Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of written prescription of physical activity program on blood sugar control in patients with type 2 diabetes, a randomized clinical trial

Protocol summary

Study aim
The effect of written prescription of physical activity program on blood sugar control in patients with type 2 diabetes

Design
This double blind clinical trial is performed on 100 patients with Type 2 diabetes that randomly divided into two equal groups In parallel. Block randomization method will be used for random allocation. The blocks size will be 4 and for this purpose; 25 blocks with 4 subjects in each block will be used. For selecting each blocks; statistical software and the block number will be selected. This procedure continued to completed the allocation and reached to sample size.

Settings and conduct
This study was conducted as a clinical trial study with 100 patients who referred to diabetic ward and clinic of Imam Hossain Hospital of Shahroud. In this study the evaluator and analyzer are blinded.

Participants/Inclusion and exclusion criteria
Including criteria include:patients with a definitive diagnosis of type 2 diabetes and having informed consent to participate in the research. Exclusive criteria include: the presence of communication or cognitive disorders in patients;inability to perform physical activities in patients;the presence of severe and advanced heart and lung diseases in patients;the presence of severe skeletal and muscular disease in patients.

Intervention groups
Intervention group: in addition to the routine treatment program , a written prescription to perform Regular walking will be prescribed for 150 minutes of walking per week (as desired in the morning or evening and preferably divided into weekdays). Control group: a routine treatment program (including prescribing medicine (if needed), giving verbal advice on following dietary instructions and having regular physical activity 150 minutes per week) will be prescribed.

Main outcome variables
Measuring fasting blood sugar;Measuring 2-hours blood sugar and Measurement of Glycosylated Hemoglobin (A1c)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221227056940N1**
Registration date: **2024-09-21, 1403/06/31**
Registration timing: **prospective**

Last update: **2024-09-21, 1403/06/31**
Update count: **0**

Registration date
2024-09-21, 1403/06/31

Registrant information
Name
Sina Sohrabi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-10-06, 1403/07/15
Expected recruitment end date
2025-02-18, 1403/11/30
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of written prescription of physical activity program on blood sugar control in patients with type 2 diabetes, a randomized clinical trial

Public title
The effect of physical activity on blood sugar control in patients with type 2 diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with a definitive diagnosis of type 2 diabetes; type 2 diabetic patients need therapeutic interventions; having stable vital signs; age range between 15 and 65 years; having informed consent to participate in the research.
Exclusion criteria:
Diabetic people who need hospitalization; the presence of communication or cognitive disorders in patients; inability to perform physical activities in patients; the presence of severe and advanced heart and lung diseases in patients; the presence of severe skeletal and muscular disease in patients; regret or withdrawal from continuing the research.
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: use block. Random unit: individual. Randomization tool: An online randomization website. Sequence building: using block randomization method with block size of 4. Concealing method: using closed and opaque envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, clinical evaluator and analyzer are blinded. The allocation of patients into two groups A and B is done by a experienced person who has no aware of the actions performed in the two groups. Clinical examination and outcome evaluation will be record by a qualified person without any information about the type of intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahroud University of Medical Sciences
Street address
Shahroud University of Medical Sciences; 7 Tir squer, Shahroud
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Shahroud
Province
Semnan
Postal code
3616647555
Approval date
2022-10-12, 1401/07/20
Ethics committee reference number
IR.SHMU.REC.1401.149

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Measuring fasting blood sugar
Timepoint
At monthly intervals from the beginning of the study until 3 months after intervention
Method of measurement
By standard laboratory method

2

Description
Measuring 2-hours blood sugar
Timepoint
At monthly intervals from the beginning of the study until 3 months after intervention
Method of measurement
By standard laboratory method

3

Description
Measurement of Glycosylated Hemoglobin (A1c)
Timepoint
At the beginning of the study and 3 months after the intervention
Method of measurement
By standard laboratory method

Secondary outcomes

1

Description
Measurement of systemic blood pressure
Timepoint
At monthly intervals from the beginning of the study until 3 months after intervention
Method of measurement
In a standard way and with a Mercury sphygmomanometer

2

Description
Body weight measurement
Timepoint
At monthly intervals from the beginning of the study until 3 months after intervention
Method of measurement
In a standard way and with a digital scale device

Intervention groups

1

Description
Intervention group: after justifying the patients and providing the necessary training, in addition to the routine treatment program (including prescribing medicine (if needed), giving verbal advice on following dietary instructions and having regular physical activity 150 minutes per week), a written prescription to perform Regular walking will be prescribed for 150 minutes of walking per week (as desired in the morning or evening and preferably divided into weekdays).
Category
Treatment - Other

2

Description
Control group: after justifying the patients and providing the necessary training, a routine treatment program (including prescribing medicine (if needed), giving verbal advice on following dietary instructions and having regular physical activity 150 minutes per week) will be prescribed.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital of Shahroud
Full name of responsible person
Dr. Tahereh Jalali
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahroud University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic

Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Seyd Mostafa Alavi
Position
Medical Student
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available