Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Determining the Effectiveness of a Combined Pedometer App and Virtual Support Group Intervention on Physical Activity Level and Physical Function among Community-Dwelling Older Adults with Low Physical Activity in Tehran

Protocol summary

Study aim

The primary objective of this study is to determine the effectiveness of a combined intervention based on a pedometer application and a virtual support group on physical activity level and physical function among community-dwelling older adults with low physical activity in Tehran.

Design

A randomized controlled clinical trial with two parallel intervention and control groups will be conducted among 60 older adults using a pretest–posttest design and simple individual randomization with a 1:1 allocation ratio in SPSS (30 participants per group).

Settings and conduct

This randomized controlled trial will be conducted in selected Comprehensive Health Service Centers in Tehran. After sampling and obtaining informed consent, 60 older adults will be randomly allocated to intervention and control groups; the intervention will be implemented for 12 weeks, with assessments conducted at pretest and posttest. Outcome assessors will be blinded to group allocation at both stages.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Community-dwelling older adults aged 60 years and older in Tehran, with low physical activity, independent walking ability, a smartphone with internet access, no evidence of cognitive impairment, and informed consent. Exclusion criteria: Severe conditions limiting physical activity, major fracture or surgery within the previous 6 months, suspected cognitive impairment, and concurrent participation in another physical activity intervention study.

Intervention groups

Intervention Groups: Installation of a pedometer app, daily step goal-setting and monitoring, combined with virtual education and support for 12 weeks. Control Group: Usual care; the pedometer app will be installed in an inactive mode, and the control virtual group will be used only for general information and study coordination.

Main outcome variables

Physical activity level; Physical function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260923071168N1**
Registration date: **2026-10-07, 1405/07/15**
Registration timing: **prospective**

Last update: **2026-10-07, 1405/07/15**
Update count: **0**

Registration date

2026-10-07, 1405/07/15

Registrant information

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Vahab Abbaszadeh
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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-12-01, 1405/09/10

Expected recruitment end date
2027-01-30, 1405/11/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Determining the Effectiveness of a Combined Pedometer App and Virtual Support Group Intervention on Physical Activity Level and Physical Function among Community-Dwelling Older Adults with Low Physical Activity in Tehran

Public title
The Effect of a Pedometer App and a Virtual Support Group on the Physical Activity among Community-Dwelling Older Adults with Low Physical Activity
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age 60 years or older and residence in Tehran Low level of physical activity (physically inactive) based on the International Physical Activity Questionnaire (IPAQ) Ability to walk independently Having a smartphone capable of installing the pedometer application and having access to the Internet No evidence of cognitive impairment based on initial screening using the Abbreviated Mental Test Score (AMTS) Willingness to participate in the study and provision of written informed consent
Exclusion criteria:
Having severe acute or chronic diseases that prevent participation in physical activity History of major fracture or major surgery within the past 6 months Suspected cognitive impairment based on an AMTS score of less than 6 Concurrent participation in other interventional studies related to physical activity
Age
From **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be allocated to the intervention and control groups using simple randomization with a 1:1 allocation ratio. The unit of randomization will be the individual participant, and individual randomization will be used; block, cluster, and stratified randomization will not be used. After identification of all eligible participants and obtaining written informed consent, a final list of participants will be prepared and each participant will be assigned a unique identification code. The participant codes will then be entered into SPSS statistical software, version 27, and using simple randomization, 30 codes will be randomly selected for the intervention group, while the remaining 30 codes will be allocated to the control group. The random allocation sequence will be generated and implemented by a person independent of the researcher and outcome assessors. The researcher and outcome assessors will not be involved in generating the random sequence or assigning participants to the study groups. Group allocation will be performed after eligibility has been confirmed and written informed consent has been obtained. Thus, group allocation will not be predetermined by the researcher and will be performed by an independent person.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study will be single-blinded. The outcome assessors and data collectors at both the pre-test and post-test stages will be blinded to the participants' group allocation. The participants and the intervention researcher will be aware of the group allocation.
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 – School of Nursing and Midwifery and Scho
Street address
No. 288, Mehr Street, Mehrshahr, Birjand, South Khorasan Province, Iran
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Tehran
Province
Tehran
Postal code
9716156478
Approval date
2026-09-21, 1405/06/30
Ethics committee reference number
IR.TUMS.FNM.REC.1405.112

Health conditions studied

1

Description of health condition studied
Lack of physical exercise

ICD-10 code
Z72.3
ICD-10 code description
Lack of physical exercise

Primary outcomes

1

Description
Participants' physical activity level assessed using the International Physical Activity Questionnaire and reported as MET-minutes/week.
Timepoint
Measured at baseline, before initiation of the intervention (week 0), and after completion of the 12-week intervention (week 12).
Method of measurement
Measured using the International Physical Activity Questionnaire (IPAQ), long form, which assesses physical activity during the previous 7 days, including vigorous-intensity, moderate-intensity activities, and walking.

2

Description
Mean daily step count over 7 days
Timepoint
Measured at baseline, before initiation of the intervention (week 0), and after completion of the 12-week intervention (week 12).
Method of measurement
Measured using the Google Fit application and the smartphone's built-in step-counting sensor, based on daily step counts recorded over 7 days.

3

Description
Participants' physical function based on the Short Physical Performance Battery (SPPB) score, including balance, gait speed, and the five-times sit-to-stand test.
Timepoint
Measured at baseline, before initiation of the intervention (week 0), and after completion of the 12-week intervention (week 12).
Method of measurement
Measured using the Short Physical Performance Battery (SPPB), comprising three components: balance, gait speed, and the five-times sit-to-stand test. Physical function is reported based on the total SPPB score.

Secondary outcomes

1

Description
Health-related quality of life score
Timepoint
Measured at baseline, before initiation of the intervention (week 0), and after completion of the 12-week intervention (week 12).
Method of measurement
Measured using the 12-Item Short Form (SF-12)

2

Description
Systolic and diastolic blood pressure levels
Timepoint
Measured at baseline, before initiation of the intervention (week 0), and after completion of the 12-week intervention (week 12).
Method of measurement
Measured using a calibrated digital upper-arm blood pressure monitor after seated rest and according to a standardized blood pressure measurement protocol. Results are reported in millimeters of mercury (mmHg).

3

Description
Depression score
Timepoint
Measured at baseline, before initiation of the intervention (week 0), and after completion of the 12-week intervention (week 12).
Method of measurement
با استفاده از مقیاس ۱۵ سؤالی افسردگی سالمندان (GDS-15؛ Geriatric Depression Scale) برای غربالگری علائم افسردگی در سالمندان. نمره کل مقیاس برای ارزیابی علائم افسردگی استفاده خواهد شد.

Intervention groups

1

Description
Intervention group: Participants in the intervention group will receive a 12-week combined intervention consisting of a pedometer application and virtual support. At the beginning of the intervention, the Google Fit pedometer application will be installed on participants' smartphones, and they will receive training on how to use the application. An individualized daily step goal will be set for each participant according to their baseline physical activity level and individual circumstances. Participants will be asked to monitor and record their daily step counts. In addition, a virtual support group will be established for the intervention participants. Throughout the 12-week intervention, education related to increasing physical activity, motivational messages, social support, and strategies for overcoming barriers to physical activity will be provided through the virtual group. Participants' progress will be regularly monitored, and individual and group feedback will be provided regarding their progress and achievement of the established goals.
Category
Lifestyle

2

Description
Control group: Participants in the control group will receive usual care and will not receive any specific

intervention aimed at increasing physical activity during the 12-week study period. To minimize intervention contamination, the Google Fit pedometer application will also be installed on the smartphones of control-group participants; however, it will remain inactive, with no step goal-setting, feedback, or motivational features enabled. In addition, control-group participants will be placed in a separate virtual group used only for general study-related information and coordination of assessments. No educational, motivational, or intervention-related supportive content will be provided through this group.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Private
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
Vahab Abbaszadeh
Position
MSc Student in Geriatric Health
Latest degree
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Person responsible for updating data

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

Clinical Study Report
Undecided - It is not yet known if there will be 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