Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of cognitive emotion regulation training on hope, psychological well-being and resilience of patients with leukemia

Protocol summary

Study aim
The Effect of Cognitive Emotion Regulation Training on Hope, Psychological Well-Being and Resilience of Patients with Leukemia in Shiraz

Design
The clinical trial will be a randomized, controlled, non-blinded, parallel-group trial that will be conducted on 30 patients.

Settings and conduct
A total of 60 patients in Shiraz city were selected using purposive sampling method, 30 of whom were randomly assigned to two experimental groups (15 patients) and a control group (15 patients). After 8 sessions of emotion regulation training in the experimental group, a post-test will be conducted among all groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: honest cooperation, diagnosis of leukemia, no hearing or speech problems, at least a basic level of literacy, no use of psychotropic drugs or psychological treatments during the study, and Exclusion criteria: other acute or chronic mental and physical disorders and age between 20 and 50 years, all of which were examined by studying the patients' records.

Intervention groups
It includes two experimental and control groups, where the experimental group is trained in emotion regulation therapy, while the control group will not be given training. After completion, the hope, psychological well-being, and resilience questionnaires will be distributed again between the experimental and control groups.

Main outcome variables
Hope, psychological well-being, and patient resilience

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251027067777N1**
Registration date: **2025-11-19, 1404/08/28**
Registration timing: **prospective**

Last update: **2025-11-19, 1404/08/28**
Update count: **0**

Registration date
2025-11-19, 1404/08/28

Registrant information

Name
Shahabodin abdollahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3872 8127

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shahab13602020@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-11-22, 1404/09/01

Expected recruitment end date
2025-12-22, 1404/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of cognitive emotion regulation training on hope, psychological well-being and resilience of patients with leukemia

Public title
The effect of cognitive emotion regulation training on

hope, psychological well-being and resilience of patients with leukemia

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
All patients with leukemia must have passed one year since their diagnosis.

Exclusion criteria:
The patient does not receive other psychological treatments at the same time. The patient should not suffer from psychological problems such as depression, etc. The patient is illiterate.

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: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on the simple random sampling method, 100 patients are selected by first numbering them. Then, using the Random Number Generator, we select random numbers between 1 and 100. And according to the entry and exit criteria, 30 patients will be selected by purposive sampling method in two experimental and control groups.

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
Islamic Azad University Zahedan Branch

Street address
University Street

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743545

Approval date
2025-10-26, 1404/08/04

Ethics committee reference number
IR.IAU.ZAH.REC.1404.083

Health conditions studied

1

Description of health condition studied
Leukemia

ICD-10 code
C91

ICD-10 code description
Lymphoid leukemia

Primary outcomes

1

Description
Patients whose hope scores are lower than the 20 cut-off point of the questionnaire.

Timepoint
This questionnaire will be administered to assess the level of hope in both the experimental and control groups before and after the intervention.

Method of measurement
The Schneider Hope Questionnaire (1999) will be used to determine the level of hope.

2

Description
Patients whose psychological well-being scores are lower than the cut-off point of the questionnaire, 54

Timepoint
This questionnaire will be administered to assess the level of psychological well-being of both experimental and control groups before and after the intervention.

Method of measurement
To determine the level of psychological well-being, the Riff Psychological Well-Being Questionnaire (1989) will be used.

3

Description
Patients whose resilience scores are below the 50 cut-off point of the questionnaire.

Timepoint
This questionnaire will be administered to assess the resilience of both experimental and control groups before and after the intervention.

Method of measurement
To determine the level of resilience, the Connor and Davidson (2003) Resilience Questionnaire will be used.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, the emotion regulation training protocol based on the Gross process model, which is a proposed method for emotion regulation training, will be used for the intervention group. This protocol will be taught by Gross in a group format in the form of 8 90-minute sessions for two months.
Category
Behavior

2

Description
Control group: Includes 15 patients who will only be given questionnaires (hopefulness, psychological well-being, and resilience) like the experimental group, both before and after the intervention. Meanwhile, the control group will not be given emotion regulation training.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Oncology Hospital
Full name of responsible person
Shahaboddin Abdollahi
Street address
Opposite the Kosar Pool, Farhangshahr, Fars, Shiraz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University, Zahedan Branch
Full name of responsible person
Mehdi Shahraki
Street address
Zahedan Branch, Islamic Azad University Complex, Sistan and Baluchestan, Zahedan, University Street
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University, Zahedan Branch
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
Islamic Azad University
Full name of responsible person
Shahab Oddin Abdollahi
Position
PhD student at Islamic Azad University, Zahedan Branch
Latest degree
Master
Other areas of specialty/work
Operating room technician
Street address
on the left side of the first door, Bahrami Dead End, next to Narenj Tool Shop, No. 5, Nezami Street, Firuzabad City, Fars Province
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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
No - There is not 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
Yes - There is a plan to make this available
Title and more details about the data/document
Some of the data will be shared in the form of statistical work.
When the data will become available and for how long
The time frame will be from 2026.
To whom data/document is available
People with expertise in psychotherapy are allowed access.
Under which criteria data/document could be used
are allowed in the form of cooperation
From where data/document is obtainable
Receiving data from scientific databases related to the field of psychology, as well as publications that cooperate with this field.
What processes are involved for a request to access data/document
After requesting and approving the topic and defending the thesis, after 1.5 years, the desired data can be accessed in the form of books and articles.
Comments