

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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)

##### Phone

+98 44 3566 1160

##### Email address

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

##### Street address

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

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Tehran

##### Province

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1419733141

##### Phone

+98 21 6693 1444

##### Email

fatima.hassani75@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Zhaleh Karimimoghaddam

##### Street address

Zanjan University of Medical Sciences, Mhadavi street

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4513956184

##### Phone

+98 24 3314 0201

##### Email

zhkarimi@zums.ac.ir

#### 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

##### Street address

Valiasr Hospital, above Valiasr Square, Sheikh Fazullah Nouri Highway

##### City

Zanjan

##### Province

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4515777978

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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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Zanjan University of Medical Sciences, Mahdavi street

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zhkarimi@zums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Valiasr hospital

**Full name of responsible person**

Fatemeh Hassani Alimolk

**Position**

psychooncologist

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

Valiasr Hospital, above Valiasr Square, Sheikh  
Fazullah Nouri Highway

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**Province**

Zanjan

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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.