

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation of the effectiveness of mobile-based inflammatory bowel disease management system by using gamification techniques on disease activity index, mental health and quality of life

Protocol summary

Study aim

Comparison of disease activity index, quality of life and anxiety and depression, self-efficacy and drug adherence

Design

Study of a three-phase, multi-center randomized clinical trial with two intervention and comparison groups designed in the intervention group to evaluate the mobile-based game program and a control group to evaluate the effect of mobile-based self-management system using gamification indicators On the indicators of self-management in patients with intestinal inflammation. The study population included all patients with inflammatory bowel disease. The goal is to include about 210 patients with inflammatory bowel disease in this study. Eligible patients will use a web-based tool to randomize the categorized classification.

Settings and conduct

Special gastrointestinal clinic of Mashhad and Babol University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of inflammatory bowel disease based on internationally accepted diagnostic criteria; Minimum age 18 years; Willingness to enter the study and complete informed written consent; Ability to access and use smartphones and read and write in Persian; Patients with at least one week off; Do not receive self-management programs at the same time. Exclusion criteria: Inability to communicate with researchers; Pregnancy; Active perianal or anal abscess disease; Existence of an anastomosis of the bladder; Having other chronic and acute diseases.

Intervention groups

This clinical trial study will have 2 arms: Control group: Patients in the control group will receive standard and routine outpatient clinics based on guidelines. Intervention group: will receive a mobile-based inflammatory bowel disease management system using

playfulness techniques in addition to standard care.

Main outcome variables

Quality of Life; Disease activity; Stress; depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200613047757N1**

Registration date: **2021-11-16, 1400/08/25**

Registration timing: **prospective**

Last update: **2021-11-16, 1400/08/25**

Update count: **0**

Registration date

2021-11-16, 1400/08/25

Registrant information

Name

narges norouzkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of mobile-based inflammatory bowel disease management system by using gamification techniques on disease activity index, mental health and quality of life

Public title

Designing a mobile-based inflammatory bowel disease management system by using gamification techniques and determining its effectiveness on disease activity index, mental health and quality of life

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of inflammatory bowel disease based on internationally accepted diagnostic criteria including clinical signs, endoscopic findings, radiological and histological studies by a physician specializing in gastroenterology and adult liver Minimum age 18 years Willingness to enter the study and complete informed written consent Ability to access and use smart phones and the Internet Ability to read and write in Persian Patients with at least one week on remission Not receiving self-management and education-oriented programs at the same time and participating in another experimental study when registering a patient

Exclusion criteria:

Inability to communicate with and match with researchers Reluctance to continue cooperation Pregnancy Active perianal or anal abscess disease Existence of an anastomosis of the bladder Participate in another experimental study that may interfere with this study Having other chronic and acute diseases diagnosed by a doctor such as liver, kidney, circulatory system and acute mental disorder

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **210**

Randomization (investigator's opinion)

Randomized

Randomization description

Combination of two methods of randomization, balanced blocks, and stratification. First, a randomized list will be generated for each center by randomization.com. Then, cards and envelopes will be prepared according to the number of samples. The cards will be placed in opaque envelopes in the order of the random allocation list created by the randomization system. Also, to keep the

generated order of the cards, the serial number will be written on the envelopes. The purpose of the study will be explained to the person who accepts to participate signs the informed consent form. They will take an envelope, and will enter the intervention or control groups based on the contents of the envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

Researchers and those involved in this research are blind to random order. After generating the randomization list, cards and envelopes will be prepared in the number of samples. The cards will be placed in the envelope in the order of the random allocation list created by the randomization system so that its contents are not visible from outside the envelope. Also, to prevent the order of the cards from being disturbed, the serial number is inserted on the envelopes. The purpose of the study is explained to the person who meets the conditions, and the person, if desired, signs the informed consent form and takes an envelope and then opens it and enters the intervention or control groups based on the contents of the envelope. The person's details include the patient's name, age, mobile number, and the doctor's name on the envelope. Finally, if patients enter the intervention group, the designed program will be installed on the patient or his mobile phone.

Placebo

Not used

Assignment

Parallel

Other design features

In this study, patients' information needs will be extracted during 3 general phases and based on the identified needs, an exclusive educational content for patients will be developed. This system will be used to evaluate its effectiveness on effective factors.

Secondary Ids

empty

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

Mashhad University of Medical Sciences

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Approval date

2021-11-07, 1400/08/16

Ethics committee reference number

IR.MUMS.REC.1400.230

Health conditions studied

1

Description of health condition studied

Ulcerative Colitis

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

2

Description of health condition studied

Crohn Disease

ICD-10 code

K50

ICD-10 code description

Crohn's disease [regional enteritis]

Primary outcomes

1

Description

quality of life index

Timepoint

At the beginning of the study, 3 and 6 months after the intervention

Method of measurement

will be measured by a 32-item Inflammatory Bowel Disease Questionnaire

2

Description

disease activity index

Timepoint

At the beginning of the study, 3 and 6 months after the intervention

Method of measurement

Harvey-Bradshaw Index (HBI) for Crohn's disease and Simple Clinical Colitis Activity Index (SCCAI) for Ulcerative Colitis patients.

3

Description

Hospital Anxiety and Depression

Timepoint

At the beginning of the study, 3 and 6 months after the intervention

Method of measurement

Hospital Anxiety and Depression Scale (HADS)

Secondary outcomes

1

Description

Self-Efficacy Scale

Timepoint

At the beginning of the study, 3 and 6 months after the intervention

Method of measurement

IBD Self-efficacy Scale

2

Description

measure non-adherence

Timepoint

At the beginning of the study, 3 and 6 months after the intervention

Method of measurement

Morisky Medication Adherence Scale

Intervention groups

1

Description

The method of intervention in the experimental group is education and disease management via mobile phone for 6 months so that it can be trained through educational intervention with playfulness techniques and symptoms related to the disease are monitored and warnings are given to the patient if necessary. To. For remote measurement of disease activity in Crohn's patients, Harvey-Bradshaw index and in patients with ulcerative colitis, simple clinical colitis activity index will be used.

Category

Other

2

Description

Control group: Patients in the control group will receive standard care and routine outpatient clinics based on guidelines.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Adult gastroenterology and liver clinic under the supervision of Mashhad University of Medical Scien

Full name of responsible person

Dr. Ali Bahari

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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
Mashhad University of Medical Sciences

Full name of responsible person
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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
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
Narges Norouzkhani

Position
Student

Latest degree
Master

Other areas of specialty/work
Medical Informatics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Not applicable