Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the Effectiveness of Pilot Implementation of Physical Activity Intervention of WHO at the Level of Physical Activity on Adults with Type 2 Diabetes

Protocol summary

Study aim

The aim of this study is to evaluate the effectiveness of the implementation of physical activity intervention of WHO at the level of physical activity on the patients with type 2 diabetes.

Design

Randomized controlled trial, community based, parallel group

Settings and conduct

Participants will be randomly assigned to intervention 1 group, intervention 2 group, and control, with a randomization computerized program. The participants and the data analyzers will be blinded to the study groups. In-person and leaflet educational materials will be provided for both intervention study groups, but only the intervention group 1 will receive text messages about physical activity.

Participants/Inclusion and exclusion criteria

Inclusion criteria include an age between 18 and 65 years old, diagnosis of type 2 diabetes, being inactive based on WHO (less than weekly 150 minutes of moderate-intensity activity), being able to read and write, having access to a mobile phone that receives text messages, and an informed consent to participate in the study. People with uncontrolled hypertension, heart failure, valvular heart disease, advanced lung disease, stroke, or myocardial infarction in the last 6 months, severe, unplanned weight loss (more than 10%) in the last 6 months, pregnant people, people with any condition or disease that prevent them from doing physical activity, or a positive response to any items of the Physical Activity Readiness Questionnaire (PARQ-10) will be excluded.

Intervention groups

Both intervention group 1 and 2 will receive primary education about physical activity using in-person explanations and leaflets. The first case group will also receive text messages regarding physical activity, unlike the other groups. The case group will receive no primary education or text message.

Main outcome variables

Physical activity levels and attitudes toward it

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180129038545N3**
Registration date: **2026-10-13, 1405/07/21**
Registration timing: **prospective**

Last update: **2026-10-13, 1405/07/21**
Update count: **0**

Registration date

2026-10-13, 1405/07/21

Registrant information

Name

Maryam Selk Ghaffari

Name of organization / entity

Sports Medicine Research Center Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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selk1360@gmail.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-12-22, 1405/10/01

Expected recruitment end date
2027-04-21, 1406/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Effectiveness of Pilot Implementation of Physical Activity Intervention of WHO at the Level of Physical Activity on Adults with Type 2 Diabetes

Public title
Physical Activity Intervention in Type 2 Diabetes
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
People aged 18-65 with diagnosed type 2 diabetes Inactive people based on WHO (less than weekly 150 minutes of moderate-intensity activity) Being able to read and write Having access to a mobile phone that receives SMS Informed consent
Exclusion criteria:
Being diagnosed with uncontrolled hypertension, heart failure, valvular heart disease, advanced lung disease, stroke, or myocardial infarction in the last 6 months Severe, unplanned weight loss (more than 10%) in the last 6 months Pregnancy Any condition or disease, including orthopedic conditions, preventing from physical activity A positive response to one or more items of the Physical Activity Readiness Questionnaire (PARQ-10)
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible participants based on inclusion and exclusion criteria, after receiving a comprehensive explanation of the study, providing written informed consent, and having their demographic information and baseline assessment data definitively recorded in the study database, will be irrevocably entered into the randomization process to prevent selection bias during participant enrollment. Participants will be individually allocated to the intervention and control groups in a 1:1 ratio. The simple randomization sequence will be generated before the commencement of participant recruitment by an independent biostatistician who is not involved in the clinical team or patient recruitment process, using the random number generation module of SPSS statistical software, version 26. To minimize selection bias at the allocation stage, sequentially numbered, opaque, sealed, foil-lined envelopes will be used for allocation concealment. Each envelope will be opened strictly in numerical sequence and only after the participant's baseline information has been definitively recorded in the study database. This procedure will ensure that the treating physician has no opportunity to predict or influence the allocation of the next participant. Thus, group allocation will remain concealed until each participant’s enrollment in the study has been finalized.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this double-blinded study, the participants and the data analyzers are blind to the study groups. The participants of both case groups will undergo primary education about physical activity, but only one case group will receive text messages during the six weeks of intervention. The control group will receive no education and text messages. The investigator of the study is not blind to the study groups, but the analyzers are not aware of the study groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
16th Azar St., Enghelab Sq., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417466191
Approval date
2023-10-08, 1402/07/16
Ethics committee reference number
IR.TUMS.NI.REC.1402.032

Health conditions studied

1

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

E11.9

ICD-10 code description

Type 2 diabetes mellitus without complications

Primary outcomes

1

Description

Level of physical activity

Timepoint

Before and after the intervention

Method of measurement

Exercise Vital Sign questionnaire

2

Description

Attitudes toward physical activity

Timepoint

Before and after the intervention

Method of measurement

Attitudes toward physical activity questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Receiving text messages about physical activity along with primary educational content. At baseline, participants receive oral and written educational content about the importance of physical activity for people with type 2 diabetes. Those who are assigned to this case group will receive text messages as well. The intervention lasts six weeks and the case group receives three text messages each week (total = 18 messages). The content of messages varies and ranges from motivation, information, and encouragement to monitoring oneself.

Category

Lifestyle

2

Description

Control group: The participants of this group will not receive text messages and they will not receive education content about physical activity.

Category

Lifestyle

3

Description

Intervention group 2: Receiving only primary educational content. At baseline, participants receive oral and written educational content about the importance of physical activity for people with type 2 diabetes. This group will not receive text messages.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Maryam Selk Ghaffari

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Jalal-e-Al-e-Ahmad Hwy., Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ramin Kordi

Street address

Tehran University of Medical Sciences, Corner of Qods St., Keshavarz Boulevard, Tehran

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ramin_kordi@tums.ac.ir

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

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
Tehran University of Medical Sciences

Full name of responsible person
Maryam Selk Ghaffari

Position
Sports medicine specialist

Latest degree
Specialist

Other areas of specialty/work
Sport Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Information of the outcomes, including physical activity levels and attitudes towards it, will be shared.

When the data will become available and for how long
The data will be available starting six months after publication.

To whom data/document is available
People working in academic institutions can apply to receive the data.

Under which criteria data/document could be used
No limitation is set.

From where data/document is obtainable
Contact the email selk1360@gmail.com

What processes are involved for a request to access data/document
Thr data will be available starting 6 months after publication by contacting selk1360@gmail.com for 6 month after obtaining contact information of the

researcher.

Comments