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

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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
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Sponsors / Funding sources

1

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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

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Name of organization / entity
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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