

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The effect of smartphone-based self-management application on asthma control

Protocol summary

Study aim

The effect of a smartphone-based asthma self-management app on asthma control

Design

A clinical trial study with an intervention and control group, with parallel, randomized groups on 60 patients. For randomization, the block randomization method with placement will be used.

Settings and conduct

The study population was patients with asthma referred to the only subspecialty clinic for asthma and allergies in Kashan, Iran. The application (app) will be installed on the smartphone of asthma patients in the intervention group, and a complete description of how to use the app will be provided to them by the physician. All patients are evaluated and trained in the inhalation technique at the beginning of the study (T0) and receive an action plan. After starting the study, patients are called to the clinic every 3 and 6 months (T1 and T2) to evaluate the outcomes.

Participants/Inclusion and exclusion criteria

Patients with asthma have a smartphone with a minimum age of 18 years and at least primary education and a diagnosis of intermittent or persistent asthma were included in the study and patients with other chronic respiratory diseases were excluded.

Intervention groups

The control group includes patients who receive their usual treatment, and the intervention group uses a smartphone-based application in addition to the usual treatment.

Main outcome variables

Asthma control test score and quality of life score of patients with asthma

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210621051651N1**

Registration date: **2021-07-08, 1400/04/17**

Registration timing: **prospective**

Last update: **2021-07-08, 1400/04/17**

Update count: **0**

Registration date

2021-07-08, 1400/04/17

Registrant information

Name

Reihane alsadat Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5531 1454

Email address

sharif-rs@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of smartphone-based self-management application on asthma control

Public title

The effect of smartphone-based self-management application on asthma control

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with asthma at least 18 years old and minimum level of primary education Patients with asthma with a diagnosis of intermittent or persistent asthma approved by a physician. Patients with asthma have a smartphone with an Android operating system that can install the application.

Exclusion criteria:

Patients with asthma who do not have the knowledge to use a smartphone properly. Patients with other chronic respiratory diseases (except asthma)

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this randomized controlled trial study, patients with asthma were divided into two groups of intervention (n = 30) and control (n = 30) by Permuted Block Randomization. In this method, first, all blocks of size 4, which include two codes A and B, are prepared (6 blocks), then, using random numbers table, random blocks are selected by placement (15 blocks). These blocks form a sequence of 60 codes A and B, each of which is randomly assigned to one of the control and intervention groups. It should be noted that the effect of confounding variables will be controlled by the block randomization method.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

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

Research Ethics Committee of Faculty of Nursing &

Midwifery, Faculty of Health & Faculty of Paramedi

Street address

Qotb-e Ravandi Blvd

City

Kashan

Province

Isfahan

Postal code

8715973474

Approval date

2021-06-09, 1400/03/19

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1400.010

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

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

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

Asthma control test score using Asthma Control Test Questionnaire (ACT)

Timepoint

Baseline, after three months, after 6 months

Method of measurement

At each visit, patients will complete an asthma control test questionnaire used to assess symptoms.

Secondary outcomes**1****Description**

Quality of Life

Timepoint

Baseline, after three months, after 6 months

Method of measurement

At each visit, patients will complete a standard Asthma Quality of Life Questionnaire (AQLQ).

Intervention groups**1****Description**

Intervention group: The intervention includes an app designed in a previous study by a team of health information management professionals and asthma and allergy specialists using Adobe Air software under the Android operating system and its usability was successfully evaluated by patients with asthma (n = 30),

IT (n = 8) and asthma and allergy specialists (n = 2). This app has various functionalities such as providing educational information, recording information, setting reminders, and communicating with the doctor that helps patients to improve their adherence to treatment and self-care.

Category

Behavior

2

Description

Control group: The control group includes patients who receive their usual treatment.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr. Marzieh Heidarzadeh Arani

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Marz_heidar@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Hamid Reza Banafsheh

Street address

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City

Kashan

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8715988141

Phone

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Email

banafsheh_h@kaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Dr. Mehrdad Farzandipour

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Information Management

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Marzieh Heidarzadeh Arani

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Immunology

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Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Reihane Alsadat Sharif

Position

Ph.D. Candidate

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Participants' data files, and statistical analysis will be available in SPSS file format. The clinical study data will be published by the open paper.

When the data will become available and for how long

6 months after study publication

To whom data/document is available

Final results for all people and the data and statistical files on scientific centers request

Under which criteria data/document could be used

Only scientific and academic institutions can request access to data for scientific analysis.

From where data/document is obtainable

Kashan University of Medical Sciences, Health Information Management and Technology department, Reihane Alsadat Sharif

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

The request must be sent by post to the Department of Health Management and Information Technology of Kashan University of Medical Sciences or to the following email: sharif-rs@kaums.ac.ir

Comments