Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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+98 31 3446 2271

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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

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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 Depresion Scale

5

Description
Depresion
Timepoint
Before the intervention, after the intervention, three months after the end of the intervention
Method of measurement
Hospital Anxiety Depresion 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 Daghaghzadeh
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
Isfahan Azad University, Isfahan (Khorasgan) Branch

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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Person responsible for updating data

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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