Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of Acceptance and Commitment Therapy (ACT) for perceived stress, special health self-efficacy, depression, psychological well-being and feelings of guilt in children between 7-15 years old with diabetes

Protocol summary

Summary

The aim of this study is to determine effectiveness of Acceptance and Commitment Therapy (ACT) in perceived stress, special health self-efficacy, depression, psychological well-being and feelings of guilt in children aged between 7-15 with diabetes in two experimental and control groups. The main inclusion criteria are: having diabetes (Type 1 and 2) for at least one year and without major psychiatric disorder. The main exclusion criteria are: need a significant change in insulin dose during the research and acute or chronic medical illness.The study population included all patients aged 7-15 that referred to the diabetes association of Tabriz of whom 34 participants were selected using convenient sampling. They were randomly allocated into two equal groups (experimental and control). Therapy sessions will be in 8 weeks and every week a session lasted 90 minutes. The control group did not receive any intervention. The primary outcomes of the study will include the five variables of perceived stress, special health self-efficacy, depression, psychological well-being and feelings of guilt.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014072616602N2**
Registration date: **2014-08-27, 1393/06/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-08-27, 1393/06/05

Registrant information

Name
Vahid Ataie Moghanloo
Name of organization / entity
Payam Noor University of Parsabad Moghan
Country
Iran (Islamic Republic of)
Phone
+98 45 2882 2371
Email address
vahidataie_3000@yahoo.com

Recruitment status

Recruitment complete

Funding source

Payam Noor University of Parsabad Ardabil

Expected recruitment start date

2013-07-23, 1392/05/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Acceptance and Commitment Therapy (ACT) for perceived stress, special health self-efficacy, depression, psychological well-being and feelings of guilt in children between 7-15 years old with diabetes

Public title

Effectiveness of Acceptance and Commitment Therapy (ACT) in children with diabetes

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: age less than 15 years; having diabetes (Type 1 and 2) for at least one year; without major psychiatric disorder; Exclusion criteria: need a significant change in the insulin dose during the research; acute or chronic medical illness; receiving psychiatric treatments or use of psychotropic drugs; drug abuse during the study period.

Age
From **7 years** old to **15 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
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
Payam Noor University of Pars Abad Ardabil

Street address
Building No. 1, Number 24, St. Daneshgah, Pars Abad, Ardabil

City
Parsabad

Postal code
5675151548

Approval date
2013-07-01, 1392/04/10

Ethics committee reference number
23285

Health conditions studied

1

Description of health condition studied
Diabetes

ICD-10 code
E10

ICD-10 code description
Diabetes mellitus

Primary outcomes

1

Description
Depression

Timepoint
Before intervention and two months after start of intervention

Method of measurement
Reynolds Child Depression Scale

2

Description
Perceived Stress

Timepoint
Before intervention and two months after start of intervention

Method of measurement
Perceived Stress Scale

3

Description
Special Health Self-efficacy

Timepoint
Before intervention and two months after start of intervention

Method of measurement
Special Health Self-efficacy Scale

4

Description
Psychological well-being

Timepoint
Before intervention and two months after start of intervention

Method of measurement
Satisfaction with Life Scale

5

Description
Feelings of Guilt

Timepoint
Before intervention and two months after start of intervention

Method of measurement
Eysenck Feelings of Guilt Scale

Secondary outcomes

empty

Intervention groups

1

Description
Process of group therapy will be done on the experimental group in 8 sessions and 90 minutes (Once a week). 1- Building the therapeutic contract, Distribution of the questionnaire. 2- Functional analysis. 3- Control expression as a problem, evaluation of performance. 4- Cognitive defusion and techniques. 5- Establishing language conventions. 6- Mindfulness techniques. 7- Value clarification. 8- Remember sessions and relapse prevention.
Category
Behavior

2

Description
The control group did not receive any intervention.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Diabetes Association
Full name of responsible person
Mr Mehdi Haghighi
Street address
Number 46, Fatemi St. Northern Ghatran, Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Payam Noor University of Pars Abad Ardabil
Full name of responsible person
Mr Mousa Moazzezi
Street address
Building No. 1, Number 24, St. Daneshgah, Pars Abad, Ardabil
City
Pars Abad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Payam Noor University of Pars Abad Ardabil
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Payam Noor University of Pars Abad Ardabil
Full name of responsible person
Vahid Ataie Moghanloo
Position
MA in Clinical Psychology
Other areas of specialty/work
Street address
Department of Psychology, Payam Noor University, Pars Abad, Ardabil
City
Pars Abad
Postal code
5675151548
Phone
+98 45 3288 2371
Fax
+98 45 2882 3557
Email
vahidataie_3000@yahoo.com
Web page address
http://parpnu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Payam Noor University of Pars Abad Ardabil
Full name of responsible person
Vahid Ataie Moghanloo
Position
MA in Clinical Psychology
Other areas of specialty/work
Street address
Department of Psychology, Payam Noor University, Pars Abad, Ardabil
City
Pars Abad
Postal code
5675151548
Phone
+98 45 3288 2371
Fax
+98 45 2882 3557
Email
vahidataie_3000@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Payam Noor University of Pars Abad Ardabil
Full name of responsible person
Vahid Ataie Moghanloo
Position
MA in Clinical Psychology
Other areas of specialty/work
Street address
Department of Psychology, Payam Noor University, Pars Abad, Ardabil
City
Pars Abad
Postal code
5675151548
Phone
+98 45 3288 2371
Fax
+98 458823557
Email
vahidataie_3000@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty