

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### The effect of acceptance and commitment therapy on anxiety, emotion regulation, psychological flexibility and treatment adherence in adolescents with diabetes type 1

#### Protocol summary

##### Study aim

to determine the effect of treatment based on acceptance and commitment on anxiety, emotional regulation and psychological flexibility of adolescents with type 1 diabetes.

##### Design

A clinical trial with a control group, with parallel groups, non-randomized and on 40 patients.

##### Settings and conduct

It is a clinical trial with a control group, which is carried out as follows: First, the researcher will refer to a child and adolescent endocrinologist in Kashan city with a written letter of introduction from the Faculty of Medicine of Kashan University of Medical Sciences. Then the people who meet the criteria to enter the research will be included in the research. The place of intervention is the Faculty of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Type 1 diabetes; having informed consent to participate in the research; 13 to 18 years of age at the time of research Exclusion criteria: Having a history of physical (cancer, MS) and severe mental (various types of psychotic disorders); having bereavement, attention deficit/hyperactivity disorder, and coping behavior disorder; receiving simultaneous psychological treatment; history of substance use

##### Intervention groups

The experimental group will be treated with acceptance and commitment therapy. For the control group, 8 sessions of life skills training will be taught.

##### Main outcome variables

anxiety; emotion regulation; psychological flexibility; Adherence to treatment

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230813059135N1**  
Registration date: **2023-10-22, 1402/07/30**  
Registration timing: **registered\_while\_recruiting**

Last update: **2023-10-22, 1402/07/30**

Update count: **0**

##### Registration date

2023-10-22, 1402/07/30

##### Registrant information

###### Name

fateme moqbeli

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 4321 1097

###### Email address

moghbeli-f@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-04, 1402/04/13

##### Expected recruitment end date

2023-12-04, 1402/09/13

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of acceptance and commitment therapy on

anxiety, emotion regulation, psychological flexibility and treatment adherence in adolescents with diabetes type 1

## Public title

The effect of acceptance and commitment therapy on anxiety, emotion regulation, psychological flexibility and treatment adherence in adolescents with diabetes type 1

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age 13 to 18 years at the time of research Type 1 diabetes

### Exclusion criteria:

Having a history of physical illness (cancer, MS) and severe mental illness (types of psychotic disorders) Having bereavement disorder, attention deficit/hyperactivity disorder, and oppositional behavior disorder Receive psychological treatment History of substance abuse

## Age

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

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## 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

Ethics committee of kashan University of Medical Sciences

##### Street address

next to beheshti hospital, qotb-ravand blvd

##### City

kashan

##### Province

Isfahan

##### Postal code

8715981151

## Approval date

2023-05-02, 1402/02/12

## Ethics committee reference number

IR.KAUMS.MEDNT.REC.1402.045

## Health conditions studied

### 1

#### Description of health condition studied

Diabetes type 1

#### ICD-10 code

E10

#### ICD-10 code description

Type 1 diabetes mellitus

## Primary outcomes

### 1

#### Description

anxiety score in beck anxiety inventory

#### Timepoint

before the start of intervention, after the intervention and 3 months after the intervention

#### Method of measurement

beck anxiety inventory

### 2

#### Description

emotion regulation score in emotion regulation questionnaire for children and adolescents

#### Timepoint

before the start of intervention, after the intervention and 3 months after the intervention

#### Method of measurement

emotion regulation questionnaire for children and adolescents

### 3

#### Description

The treatment compliance score in the treatment compliance questionnaire in chronic diseases

#### Timepoint

before the start of intervention, after the intervention and 3 months after the intervention

#### Method of measurement

questionnaire in chronic diseases

### 4

#### Description

Psychological flexibility score in psychological flexibility questionnaire for teenagers

#### Timepoint

before the start of intervention, after the intervention and 3 months after the intervention

#### Method of measurement

Psychological flexibility questionnaire for teenagers

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: For 2 months, one session every week (8 sessions in general), acceptance and commitment therapy will be received. Each session will take one to two hours. During the youth session, with the help of art (crayon, gouache, clay and coal) concepts such as acceptance, mindfulness and ... They will be trained.

#### Category

Treatment - Other

### 2

#### Description

Control group: For 2 months, One session every week (8 sessions in general), they will receive life skills training. Each session will take one to two hours. During the session, adolescents will be taught the content of adolescent care.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

shahid beheshti hospital

##### Full name of responsible person

dr.marziye talebian

##### Street address

beheshti hospital, qotb-ravand blvd

##### City

kashan

##### Province

Isfahan

##### Postal code

8715973447

##### Phone

+98 31 5500 9999

##### Fax

+98 31 5558 9200

##### Email

beheshthospital@kaums.ac.ir

##### Web page address

https://beheshti.kaums.ac.ir/

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Kashan University of Medical Sciences

#### Full name of responsible person

Gholam Ali Hamidi

#### Street address

next to beheshti hospital, qotb-ravand blvd

#### City

kashan

#### Province

Isfahan

#### Postal code

8715973474

#### Phone

+98 31 5510 9999

#### Fax

+98 31 5546 4950

#### Email

info@kaums.ac.ir

#### Web page address

https://kaums.ac.ir/

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Kashan 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

Kashan University of Medical Sciences

##### Full name of responsible person

zahra zanjani

##### Position

science Committee

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Psychology

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next to beheshti hospital, qotb-ravand blvd

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##### Province

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**Email**

z\_zanjani2005@yahoo.com

## Person responsible for scientific inquiries

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**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

zahra zanjani

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**Email**

z\_zanjani2005@yahoo.com

## 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**

A part of the data, such as the information related to the main outcome or the like, can be shared.

**When the data will become available and for how long**

The access period starts from 1403 after the results are printed

**To whom data/document is available**

Only for researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

For the purpose of scientific analysis

**From where data/document is obtainable**

Department of Clinical Psychology, Kashan University of Medical Sciences, Kashan, Iran Tel: +983155109999

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

The applicant is required to refer to Kashan University of Medical Sciences and submit his application with the Director of Clinical Psychology Department. After his approval by referring to Dr. Zahra Zanjani it is possible to get the document file in a short time.

**Comments**