

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effect of Training and Using the Capabilities of the Smartphone Pedometer Program on Sedentary Behavior and Physical Activity in Students

Protocol summary

Study aim

Determine the Effect of Training and Use of the Smartphone Pedometer Program on Sedentary behavior and physical activity in students

Design

A randomized clinical trial with a intervention and control group, double blind, stratified randomization, the sample of this research is a total of 100 people.

Settings and conduct

This study is a randomized clinical trial study. Samples will be selected from among non-medical students of Tehran University in a continuous sampling method based on entry and exit criteria, and after obtaining informed written consent, will be classified into two groups of control and intervention by stratified random allocation. Double blinding will be done on the researcher and the participants. This intervention involves installing pedometer software and training on the use of its capabilities, as well as intervention team will daily receive 7 short messages each week from the researcher.

Participants/Inclusion and exclusion criteria

The criteria for entering the study include the first or second year students studying at comprehensive universities in Tehran; inadequate physical activity according to the WHO guidelines. Non-entry criteria include obvious disability and physical disability which affects the person's ability to exercise physically. Also the active use of Pedometer Software.

Intervention groups

The intervention will take place for one month. This intervention involves installing pedometer software and training on the use of the program's capabilities. The intervention team will daily receive 7 short messages each week from the researcher, including 5 messages with informative content and 2 messages with motivational content. At the end of the study, the content of texting and teaching the use of pedometer program

capabilities in the form of pamphlets will be provided to the control group.

Main outcome variables

Physical Activity, Sedentary Behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190710044170N1**

Registration date: **2019-07-16, 1398/04/25**

Registration timing: **prospective**

Last update: **2019-07-16, 1398/04/25**

Update count: **0**

Registration date

2019-07-16, 1398/04/25

Registrant information

Name

Adel Alizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 5273 5114

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-07, 1398/06/16

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Training and Using the Capabilities of the Smartphone Pedometer Program on Sedentary Behavior and Physical Activity in Students

Public title
Effect of Training and Using the Capabilities of the Smartphone Pedometer Program on Sedentary Behavior and Physical Activity in Students

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Students of the first or second year of studying at comprehensive universities in Tehran inadequate physical activity according to the WHO guidelines (at least 150 minutes of moderate intensity or 75 minutes of intense activity per week) Owning a smartphone that owns the student and has a continuous presence Internet access via smartphone Ability to read and write in Persian language run the pedometer application completely by researcher
Exclusion criteria:
 Manifest disability and physical disability that affecting the individual's ability to exercise physically Psychological disorder such as depression is a psychiatric diagnosis and a student statement that lowers his desire for mobility Active use of pedometer software

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples will be randomly Stratified assign into two groups of control and intervention; in this type of allocation, people will be placed in two layers of software installation without active use and no installation of the software on the smartphone. Then samples of each layer in the method Blocks will be divided into two groups of intervention and control; random sequences will be created based on web-based randomization and will be used to hide random assignments from sealed non-transparent envelopes that are numbered.

Blinding (investigator's opinion)
Double blinded

Blinding description

The double blinding will be implemented in the participants and the researcher in such a way that the participants will be provided with the questionnaire after knowing the goals of the study and willing to participate in the study and signing informed written consent. Participants are unaware that they will be in the intervention group or in the control group. The researcher does not know whether the participant is in the intervention or control group.

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

Qods St., Keshavarz Blvd, Tehran

City

Tehran

Province

Tehran

Postal code

7434115761

Approval date

2019-05-15, 1398/02/25

Ethics committee reference number

IR.TUMS.VCR.REC.1398.143

Health conditions studied

1

Description of health condition studied

Educational intervention in the field of healthy lifestyle

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

To determine the physical activity of students, a short form of the International Physical Activity Questionnaire will be used. This questionnaire measures the physical activity of individuals in the past 7 days and based on the formula for the participants' energy consumption (METs-min / week) during activity Light, moderate and severe, and individuals will take place in three groups with low physical, moderate, and high levels of physical

activity.
Timepoint
Before the intervention and one month after the intervention
Method of measurement
International Questionnaire of Physical Activity (Short Form)

Secondary outcomes

1

Description

Sedentary behavior in this research is a score that a person takes from the ASAQ questionnaire. Using this questionnaire, student sitting sessions (watching TV, watching a movie, using a computer, etc.) that are grouped into five general categories during a The week is measured in min / day and then the sitting behavior of individuals will be accumulated over a week.

Timepoint

Before the intervention and one month after the intervention

Method of measurement

Adolescent Sedentary Activity Questionnaire

Intervention groups

1

Description

Intervention group: For the test group, the intervention will take place for one month. This intervention involves installing step-by-step software and training on the use of the program's capabilities. The intervention team will receive 7 short messages each week from the researcher who will send them on a daily basis, including 5 messages with informative content and 2 messages with motivational content.

Category

Lifestyle

2

Description

Control group: The control group will not receive training during the intervention but at the end of the study, the content of texting and teaching the use of step-by-step program capabilities in the form of pamphlets will be provided to the control group.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University

Full name of responsible person

Adel Alizadeh

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Sponsors / Funding sources

1

Sponsor

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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

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

Adel Alizadeh

Position

Master of Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Some of the information, such as a sample demographic profile form without personal information of individuals, as well as some information on the primary consequences (primary and secondary), can be shared.

When the data will become available and for how long

Start the access period 9 months after printing results

To whom data/document is available

Researchers working in academic and scientific institutions, students as well as people working in the industry

Under which criteria data/document could be used

After the publication of the article, the use of the results of the study by reference to the article in question or the use of the results with respect to the author in the industry is not permitted.

From where data/document is obtainable

Adel Alizadeh by email alizadeh-a@razi.tums.ac.ir or mobile number 09174457463

What processes are involved for a request to access data/document

After the call by applicant the documentation will be provided by researcher; authorize researcher is important.

Comments

