Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effectiveness of Using Digital Health and Physical Activity Monitoring Tools on Health Indicators and Treatment Adherence in Older Adults: A Randomized Controlled Study

Protocol summary

Study aim

Investigating the effectiveness of using digital health monitoring tools on improving physical health indicators and medication adherence in the elderly

Design

A randomized, single-blind, parallel-group, controlled clinical trial on 80 individuals over 60 years of age.

Settings and conduct

This randomized controlled trial enrolls adults ≥60 years attending six Tehran Oil Industry family health centers. Participants are selected through stratified random sampling proportional to each center's share and gender balance, yielding 80 individuals. Assignment to the intervention (40) and control (40) groups uses stratified-block randomization by an independent statistician with allocation concealment via opaque numbered envelopes. Because the intervention—a digital package with a smartwatch and mobile app—cannot be blinded to participants, only the outcome assessor and statistical analyst are blinded. The 12-week intervention includes training, technical support, and adherence monitoring through weekly reports and motivational calls. Measurements are obtained at baseline and every two weeks using questionnaires, blood pressure/glucometer readings, and wearable-device data, and analyses employ appropriate statistical tests such as paired/independent t-tests, chi-square, and multivariate regression.

Participants/Inclusion and exclusion criteria

People aged 60 and over who visit family health centers and are literate or have a caregiver are included in this plan, and those who do not cooperate or have cognitive impairments are excluded.

Intervention groups

In the intervention group, people use a digital watch with a medication reminder app, a pedometer, and a heart rate monitor. The control group receives only usual care.

Main outcome variables

Fasting blood sugar; medication adherence; satisfaction with technology; use of devices, diastolic and systolic blood pressure.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251102067858N2**
Registration date: **2025-12-09, 1404/09/18**
Registration timing: **prospective**

Last update: **2025-12-09, 1404/09/18**
Update count: **0**

Registration date

2025-12-09, 1404/09/18

Registrant information

Name

Farhad Moradi Shahpar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8863 0228

Email address

f_moradishahpar@sbu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-22, 1404/10/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Using Digital Health and Physical Activity Monitoring Tools on Health Indicators and Treatment Adherence in Older Adults: A Randomized Controlled Study

Public title

The effectiveness of digital tools in improving the health of the elderly

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Elderly people over 60 years of age visiting family health centers Being literate or having a home caregiver

Exclusion criteria:

Non-cooperation Severe cognitive problems

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling method Sampling of elderly people ≥60 years old is done by stratified random sampling from six family health centers of Tehran Oil Industry. Each center has a quota proportional to the population covered and gender distribution (50% female, 50% male) is maintained in the initial selection process. Random allocation method Eligible participants enter the study after written consent. The method of allocation of participants to groups is based on "stratified block randomization"; in this way, according to the combination of "health center × gender", twelve layers are formed and in each layer, variable blocks of 4 and 6 people are used to prevent predictability of the sequence. The allocation ratio in all layers is 1:1 so that in the end, each group consists of 40 people (20 women and 20 men) with complete gender balance. Random sequences are generated by an independent statistician using Random Allocation Software. To conceal the allocation, opaque, sealed, and numbered envelopes are used, and the researcher responsible for registration will be unaware of the allocation sequence until the envelope is opened.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the intervention, blinding of participants is not possible, but the outcome assessor and statistical analyst will be blinded to the type of intervention. The master sequence file will be kept by an independent statistician, and a full description of the randomization method will be recorded and documented in an appendix to the protocol.

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 Sceinces

Street address

6th floor, Headquarters of Tehran University of Medical Sceinces, Corner of Qods St. Kehsavarz Blvd

City

Tehran

Province

Tehran

Postal code

141765383761

Approval date

2025-07-13, 1404/04/22

Ethics committee reference number

IR.TUMS.NI.REC.1404.019

Health conditions studied

1

Description of health condition studied

Hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

2

Description of health condition studied

Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Using tools
Timepoint
At the beginning of the study and 2 weeks, 4 weeks, 6 weeks, 8 weeks, 10 weeks and 12 weeks after the start of the intervention (use of the bracelet/smartwatch)
Method of measurement
Questionnaire (yes/no)

Secondary outcomes

1

Description
Fasting Blood Sugar
Timepoint
At the beginning of the study and 2 weeks, 4 weeks, 6 weeks, 8 weeks, 10 weeks and 12 weeks after the start of the intervention (use of the bracelet/smartwatch)
Method of measurement
Glucometer

2

Description
Systolic and diastolic blood pressure
Timepoint
At the beginning of the study and 2 weeks, 4 weeks, 6 weeks, 8 weeks, 10 weeks and 12 weeks after the start of the intervention (use of the bracelet/smartwatch)
Method of measurement
Digital blood pressure monitor

3

Description
Medication adherence
Timepoint
At the beginning of the study and 2 weeks, 4 weeks, 6 weeks, 8 weeks, 10 weeks and 12 weeks after the start of the intervention (use of the bracelet/smartwatch)
Method of measurement
Score from the MMAS-8 questionnaire

4

Description
Satisfaction with technology
Timepoint
At the beginning of the study and 2 weeks, 4 weeks, 6 weeks, 8 weeks, 10 weeks and 12 weeks after the start of the intervention (use of the bracelet/smartwatch)
Method of measurement
Average scores on the TAM (Technology Acceptance Model) questionnaire

Intervention groups

1

Description
The intervention includes a “digital elderly monitoring package” consisting of a TCHZ10 smartwatch capable of measuring steps, hourly activity, heart rate, and data transmission to a dedicated study app; the app is activated with a participant-specific user account, daily status dashboard, educational messages, and the ability to automatically send data to a secure research server. The intervention will be implemented for 12 weeks, and participants are required to use the device for at least 10 hours per day. At the beginning, a 30- to 45-minute in-person session will be held at the center for installation, instruction in use, and brochure presentation, and telephone support will be provided for technical issues and reporting of potential complications throughout the study. Adherence will be monitored by receiving weekly reports of usage hours and key indicators, and in the event of decreased adherence, motivational calls and troubleshooting guidance will be made. The control group will receive the center’s usual care without any digital tools. All device settings, app version, and educational instructions are fully documented in the protocol’s technical appendix, allowing for accurate replication of the intervention.
Category
Prevention

2

Description
Control group: The control group only receives the usual care provided in family health centers, namely examination, prescription of medication and diagnostic procedures, drug counseling, and specialist referral if necessary.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Oil Industry Family Health Centers
Full name of responsible person
Kourosh Hashemi Asl
Street address
No.27, Behafarin St. Karimkhan Ave, Valiasr Square
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1415814687
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ramin Kordi
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6th floor, Headquarter of Tehran University of Medical Sceinces, Corner of Qods St. Keshavarz Blvd
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141765383761
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vcr@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
Farhad Moradi Shahpar
Position
Reseacher
Latest degree
Ph.D.
Other areas of specialty/work
Sport Medicine
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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
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
If requested by the researchers, after observing ethical and legal considerations, all data will be made available exclusively to the researcher in the form of an Excel or SPSS file in order to advance knowledge, without mentioning the names and characteristics of the subjects.

When the data will become available and for how long
Up to one year after publication of the article

To whom data/document is available
Reputable researchers at academic institutions

Under which criteria data/document could be used
For use in subsequent research, which must be approved by the research ethics committee of a university or an accredited scientific center. This request is subject to approval by the Research Council of the Sports Medicine Research Center. Therefore, the subsequent analysis of the data must be based on research ethics and contribute to the advancement of knowledge.

From where data/document is obtainable
The research manager Dr. Farhad Moradi Shahpar should be emailed. E-mail address: drfmoradi@yahoo.com

What processes are involved for a request to access data/document
After receiving the request from the Research Council of the Research Center, the research plan is prepared and, if approved, the desired information is made available to the researcher, in compliance with legal requirements.

Comments