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 survay (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 cholestrol

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

Contact

Name of organization / entity

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Full name of responsible person

Haleh Dadgostar, MD

Position

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Contact

Name of organization / entity
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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