

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparing the effectiveness of cognitive-behavioral therapy (CBT) and Acceptance and Commitment Therapy (ACT) on anxiety, perceived stress and coping with pain in patients with Leukemia

Protocol summary

Study aim

Comparing the effectiveness of cognitive-behavioral therapy (CBT) and Acceptance and Commitment Therapy (ACT) on anxiety, perceived stress and coping with pain in patients with Leukemia

Design

A randomized controlled clinical trial with parallel groups; sample size 45

Settings and conduct

At first, the patients with leukemia were introduced to the researcher in coordination with Sayyed Shohada Hospital in Isfahan. Then, the researcher, by interviewing and examining the inclusion and exclusion criteria, selected 45 of them by available sampling method and randomly divided into three groups. Then, the researcher randomly selected two groups as the experimental group and one group as a control group. Then, one of the experimental groups received 9 sessions of Acceptance and Commitment Therapy, and the other group received 12 sessions of Cognitive-Behavioral Therapy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged 30-80 years, Having a minimum reading and writing literacy, normal listening ability and informed consent to attend therapy sessions. Exclusion criteria: mental disorders that require urgent treatment, disruption of the normal course of treatment, lack of cooperation, and severe physical disability.

Intervention groups

In the first group, acceptance and commitment therapy, in the second group cognitive-behavioral therapy, in the third group no intervention will be performed.

Main outcome variables

anxiety; perceived stress; coping with pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191214045733N1**

Registration date: **2020-02-28, 1398/12/09**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-28, 1398/12/09**

Update count: **0**

Registration date

2020-02-28, 1398/12/09

Registrant information

Name

manoochehr faryabi

Name of organization / entity

Islamic azad university kish international

Country

Iran (Islamic Republic of)

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+98 34 4326 4000

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rafiepoor@pnu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-13, 1398/09/22

Expected recruitment end date

2020-03-05, 1398/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of cognitive-behavioral therapy (CBT) and Acceptance and Commitment Therapy (ACT) on anxiety, perceived stress and coping with pain in patients with Leukemia	
Public title	Comparing the effectiveness of cognitive-behavioral therapy (CBT) and Acceptance and Commitment Therapy (ACT) on anxiety, perceived stress and coping with pain in patients with Leukemia
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	Age range 30 to 80 years Having a minimum reading and writing literacy Normal listening ability Informed consent to attend therapy sessions
Exclusion criteria:	Having any chronic diseases like diabetes, heart disease and lung disease Having any physical or mental disability Any drug use Taking any sedative medication History of psychiatric illness Absence in more than 3 treatment sessions
Age	From 30 years old to 80 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 45
Randomization (investigator's opinion)	Randomized
Randomization description	Block randomization was performed by the statistical consultant as follows: Randomization was performed in three groups: Acceptance and Commitment Therapy, Cognitive-Behavioral Therapy, and Control group. Block randomization was done by building blocks of sequences so that the same number of participants was assigned to study groups within each group. We first coded the groups in Latin letters as follows: A = Acceptance and Commitment Therapy, B = Cognitive-Behavioral Therapy, and C= Control Group In this study with three groups A, B and C we created the following six groups and assign 1 to 6 each: ABC-ACB-BAC-BCA-CAB-CBA Then we used a random number table to select one of these blocks whenever the numbers 1, 2, 3, 4, 5 and 6 appear, and if the other number appears, considered null and go to the next choice. In fact, we obtained a random sequence of numbers with a random number table that we considered the order of assignment for each number. As such, the number of people in the groups was approximately equal.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	
	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Hormozgan University of Medical Sciences
Street address	Shahid Chamran Blvd, Bandar Abbas University of Medical Sciences
City	Bandar Abbas
Province	Hormozgan
Postal code	7916613885
Approval date	2019-12-07, 1398/09/16
Ethics committee reference number	IR.HUMS.REC.1398.329
Health conditions studied	
<u>1</u>	
Description of health condition studied	Leukemia
ICD-10 code	C91
ICD-10 code description	Lymphoid leukemia
Primary outcomes	
<u>1</u>	
Description	Anxiety
Timepoint	Measurement will be done in pre-test, post-test and follow-up three months after post-test
Method of measurement	Beck Anxiety Inventory (1988)
<u>2</u>	
Description	Coping with pain
Timepoint	Measurement will be done in pre-test, post-test and follow-up three months after post-test
Method of measurement	Pain coping strategies Questionnaire Roseneshteil and kiev (2000)

Description

Perceived Stress

Timepoint

Measurement will be done in pre-test, post-test and follow-up three months after post-test

Method of measurement

Perceived Stress Scale Cohen et.al (1983)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention Group One: Acceptance and commitment Therapy - For the first experimental group, 9 sessions of 90-minute Acceptance and commitment Therapy will be taught in groups (Hayes, 2004).

Category

Treatment - Other

2**Description**

Second Group Intervention: Cognitive Behavioral Therapy - For the second group Cognitive Behavioral Therapy (Beck, 1988) will be administered in 12 sessions and each session for 90 minutes.

Category

Treatment - Other

3**Description**

Control group: No Intervention

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Isfahan Seyed al-Shohada Hospital

Full name of responsible person

Manouchehr Faryabi

Street address

No. 313, Jiroft, Azadi Street, Jiroft

City

Kerman

Province

Kerman

Postal code

7861733869

Phone

+98 34 4326 4000

Email**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Alireza Roosta

Street address

Islamic Azad University of Kish International Branch,
Free Zone Organization Square, Sana'i Boulevard,
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Hormozgan

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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

Proportion provided by this source

20

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

Manouchehr Faryabi

Position

Psychology

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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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

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any type of analysis on the data delivered is permitted

From where data/document is obtainable

Manouchehr Faryabi, Postal address: Kerman, Jiroft, Azadi St., No.313

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

The request will be sent by email to:
faryabi_m@yahoo.com

Comments