

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Development of Lifestyle educational Package and Comparing its Effectiveness with Mindfulness-Based Cognitive Therapy on Disease Activity and Related Psychological Variables in Patients with Ulcerative Colitis

#### Protocol summary

##### Study aim

The purpose of this study is to develop of Lifestyle educational package and comparing its effectiveness with mindfulness-based cognitive therapy on disease activity and related psychological variables in patients with ulcerative colitis

##### Design

Clinical trial with control group, lifestyle, cmindfulness based cognitive therapy, simple randomized

##### Settings and conduct

50 UC patients who have been enrolled in the Isfahan Liver and Gastroenterology Research Center are selected based on entry criteria and are randomly assigned into 3 groups. The two intervention groups undergo life-style education (1 group) and mindfulness based cognitive therapy (2 group) and control group under an individual training session. Psychological evaluation is performed in three stages

##### Participants/Inclusion and exclusion criteria

Entry Criteria: Diagnosis of Ulcerative Colitis, Conscious Consent to Participate in Research, Physical and mental ability to participate in interview or intervention, The level of education at least the end of the elementary school period, The age range of between 18-70 years old, Call number to invite to participating in intervention, Resident of the city. Exit criteria: The acute phase of psychiatric disorders (such as bipolar disorder, severe depression), Participating in counseling or psychotherapy sessions during the last 6 months, Lack of motivation to participate in the interview and the ability to express thoughts and feelings, Unwillingness to continue to participating in intervention

##### Intervention groups

Group 1. the education of Lifestyle Group 2. the education of mindfulness based cognitive therapy Group 3.on the waiting list: An individual counseling session

during interventions

##### Main outcome variables

Severity of fatigue, disease activity, self-care agency, anxiety, depression, quality of life, illness perception, perceived stress, and disease- related worries and concerns

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180520039736N1**

Registration date: **2018-06-13, 1397/03/23**

Registration timing: **retrospective**

Last update: **2018-06-13, 1397/03/23**

Update count: **0**

##### Registration date

2018-06-13, 1397/03/23

##### Registrant information

##### Name

Mina Mazaheri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3446 2271

##### Email address

mina.mazaheri@mail.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-05-24, 1396/03/03  
**Expected recruitment end date**  
2017-06-22, 1396/04/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Development of Lifestyle educational Package and Comparing its Effectiveness with Mindfulness-Based Cognitive Therapy on Disease Activity and Related Psychological Variables in Patients with Ulcerative Colitis

**Public title**  
Development of Lifestyle educational Package and survey its Effectiveness in Patients with Ulcerative Colitis

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Diagnosis of Ulcerative Colitis Conscious Consent to Participate in Research Physical and mental ability to participate in interview or intervention The level of education at least the end of the elementary school period The age range of between 18-70 years old Call number to invite to participating in intervention Resident of the city  
**Exclusion criteria:**  
The acute phase of psychiatric disorders (such as bipolar disorder, severe depression) Participating in counseling or psychotherapy sessions during the last 6 months Lack of motivation to participate in the interview and the ability to express thoughts and feelings Unwillingness to continue to participating in intervention

**Age**  
From **18 years** old to **70 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**  
Target sample size: **45**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**  
randomized simple

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**  
Participants, Data analyzer

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

survey of the validity of developed Lifestyle educational Package through a nested design(qualitative approach)

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan Azad University, Isfahan (Khorasgan) Branch

##### Street address

Daneshgah Bolvar, Arghavaniye, Sharghi Jey Ave, Isfahan Azad University (Khorasgan), Isfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8148617961

#### Approval date

2018-04-16, 1397/01/27

#### Ethics committee reference number

IR.IAU.KHUISF.REC.1397-28

## Health conditions studied

### 1

#### Description of health condition studied

Ulcerative Colitic

#### ICD-10 code

K51

#### ICD-10 code description

Ulcerative colitis

## Primary outcomes

### 1

#### Description

disease activity

#### Timepoint

Before the intervention, after the intervention, three months after the end of the intervention

#### Method of measurement

Lichtiger Colitis Activity Index

### 2

#### Description

Fatigue Severity

#### Timepoint

Before the intervention, after the intervention, three months after the end of the intervention

#### Method of measurement

Fatigue Severity Scale

### 3

**Description**

Self-Care Agency

**Timepoint**

Before the intervention, after the intervention, three months after the end of the intervention

**Method of measurement**

Exercise of Self-Care Agency Scale

### 4

**Description**

Anxiety

**Timepoint**

Before the intervention, after the intervention, three months after the end of the intervention

**Method of measurement**

Hospital Anxiety Depression Scale

### 5

**Description**

Depression

**Timepoint**

Before the intervention, after the intervention, three months after the end of the intervention

**Method of measurement**

Hospital Anxiety Depression Scale

### 6

**Description**

quality of life

**Timepoint**

Before the intervention, after the intervention, three months after the end of the intervention

**Method of measurement**

Crohn's and Ulcerative Colitis Questionnaire

### 7

**Description**

Perceived stress

**Timepoint**

Before the intervention, after the intervention, three months after the end of the intervention

**Method of measurement**

Perceived stress scale

### 8

**Description**

Illness Perception

**Timepoint**

Before the intervention, after the intervention, three months after the end of the intervention

**Method of measurement**

Brief-Illness Perception Questionnaire

### 9

**Description**

disease related Concerns

**Timepoint**

Before the intervention, after the intervention, three months after the end of the intervention

**Method of measurement**

The Rating Form of Inflammatory Bowel Disease Patient Concerns

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: The education of discovered Lifestyle educational Package

**Category**

Lifestyle

### 2

**Description**

Intervention group: The education of Mindfulness-Based Cognitive Therapy

**Category**

Treatment - Other

### 3

**Description**

Control group: Individual counseling in a session

**Category**

N/A

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Isfahan Liver and Digestive Research Center

**Full name of responsible person**

Dr. Hamed Daghighzadeh

**Street address**

No. 222, Hakimnezami Ave., Daghighi crossroad, Shariati St., Opposite Sepahan Syman Company

**City**

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**Postal code**

8173948763

**Phone**

+98 31 3626 0709

**Email**

Daghigh@gmail.com

## Sponsors / Funding sources

1

**Sponsor**

**Name of organization / entity**

Isfahan Azad University, Isfahan (Khorasgan) Branch

**Full name of responsible person**

Researcher: Mina Mazaheri Tehrani

**Street address**

Daneshgah Bolvar, Arghavaniye, Sharghi Jey Ave,  
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**Phone**

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mina.mazaheri@mail.mui.ac.ir

**Web page address**

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Isfahan Azad University, Isfahan (Khorasgan) Branch

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Persons

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mina Mazaheri Tehrani

**Position**

Psychologist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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mina.mazaheri@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University, Isfahan (Khorasgan) Branch,

**Full name of responsible person**

Dr. Asghar Aghaei

**Position**

Professor of Department of Educational Science and  
Psychology, Isfahan (Khorasgan) Branch, Islamic

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mina Mazaheri Tehrani

**Position**

Psychologist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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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

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

Undecided - It is not yet known if there will be a plan to make this available

### Title and more details about the data/document

The results of the research

### When the data will become available and for how long

6 months after printing results

### To whom data/document is available

For researchers who work in academic and scientific institutions

### Under which criteria data/document could be used

To report the results in other research studies by maintaining its source

### From where data/document is obtainable

mina.mazaheri@gmail.com

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

Request by email

### Comments