# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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
**Street address**
Knowledge and Health City – In the end of Shahid Fakouri Blvd (In front of Fakouri 94) – Mashhad - Iran
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**Province**
Razavi Khorasan
**Postal code**
91778-99191
**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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**2**

**Recruitment center**
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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**
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Student
**Latest degree**
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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