

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

The effect of exercise consultation and exercise therapy on quality of life in patients with type 2 diabetes: A randomized clinical trial

Protocol summary

Summary

This study is done to evaluate the effect of exercise consultation and a period of 6-week exercise therapy on quality of life in patients with type 2 diabetes. A total of 102 cases of patients with diabetes (visited in Firoozgar Hospital Endocrinology Research Center) based on inclusion and exclusion criteria are enrolled in this study. Half of the participants will receive exercise therapy and exercise consultation as group therapy and other group will only receive an educational booklet and a medical examination session individually for exercise prescription. Blood pressure, weight, waist circumference, BMI, fasting plasma glucose, total cholesterol, LDL, HbA1c, TG, and quality of life using the Short Form Health Survey (SF-36) will be assessed at the baseline and after six weeks of the study and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011044251N3**

Registration date: **2010-12-01, 1389/09/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-12-01, 1389/09/10

Registrant information

Name

Haleh Dadgostar

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2200 4050

Email address

dadgostar.h@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ethics committee in Iran University of Medical Sciences

Expected recruitment start date

2010-11-22, 1389/09/01

Expected recruitment end date

2011-03-21, 1390/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of exercise consultation and exercise therapy on quality of life in patients with type 2 diabetes: A randomized clinical trial

Public title

The effect of group therapy in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: known history of type 2 diabetes, age more than 30 years old, not engaged in physical activity more than 2 hours/week, not receiving insulin, the absence of ST changes in ECG; history of chest pain or pressure, dyspnea on exertion, unexplained gastrointestinal complaints; uncontrolled BP (resting systolic BP >200mmHg or diastolic BP >110mmHg); resting tachycardia (100 beats/min); absence of clinical findings of diabetic micro- or macrovascular complications (retinopathy, autonomic neuropathy,

nephropathy), Not orthopedic problem for patient's activity, ability to read and speak in Persian Exclusion criteria: taking glucocorticoids, absence in more than one session of group therapy session

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee in Iran University of Medical Sciences

Street address

Hemmat Highway

City

Tehran

Postal code

5983-14155

Approval date

2010-10-24, 1389/08/02

Ethics committee reference number

896/5

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Quality of life

Timepoint

before intervention and after 6 weeks of intervention

Method of measurement

The short form health survey (SF-36)

2

Description

TG

Timepoint

before intervention and after 6 weeks of intervention

Method of measurement

Blood sample

3

Description

HDL

Timepoint

before intervention and after 6 weeks of intervention

Method of measurement

Blood sample

4

Description

LDL

Timepoint

before intervention and after 6 weeks of intervention

Method of measurement

Blood sample

5

Description

Total cholesterol

Timepoint

before intervention and after 6 weeks of intervention

Method of measurement

Blood sample

6

Description

Diastolic pressure

Timepoint

before intervention and after 6 weeks of intervention

Method of measurement

Sphygmomanometer

7

Description

FBS

Timepoint

before intervention and after 6 weeks of intervention

Method of measurement

Blood sample

8

Description

systolic blood pressure

Timepoint

before intervention and after 6 weeks of intervention

Method of measurement

Sphygmomanometer

9

Description

Hb A1c

Timepoint

before intervention and after 6 weeks of intervention

Method of measurement

Blood sample

10

Description

weight

Timepoint

before intervention and after 6 weeks of intervention

Method of measurement

scale

11

Description

BMI

Timepoint

before intervention and after 6 weeks of intervention

Method of measurement

weight(kg)/Square of height(meter)

12

Description

waist circumference

Timepoint

before intervention and after 6 weeks of intervention

Method of measurement

meter

13

Description

Physical functioning

Timepoint

before intervention and after 6 weeks of intervention

Method of measurement

The short form health survey(SF-36)

14

Description

Role physical

Timepoint

before intervention and after 6 weeks of intervention

Method of measurement

The short form health survey(SF-36)

15

Description

Social functioning

Timepoint

before intervention and after 6 weeks of intervention

Method of measurement

The short form health survey(SF-36)

16

Description

Mental health

Timepoint

before intervention and after 6 weeks of intervention

Method of measurement

The short form health survey(SF-36)

17

Description

Bodily pain

Timepoint

before intervention and after 6 weeks of intervention

Method of measurement

The short form health survey(SF-36)

18

Description

Vitality

Timepoint

before intervention and after 6 weeks of intervention

Method of measurement

The short form health survey(SF-36)

19

Description

General health

Timepoint

before intervention and after 6 weeks of intervention

Method of measurement

The short form health survey(SF-36)

20

Description

Role emotional

Timepoint

before intervention and after 6 weeks of intervention

Method of measurement

The short form health survey(SF-36)

Secondary outcomes

empty

Intervention groups

1

Description

The control group will only receive an educational

booklet, and a systematic intervention program will not be given. They have just one session (30 minutes) by sports medicine specialist about health screening, education of booklet and exercise prescription, individually. They don't have another session during 6 weeks of the study. Also, consultation to change other aspects of lifestyle (nutrition and diet consultation) will be given to all patients.

Category

Lifestyle

2

Description

The intervention group: The 6-week group therapy will be provided in 6 sessions once a week by sports medicine specialist (2 hours) consisted of: health screening (blood pressure and body weight check), education, exercise prescription and counseling. Also, once a week, contact with participants by phone will be done for giving necessary recommendations about exercise training by sports medicine specialist. Exercise program will be 3 sessions per week consisted of warm-up, stretching, strength training, aerobic and cool-down exercises for 60 minutes per session. Participants will be encouraged to perform walking exercise in other days. Also, consultation to change other aspects of lifestyle (nutrition and diet consultation) will be given to all patients. The patients can call during the week for receiving the necessary exercise consultation.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital Endocrinology Research Center

Full name of responsible person

Sahar Firouzinezhad MD. Assistant of sports medicine

Street address

Beh Afarin street -Karim khan zand street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences (Research Department)

Full name of responsible person

Abbas Motavalian, MD

Street address

Hemmat highway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences (Research Department)

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

Tehran University of Medical Sciences

Full name of responsible person

Haleh Dadgostar, MD

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

Haleh Dadgostar, MD

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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