

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the effect of self-care education with two methods smartphone app and Teach Back methods on the lifestyle and quality of life of patients with inflammatory bowel disease

Protocol summary

Study aim

Comparison of the effect of self-care education with two methods smartphone app and Teach Back methods on the lifestyle and quality of life of patients with inflammatory bowel disease

Design

A three-group randomized clinical trial with a control group, with parallel groups, randomized by block, on inflammatory bowel patients, 90 patients

Settings and conduct

This study will include all patients with inflammatory bowel disease referred to the inflammatory bowel disease clinic of Ghaem Hospital and a gastroenterologist's clinic in Mashhad. Participants will be randomly assigned to three groups (two intervention groups and one control group) based on Inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years- Have Literacy for reading and writing to complete the questionnaire- Diagnosis by a specialist physician- Having a smartphone (For app group)- Ability to use smartphone apps(For app group)- Patients with at least 6 months of disease diagnosis- Not having other chronic illness with a doctor's diagnosis Not having mental illness with a doctor's diagnosis Exclusion criteria: The Occurrence of surgical procedure (maximum one month before post-test) The occurrence of specific medical conditions- Lack of willingness to continue participating in the study-

Intervention groups

Teach back group (Content will be taught to patients in 2 sessions (2 days) for 45 minutes. The training package will finally be provided to the patient within 7 days. The interval between training sessions will be 1-3 days.) App group: The app will be installed in a 30-minute session for patients, and they will be explained how to use the app.

Main outcome variables

Quality of life - lifestyle

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191026045251N1**

Registration date: **2020-08-30, 1399/06/09**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-30, 1399/06/09**

Update count: **0**

Registration date

2020-08-30, 1399/06/09

Registrant information

Name

Mohamad hossein Mafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3377 2208

Email address

mafimh971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of self-care education with two methods smartphone app and Teach Back methods on the lifestyle and quality of life of patients with inflammatory bowel disease

Public title
Effect of self-care education on the lifestyle and quality of life of patients with inflammatory bowel disease

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Have Literacy for reading and writing to complete the questionnaire Diagnosis by a specialist physician Having a smartphone Ability to use smartphone apps Patients with at least 6 months of disease diagnosis Not having other chronic illness with a doctor's diagnosis Not having mental illness illness with a doctor's diagnosis
Exclusion criteria:
Lack of willingness to continue participating in the study The occurrence of special medical conditions (leads to hospitalization of the patient) Occurrence of surgical procedure (maximum one month before post-test)

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: is block. Random unit: is individual. Randomization tool in study: statistical software SPSS. Randomization sequence of randomization software: Randomization software for sequencing people in blocks and drawing lots for the order of the blocks themselves. Allocation concealment method: The sequence created by randomization in opaque envelopes is closed.

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

Ethics committee of Mashhad University of Medical Sciences

Street address

University Ave, Next to the Hoveyze Cinema, Ghorashi building

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2019-10-12, 1398/07/20

Ethics committee reference number

IR.MUMS.REC.1398.200

Health conditions studied

1

Description of health condition studied

Crohn disease

ICD-10 code

K50

ICD-10 code description

Crohn's disease [regional enteritis]

2

Description of health condition studied

Ulcerative colitis

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes

1

Description

Quality of Life

Timepoint

Before and one month after the intervention

Method of measurement

Crohn's and ulcerative colitis questionnaire (CUCQ)

2

Description

life style

Timepoint

Before and one month after the intervention

Method of measurement

Miller-Smith questionnaire

Secondary outcomes

1

Description

Illness severity

Timepoint

Before the intervention, one month after the intervention

Method of measurement

questionnaire (Crohn's Disease Activity Index (CDAI),
Ulcerative Colitis Activity Index (UCAI))

2

Description

Recurrence and remission of the disease

Timepoint

Before the intervention, one month after the intervention

Method of measurement

questionnaire (Crohn's Disease Activity Index (CDAI),
Ulcerative Colitis Activity Index (UCAI))

Intervention groups

1

Description

The first Intervention group (Application group): In this group, self-care training will be provided to patients by the smartphone application. The content of the app will include (nutrition and diet, medication diet, sleep and rest, activity and exercise, smoking, social relations, sex and pregnancy, treatment follow-ups and periodic monitoring, vaccinations). The app will be provided to the patient for free and then after a month, a post-test will be taken from the patient. The patient will be contacted every 10 days to express their problems about using the app.

Category

Behavior

2

Description

Second intervention group (Teach back group): In this group, self-care training in two face-to-face sessions will be provided to patients individually. There will be two sessions a week. The interval between sessions is between 1 and 3 days.

Category

Behavior

3

Description

Control group: In this group, self-care training will not be provided to patients.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital, Inflammatory bowel disease clinic

Full name of responsible person

Mohamad Hossein Mafi

Street address

Ahmadabad Ave, Dr. Shariati Square

City

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Razavi Khorasan

Postal code

99199-91766

Phone

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Email

b.ghaem@mums.ac.ir

2

Recruitment center

Name of recruitment center

Dr. Hassan Vossoughinia's clinic

Full name of responsible person

Mohamad Hossein Mafi

Street address

No 20, Negin Sajjad building, Between Khayyam crossroads and Golriz crossroads, Sajjad Blvd

City

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+98 51 3760 1818

Email

VosoghiniaH@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Saeid Eslami Hasanabadi

Street address

Knowledge and Health City, In the end of Shahid Fakouri Blvd (In front of Fakouri 94)

City

Mashhad

Province

Razavi Khorasan

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99191-91778

Phone

+98 51 3841 2081

Email

p.relations@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mohamad Hossein Mafi

Position

MSc. Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Ibn Sina Ave,
Doctora Crossroads, University Blv

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Email

mafi1404@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Sadat Manzari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohamad Hossein Mafi

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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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

Part of the data is published as the main results.

When the data will become available and for how long

One year after the results are published

To whom data/document is available

Researchers who are researching in this field (inflammatory bowel disease).

Under which criteria data/document could be used

Analysis of main variables

From where data/document is obtainable

Researcher email

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

The data will be provided to the applicants after 1 month.

Comments