

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Effectiveness of behavioral activation therapy based on changing lifestyles for depression symptoms, 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 behavioral activation therapy based on changing lifestyles for 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 three variables of depression, psychological well-being and feelings of guilt.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012616602N4**

Registration date: **2015-02-04, 1393/11/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-04, 1393/11/15

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

2014-07-23, 1393/05/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of behavioral activation therapy based on changing lifestyles for depression symptoms, psychological well-being and Feelings of guilt in children between 7-15 years old with diabetes

Public title

Effectiveness of behavioral activation therapy in children with diabetes

Purpose

Supportive

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: **38**

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

2011-07-01, 1390/04/10

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

Psychological well-being

Timepoint

Before intervention and two months after start of intervention

Method of measurement

Satisfaction with Life Scale

3

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- The training of simple behavioral contracts. 2- The training of behavioral activation and focus on behavioral activation in interaction between individual and the environment. 3- The psychological training in the case of healing processes in a group. 4- In the fourth session the focused was on anxiety aspects of diabetes and expressing positive and hopeful sentences about the small improvements in patient. 5- The focus on the anxiety aspects of diabetes. 6- The focus on the recurrence symptoms of anxiety in patients. 7- Training of patient regarding coping skills, and training of cognitive reconstruction. 8- In the end wrapping, summary of treatment and providing the preventive strategies were done.

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 2882 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

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Pars Abad

Postal code

5675151548

Phone

+98 45 2882 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

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Street address

Department of Psychology, Payam Noor University, Pars Abad, Ardabil

City

Pars Abad

Postal code

5675151548

Phone

+98 45 2882 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