

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of applicability and feasibility and the effectiveness of acceptance and commitment therapy on quality of life and psychological flexibility of adolescent survivors with cancer experience

Protocol summary

Study aim

Investigating the feasibility and effect of ACT treatment on acceptance, psychological flexibility and quality of life of adolescents recovered from cancer.

Design

The clinical trial has a control group and an intervention group, double-blind, randomized block allocation, phase 3 on 42 patients.

Settings and conduct

The community consists of all recovered teenagers from Sartalan who have previously referred to Tehran Cancer Institute. The patients are selected as available, and then the statistician divides the patients into two groups without the knowledge of the patients and the therapist (double-blind), using the block random assignment method. Group therapy will be weekly for three sessions. Finally, according to the wishes of the patients in the control group, they can receive the mentioned treatment after follow-up.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 13-18 years Completion of cancer treatment Not having psychiatric medicine for reducing anxiety or depression Not having psychotherapy now or last 3 months No diagnosis of conduct disorders, confrontational disobedience, ADHD, and psychotic and bipolar spectrum disorders Exclusion criteria: Dissatisfaction of the adolescent or family with the continuation of treatment Cancer recurrence

Intervention groups

Intervention: online group therapy based on acceptance and commitment during three 90-minute sessions (one session per week) Control: They will not receive treatment. If desired, after the follow-up treatment of the intervention group, it will be implemented on them as well.

Main outcome variables

quality of life; acceptability of intervention; acceptance;

psychological flexibility

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210727052000N3**

Registration date: **2023-09-25, 1402/07/03**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-25, 1402/07/03**

Update count: **0**

Registration date

2023-09-25, 1402/07/03

Registrant information

Name

Fatemeh Hassani alimolk

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 44 3566 1160

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fatima.hassani75@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-21, 1402/05/30

Expected recruitment end date

2024-11-20, 1403/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of applicability and feasibility and the effectiveness of acceptance and commitment therapy on quality of life and psychological flexibility of adolescent survivors with cancer experience

Public title

Acceptance and Commitment Therapy on adolescents with cancer experience

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 13-18 years Completion of cancer treatment Not having psychiatric medicine for reducing anxiety or depression Not having psychotherapy now or last 3 months No diagnosis of conduct disorders, confrontational disobedience, ADHD, and psychotic and bipolar spectrum disorders

Exclusion criteria:

Dissatisfaction of the adolescent or family with the continuation of treatment Cancer recurrence

Age

From **13 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be available, but random allocation will be done by the professor of biostatistics without the knowledge of the patients and the therapist using the block method with the size of blocks of 3 and using sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

After the initial sampling, patients and therapists are unaware that the patients will be in the control or intervention group. The statistical consultant professor performs block randomization.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Cancer Institute of Tehran university of the medical sciences

Street address

Iran cancer institute/ East door of Imam Khomeini Hospital (RA)/ End of Keshavarz Blvd/ Tehran/ Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2022-11-15, 1401/08/24

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.223

Health conditions studied**1****Description of health condition studied**

Adolescents survivors of cancer

ICD-10 code

COO-D48

ICD-10 code description

adolescent with cancer

Primary outcomes**1****Description**

Quality of life

Timepoint

pre-test, post-test, 3 months follow-up

Method of measurement

The score of a person from the Adolescent Quality of Life Questionnaire (13-18 years old).

2**Description**

Experimental avoidance

Timepoint

pre-test, post-test, follow-up

Method of measurement

Person's score from the Acceptance Avoidance subscale of the Acceptance and Action Questionnaire (AAQ-II).

3**Description**

Psychological flexibility

Timepoint

pre-test, post-test, follow-up

Method of measurement

Person's score from the Acceptance and Practice Questionnaire (AAQ-II).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the experimental group, survival adolescents from cancer receive 3 sessions that each session lasts 90-minute based on acceptance and commitment therapy that is compatible to their illness's conditions. Acceptance and commitment therapy is a type of contextual and experimental behavioral therapy and based on mindfulness that was developed by Dr. Steven Hayes in 1982, mentioned therapy is one of the third wave of psychological therapies. It consists of six basic processes: acceptance, cognitive defusion, being in the present moment, self as context, values and commitment. In fact, acceptance and commitment therapy means: accepting what is out of your control and committing to something that you can change and improves your living conditions.

Category

Other

2

Description

Control group: They donot recieve a psychotherapy. After the 3-months follow-up, they can recieve it if they want.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam khomeini hospital of Tehran

Full name of responsible person

Fatemeh Hassani Alimolk

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Anistitue cancer of Emam khomeini of Tehran, street of Dr. Gharib

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zhaleh Karimimoghaddam

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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

Tehran 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

Valiaasr Hospital

Full name of responsible person

Fatemeh Hassani Alimolk

Position

Psycho-oncologist

Latest degree

Master

Other areas of specialty/work

Psychology

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Valiasr Hospital, above Valiasr Square, Sheikh Fazullah Nouri Highway

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Zhaleh Karmimoghaddam

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Medical Education

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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

The data will be presented in the form of tables and graphs in the article. If requested by the judges or the editor, it will be made available to them after de-identification.

When the data will become available and for how long

The access period starts 6 months after the publication of the article

To whom data/document is available

Only researchers

Under which criteria data/document could be used

In order to use the results, methodology and tools used by researchers, they can send a request.

From where data/document is obtainable

To the responsible author or Fatima Hassani Ali Malek by email: fatima.hassani75@yahoo.com

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

After receiving the email, the responsible author will be talked to, and if the request is correct, the requested information will be provided to the requester as soon as possible.

Comments

Not worth mentioning.