

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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		Approval date 2023-05-02, 1402/02/12
Public title The effect of acceptance and commitment therapy on anxiety, emotion regulation, psychological flexibility and treatment adherence in adolescents with diabetes type 1		Ethics committee reference number IR.KAUMS.MEDNT.REC.1402.045
Purpose Supportive		Health conditions studied
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		1 Description of health condition studied Diabetes type 1 ICD-10 code E10 ICD-10 code description Type 1 diabetes mellitus
Age From 13 years old to 18 years old		Primary outcomes
Gender Both		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
Phase N/A		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
Groups that have been masked <i>No information</i>		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
Sample size Target sample size: 40		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
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		

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

beheshtihospital@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

Street address

next to beheshti hospital, qotb-ravand blvd

City

kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5510 9999

Fax

+98 31 5546 4950

Email

z_zanjani2005@yahoo.com

Person responsible for scientific 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

Street address

next to beheshti hospital, qotb-ravand blvd

City

kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5510 9999

Fax

+98 31 5546 4950

Email

z_zanjani2005@yahoo.com

Person responsible for updating data

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

Street address

next to beheshti hospital, qotb-ravand blvd

City

kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5510 9999

Fax

+98 31 5546 4950

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