

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Investigating the effect of using the mobile health program in communities on reducing the incidence of seasonal diseases

Protocol summary

Study aim

Investigating the effect of using the mobile health program in communities on reducing the incidence of seasonal diseases

Design

The study will be conducted as a clinical trial with a control group, with parallel groups, one-sided blind, with the participation of 80 patients hospitalized due to trauma. Randomization will be done using white and black colored cards.

Settings and conduct

People participating in the mass gatherings, if they are eligible, will be included in the study and will be randomly assigned to two intervention and control groups using colored cards. This study will be performed in a blind way. In this way, researcher A will do the evaluation and error checking will be done by researcher B, who will be unaware of the allocation of groups. Also, the data analyst will not know about the grouping of the participants.

Participants/Inclusion and exclusion criteria

The condition for entering the study is hospitalization due to trauma, and the condition for not entering is not having a smart phone and not wanting to use a mobile app.

Intervention groups

In the intervention group, using health software in the prepared communities, they are taught about common seasonal diseases such as influenza, covid, heatstroke, etc., and their ability to identify early symptoms and self-care is improved. In the control group, regular training is given using pamphlets.

Main outcome variables

Reducing the incidence of seasonal diseases such as flu, heat stroke, etc.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210131050189N8**
Registration date: **2023-12-29, 1402/10/08**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-29, 1402/10/08**

Update count: **0**

Registration date

2023-12-29, 1402/10/08

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

Recruitment complete

Funding source

Expected recruitment start date

2023-12-21, 1402/09/30

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of using the mobile health program in communities on reducing the incidence of seasonal diseases

Public title

The effect of the mobile health program in communities on reducing the incidence of seasonal diseases

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a smart phone Hospitalized due to trauma

Exclusion criteria:

Reluctance to use mobile application for initial assessment after 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

Before starting the research, 40 white color cards and 40 black cards will be prepared. All the cards will be placed in an envelope, then the cards will be taken out randomly and numbered from 1 to 80 in order of exit. Each card will then be placed in a sealed envelope and its number will be written on the envelope. As each patient enters the study, a special envelope from number 1 to 80 will be opened for him. If the card is white, the participant will be assigned to the intervention group, and if the card is black, the participant will be assigned to the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluation of patients is done by researcher A, and the evaluation of the incidence of seasonal diseases (heatstroke, flu) is checked by researcher B. Also, the data analyst will not know the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Shahid Beheshti

University of Medical Sciences

Street address

Shahid Arabi Street, Yemen Street, Shahid Chamran Highway, Tehran, Iran

City

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Province

Tehran

Postal code

1985717443

Approval date

2023-10-09, 1402/07/17

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1402.109

Health conditions studied**1****Description of health condition studied**

Heat stroke

ICD-10 code

T67.0

ICD-10 code description

Heatstroke and sunstroke

2**Description of health condition studied**

Influenza

ICD-10 code

J10

ICD-10 code description

Influenza due to other identified influenza virus

Primary outcomes**1****Description**

Getting heatstroke

Timepoint

One month after using the program

Method of measurement

Occurrence of heatstroke symptoms: dizziness, pressure drop and heart palpitations in hot environments

2**Description**

Getting the flu

Timepoint

One month after using the program

Method of measurement

Influenza symptoms: fever, weakness, lethargy and fatigue

Secondary outcomes

empty

Intervention groups

taleghani@sbmu.ac.ir

1

Description

Intervention group: In the intervention group, using health software in the prepared communities, they are taught about common seasonal diseases such as influenza, covid, heatstroke, etc., and their ability to identify early symptoms and self-care in prevention of common seasonal diseases is improved.

Category

Prevention

2

Description

Control group: In the control group, regular training is given using pamphlets.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital, Tehran

Full name of responsible person

Raziyeh Ghafouri

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Recruitment center

Name of recruitment center

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Full name of responsible person

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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 Zergi

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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

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

Assistant 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

By email to the corresponding author
raziehghafouri@gmail.com

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