

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The effect of group cognitive- behavioral therapy with aerobic exercise in General Health, Mental Well-Being and Life Expectancy in People with Type 2 Diabetes

Protocol summary

Summary

The aim of current study is the comparison of the efficiency of group cognitive- behavioral therapy with aerobic exercise in General Health, Mental Well-Being and Life Expectancy in People with Type 2 Diabetes. This study is a pretest- posttest study with control group. The research community is all patients referred to Kermanshah diabetes centers. The sample consisted of 36 patients with diabetes who have low scores on the General Health Questionnaire and The sample consisted of 36 patients with diabetes who have low scores on the General Health Questionnaire. Inclusion criteria are: Having type 2 diabetes Having at least a high school diploma Age above 35 years and below 60 years Non-use of psychiatric medications or other treatment before or during the intervention Exclusion criteria include: The presence of significant psychiatric disorder Any impairment and physical disability There are other current or past abuses or drug dependence Thoughts of suicide After sampling the subjects are randomly divided into three groups: cognitive behavior therapy, aerobic exercise and control groups. Data are collected at baseline and after interventions (after 8 week). The primary outcome measure include: General Health, Mental Well-Being and Life Expectancy and HbA1C.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012610063N5**
Registration date: **2015-02-07, 1393/11/18**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-07, 1393/11/18

Registrant information

Name

Kheirollah Sadeghi

Name of organization / entity

Kermanshah University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2014-06-01, 1393/03/11

Expected recruitment end date

2014-09-01, 1393/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group cognitive- behavioral therapy with aerobic exercise in General Health, Mental Well-Being and Life Expectancy in People with Type 2 Diabetes

Public title

The effect of group cognitive- behavioral therapy with aerobic exercise in General Health, Mental Well-Being and Life Expectancy in People with Type 2 Diabetes

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria are: 1. Having a higher score of 22 on the general health questionnaire 2. Having type 2 diabetes 3. Having at least a high school diploma 4. Age above 35 years and below 60 years 5. Non-use of psychiatric medications or other treatment before or during the intervention Exclusion criteria include: 1. The presence of significant psychiatric disorder 2. Any impairment and physical disability 3. There are other current or past abuses or drug dependence 4. Thoughts of suicide

Age
From **35 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Science

Street address

Vice – Chancellery of Research & Technology Affairs,
building No.2,shahid beheshti blvd, Kermanshah

City

Kermanshah

Postal code

Approval date

2014-05-19, 1393/02/29

Ethics committee reference number

4676

Health conditions studied

1

Description of health condition studied

Type II of diabets

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Well-Being

Timepoint

Before and after the intervention

Method of measurement

General Well-Being Questionnaire

2

Description

Life Expectancy

Timepoint

Before and after the intervention

Method of measurement

Life Expectancy Questionnaire

3

Description

General health

Timepoint

Before and after the intervention

Method of measurement

general health Questionnaire(GHQ)

Secondary outcomes

empty

Intervention groups

1

Description

Type of intervention:group cognitive behavior therapy
Duration: eight weeks, 12 sessions Two days a week, for
45-60 minutes / session

Category

Other

2

Description

Type of intervention:aerobic exercise Duration: eight
weeks intensity 60-80% heart rate reserve, frequency 3
days/week, duration 45-60 min/session

Category

Other

3

Description

The control group does not receive any treatment

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital

Full name of responsible person

Mohammad Hossien Dehghan

Street address

Kermanshah, shahid shirodi Blvd, medicene college

City

Kermanshah

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Vice – Chancellery of Research & Technology Affairs
of Kermanshah University of Medical Science**Full name of responsible person**

Dr.Frid Najafi

Street address

Kermanshah, shihid beheshti Blvd, Building No. 2

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceVice – Chancellery of Research & Technology Affairs of
Kermanshah University of Medical Science**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**

Kermanshah University of Medical Science

Full name of responsible person

Seyed Mojtaba Ahmadi

Position

Master of Science

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

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Dr.Khirollah Sadeghi

Position

Assistant professor of psychology/ph.d

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Kermanshah University of Medical Sciences

Full name of responsible person

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Position

Post graduate student of clinical psychology

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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