

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of cognitive group therapy on depression of diabetic patients referred to diabetic clinic affiliated to Shiraz University of Medical Sciences-2009

Protocol summary

Summary

The most common metabolic disorder is diabetes mellitus. Depression is one of the psychological disorders commonly accompanying diabetes. The objective of this randomized, double blind trial is to investigate the effect of cognitive behavior therapy on depression of diabetic patients referred to diabetic clinic affiliated to Shiraz University of Medical Sciences in 2009. In this study 60 patients with required criteria were divided into two groups based on the convenience sampling method, using random block allocation. 30 patients in control group and 30 patients in experimental group. The experimental group was randomly divided into three groups of 10 and received 8 sessions of cognitive-behavior therapy. The level of depression was checked before, two weeks, four weeks, and two months after intervention in both groups. Blood glucose (glycosylated hemoglobin) was also checked before and two months after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110012812N4**

Registration date: **2012-03-29, 1391/01/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-03-29, 1391/01/10

Registrant information

Name

Farkhondeh Sharif

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1212 2401

Email address

fsharif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2009-04-03, 1388/01/14

Expected recruitment end date

2009-10-23, 1388/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cognitive group therapy on depression of diabetic patients referred to diabetic clinic affiliated to Shiraz University of Medical Sciences-2009

Public title

The effect of cognitive group therapy on depression of diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria were as follows: willing to participate in the study, suffering from diabetes type 2 and not having major depression according to DSM-IV criteria, having a history of diabetes for more than one year, no background of committing suicide, mental

disorder, or drug abuse. exclusion criteria were absence of more than 3 sessions and consuming psychiatric drugs. psychotherapeutic medication.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study 60 patients with required criteria were divided into two groups based on the convenience sampling method, using random block allocation.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand street, central Building

City

Shiraz

Postal code

71345-1359

Approval date

2009-06-22, 1388/04/01

Ethics committee reference number

CT88-4714

Health conditions studied

1

Description of health condition studied

Dibetic Mellitus

ICD-10 code

E10-14

ICD-10 code description

Endocrine, nutritional and metabolic diseases

Primary outcomes

1

Description

Depression

Timepoint

Before the Intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The experimental group attended eight sessions of cognitive behavior therapy. each session lasting for 1.5 hour.

Category

Behavior

2

Description

Control Group received only the routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Mottahari Clinic

Full name of responsible person

Farkhondeh Sharif

Street address

Zand street, Shiraz University of Medical Sciences

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences, Vice chancellor for research

Full name of responsible person

DrGholamreza Hatam

Street address

Shiraz University of Medical Sciences, University Central Building, Zand street, beside red cross

City

Shiraz

Grant name**Grant code / Reference number**

CT88-4714

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences, Vice chancellor for research

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**

Shiraz University of Medical Sciences,

Full name of responsible person

Dr Hatam

Position

VICE CHANCELLOR FOR RESEARCH

Other areas of specialty/work**Street address**

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Person responsible for updating data**Contact****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