Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Impact of a Self-Care Navigator Application on Physical and Spiritual Health Behaviors

Protocol summary

Study aim
Investigating the Impact of a Self-Care Navigator Application on Physical and Spiritual Health Behaviors

Design
This is a randomized, single-blind, parallel-group, controlled clinical trial involving 80 volunteers. The intervention group will be provided with a self-care application, while the control group will receive a pamphlet. Health behaviors will be assessed in both groups before and after the educational intervention.

Settings and conduct
Eligible individuals referring to Taleghani Hospital in Tehran will be enrolled in the study after completing informed consent and will be randomly assigned to the control and intervention groups. The researcher, outcome collector, and data analyst will be blinded to the allocation of participants to the study groups.

Participants/Inclusion and exclusion criteria
They must be over 18 years of age, willing to install the self-care app on their mobile phones, and not suffer from an illness requiring hospitalization.

Intervention groups
The intervention group receives a self-care application—a mobile-based program featuring educational content on health behaviors. The control group receives instruction via a pamphlet containing educational content on health behaviors.

Main outcome variables
Health behaviors

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210131050189N20**
Registration date: **2026-10-18, 1405/07/26**
Registration timing: **registered_while_recruiting**
Last update: **2026-10-18, 1405/07/26**
Update count: **0**

Registration date
2026-10-18, 1405/07/26

Registrant information

Name
Raziyeh Ghafouri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 28 3335 4520

Email address
ghafouri@sbmu.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-17, 1405/07/25

Expected recruitment end date
2027-10-22, 1406/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the Impact of a Self-Care Navigator Application on Physical and Spiritual Health Behaviors

Public title
Impact of a Self-Care Navigator Application

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Ability to use a smartphone. Being literate (able to read

and write).

Exclusion criteria:

Contracting an illness requiring hospitalization

Age

From **18 years** old to **65 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

Random assignment of participants to two intervention and control groups will be done with the help of statistical randomization software using simple randomization methods and in parallel. Before the intervention, the study is registered in the Study Randomizer web application software, available at (https://www.studyrandomizer.com). The research information, including the number of 80 participants, two intervention groups, and random and parallel allocation to the two groups, is given to the software. After registering the study, by clicking on the participant entry option, the software randomly enters the individual into one of the two groups and gives him a code. 80 samples are entered into the software in the same way, and a random sequence is prepared with the software from 1 to 80. To conceal the random sequence, 80 sealed envelopes are then prepared, and the envelopes are numbered from 1 to 80. Then, the random sequence prepared by the software is placed in the envelopes in the intervention groups from 1 to 80 in order. Then, as each person enters the study, their envelope is opened, and they are placed in one of two study groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this way, researcher A makes the allocation and the results are recorded by researcher B, who is unaware of the group allocation. The data analyst will also be unaware of the grouping of participants.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of School of Pharmacy and Nursing & Midwifery- SBMU

Street address

SBMU School of Pharmacy and Nursing & Midwifery, Vali-Asr Avenue, Cross of Vali-Asr Avenue and Hashemi Rafsanjani (Neiaiesh) Highway, Tehran.

City

Tehran

Province

Tehran

Postal code

1996835119

Approval date

2026-09-15, 1405/06/24

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1405.179

Health conditions studied

1

Description of health condition studied

Unhealthy lifestyle

ICD-10 code

Z72

ICD-10 code description

Problems related to lifestyle

Primary outcomes

1

Description

Health behaviors

Timepoint

One week before the intervention, two weeks after the completion of the educational intervention.

Method of measurement

Health Behavior Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group is provided with a self-care application. This application is mobile-based software containing educational content and information on health behaviors.

Category

Lifestyle

2

Description
Control group: In the control group, education is provided via a pamphlet containing educational content on health behaviors.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
(Ayatollah) Taleghani Educational Hospital
Full name of responsible person
Raziyeh Ghafouri
Street address
Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
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19839-63113
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zargi
Street address
Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
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Email
Intl_office@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Raziyeh Ghafouri
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Nursery
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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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

All data is shareable after de-identifying individuals

When the data will become available and for how long

After the publication of the article

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

More research

From where data/document is obtainable

By email to the corresponding author: raziehghafouri@gmail.com

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

By email to the corresponding author: raziehghafouri@gmail.com

Comments