Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Isfehan
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 talebiyan
Street address
beheshti hospital, qotb-ravand blvd
City
kashan
Province
Isfehan
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
Isfehan
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
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kashan
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Postal code
8715981151
Phone
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+98 31 5546 4950

Email

z_zanjani2005@yahoo.com

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Contact

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Person responsible for updating data

Contact

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Full name of responsible person

zahra zanjani

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Fax

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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