

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 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**

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**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*