

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

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Province

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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

Depresion

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Researcher: Mina Mazaheri Tehrani

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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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Person responsible for scientific inquiries

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Islamic Azad University, Isfahan (Khorasgan) Branch,

Full name of responsible person

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Position

Professor of Department of Educational Science and
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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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