Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

Phone
+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

1

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

1

Description of health condition studied

Leukemia

ICD-10 code

C91

ICD-10 code description

Lymphoid leukemia

Primary outcomes

1

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)

2

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)

3

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
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7861733869
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faryabi_m@yahoo.com

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, Kish Island.
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7941775883
Phone
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Email
Info@laukishint.ac.ir
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 updating data

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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