2

Description

Score of positive and negative affect of PANAS questionnaire

Timepoint

Before the study and 9 days after the intervention

Method of measurement

PANAS positive and negative affect questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group samples will be trained during 9 sessions of 1 hour. Meetings will be held daily. The content of training sessions has been developed by a clinical psychologist.

Category

Behavior

2

Description

Control group: Control group samples do not receive intervention during this period.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Kabir Hospital
Full name of responsible person
Alireza Kamali
Street address
Shahid Shiroodi St., Parastar Sq.
City
Arak
Province
Markazi
Postal code
3819693345
Phone
+98 86 3313 4717
Email
info@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohammad Arjomandzadegan
Street address
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

Mahbobeh Sajadi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Basij Sq., Sardasht Region
City
Arak
Province
Markazi
Postal code
3819693345
Phone
+98 86 3417 3505
Email
vahidnaseri1994@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Vahid Naseri Salahshour
Position
MSc of Nursing
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Basij Sq., Sardasht Region
City
Arak
Province
Markazi
Postal code
3819693345
Phone
+98 86 3417 3505
Email
vahidnaseri1994@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Vahid Naseri Salahshour
Position
MSc of Nursing
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Basij Sq., Sardasht Region

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3505

Email

vahidnaseri1994@yahoo.com

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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the data, such as information on the main outcome and the demographic information, can be shared.

When the data will become available and for how long

48 months after the publishing of the results.

To whom data/document is available

Researchers in academic and scientific institutions.

Under which criteria data/document could be used

In order to utilize scientific purposes and mention the source used.

From where data/document is obtainable

E-mail address: sajadimahbobeh@yahoo.com

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

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

Comments