Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of prescription of physical activity on quality of life of patients with diabetes

Protocol summary

Summary

Background and aim: The overall goal of this study is to evaluate the effectiveness of a physical activity prescription on type 2 diabetic patients' quality of life. Material & methods: consenting eligible type 2 diabetic patients referred to endocrine research clinic of Iran University of Medicine will be enrolled in the study by convenience method. They then will be randomly allocated in two 40 person groups (block randomization) receiving either routine education about life style modification or the physical activity prescription plus the routine education. The WHO quality of life questionnaire will be completed by each participant at the beginning of the study and then 3 months after the enrollment. Patients in the prescription group will receive set tables of physical activity which they will bring to each visit. The physical activity questionnaire IPAQ (long form) will be completed for each participant at first, 1.5 and 3months visits. The results will be analyzed and compared between the 2 groups and if effective the physical activity prescription will be included in the routine type 2 diabetic patients' care.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082029372N4**
Registration date: **2016-08-24, 1395/06/03**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-08-24, 1395/06/03

Registrant information

Name

Marzieh Molavi Nojomi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8860 2225

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research & Technology Iran University of Medical Sciences

Expected recruitment start date

2016-09-05, 1395/06/15

Expected recruitment end date

2017-03-05, 1395/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of prescription of physical activity on quality of life of patients with diabetes

Public title

The effectiveness of physical activity on quality of life of patients with diabetes type 2

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : The men≤45 years and women ≤55 years; patients with type 2 diabetes are treated with blood glucose lowering drugs or basal Insulin; HbA1C ≤8.5 Exclusion criteria : patients with type 1 diabetes; diabetic patients unable to do physical activity

Age
From **20 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
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

1

Registry name
-
Secondary trial Id
-
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Hemmat High way, Tehran
City
Tehran
Postal code
Approval date
2016-08-08, 1395/05/18
Ethics committee reference number
IR.IUMS.REC 1395.9411220005

Health conditions studied

1

Description of health condition studied
Diabetes melitus type 2
ICD-10 code
E11
ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
quality of life
Timepoint
before intervention, 3 month after begining of intervention
Method of measurement
WHO quality of life questionnaire

Secondary outcomes

1

Description
-
Timepoint
-
Method of measurement
-

Intervention groups

1

Description
Intervention group: Prescription of physical activity and life style education, education time : 30 minutes
Category
Lifestyle

2

Description
Control group : life style education, education time : 30 minutes
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Institue of Endocrinology, Iran university of medical sciences
Full name of responsible person
Mohammad Ebrahim Khamseh
Street address
No.10, Firozeh Alley,Valliasr Avenue. Tehran,Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research and technology Iran University of Medical Sciences
Full name of responsible person
Seyed Ali Javad Moosavi
Street address
Hemmat High way, Tehran
City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research and technology Iran University of Medical Sciences

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
Iran university of medical sciences
Full name of responsible person
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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