Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 2026

The effect of an educational-supportive program based on chronic care model on self-efficacy and health related quality of life of patients with ulcerative colitis

Protocol summary

Study aim

Determining the effect of an educational-supportive program based on chronic care model(CCM) on self-efficacy and health related quality of life(HRQOL) of patients with ulcerative colitis(UC)

Design

This study is a clinical trial with control group, two stages as a before and after test on 70 patients, a blind (statistical analyzer), randomized by randomized block method.

Settings and conduct

The environment of this research is described by Poorsina Hakim Gastroenterology Clinic located in Isfahan Health Town and how to do it in the intervention groups section.

Participants/Inclusion and exclusion criteria

Definitive diagnosis of UC 6 months after the diagnosis of UC and the stability of the drug phase during the study Age 18 to 65 years Not having confirmed mental illnesses Not having other chronic diseases Not having Primary sclerosing cholangitis (inflammation of bile ducts)

Intervention groups

In this program, based on 4 components of the chronic care model, interventions are performed, which include delegating the task of teaching and reminding and supervising the practice of trainings, answering questions and taking patients' histories, from doctor to nurse, in addition to following tests, procedures. , Patient status between visits and active management of the time of the doctor's appointment with the nurse, educating the patient and providing various educational resources and psychosocial support through dialogue with peers, answering patients' questions based on the results of recent studies in the field of UC and attention to their preferences to decide on treatment and care and electronic registration of information and patient history. The control group is visited only by a physician and does not receive training or support from a nurse.

Main outcome variables

the health related quality of life and self-efficacy of patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170731035424N2**
Registration date: **2021-09-19, 1400/06/28**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-19, 1400/06/28**
Update count: **0**

Registration date

2021-09-19, 1400/06/28

Registrant information

Name

Sedigheh Farzi

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-02, 1400/05/11

Expected recruitment end date

2021-10-18, 1400/07/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of an educational-supportive program based on chronic care model on self-efficacy and health related quality of life of patients with ulcerative colitis

Public title

The effect of an educational-supportive program on self-efficacy and quality of life of patients with ulcerative colitis

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of ulcerative colitis With the approval of a specialist doctor and the results of colonoscopy and pathology 6 months after the diagnosis of ulcerative colitis and the stability of the drug phase during the study according to the doctor diagnose Willingness to participate in the study Not participating in the same study at the same time The ability to use WhatsApp software by the patient or his primary caregiver The possibility of making a telephone call to the patient Age 18 to 65 years Having the ability to understand Persian language

Exclusion criteria:

having confirmed mental illnesses (according to the patient and family statements) Having other chronic diseases Having Primary sclerosing cholangitis (inflammation of bile ducts)

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Before entering the study, the samples are divided into 8 groups, which are 4 groups of women with age group under 30 years, 30 to 40 years, 40 to 50 years, 50 years and above and 4 groups of men with the same division classification in terms of age. Then, randomly in each of the 8 groups, individuals are assigned to the control or intervention group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data analyzer will not know which of the two intervention and control groups the data under analysis belongs to.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Science

Street address

Hezar-Jerib Ave

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Province

Isfehan

Postal code

81746 73461

Approval date

2021-07-14, 1400/04/23

Ethics committee reference number

IR.MUI.NUREMA.REC.1400.049

Health conditions studied

1

Description of health condition studied

Ulcerative Colitis

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes

1

Description

Self-efficacy score based on Strategies Used by People to Promote Health questionnaire

Timepoint

Before the intervention, immediately and 3 months after the end of the intervention

Method of measurement

Strategies Used by People to Promote Health questionnaire

2

Description

Health-related quality of life score based on

Inflammatory Bowel Disease Questionnaire(IBDQ-9)

Timepoint

Before the intervention, immediately and 3 months after the end of the intervention

Method of measurement

Inflammatory Bowel Disease Questionnaire (IBDQ-9)

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group: the intervention group has a program containing 4 components of the chronic care model, including redesign of the care delivery system, self-management support, decision support, and the clinical information system or system which includes interventions such as delegating training and reminders and monitoring the practice of training, Answering questions and taking patients' histories, from doctor to nurse, in addition to following up on tests, procedures, patient status between visits and active management of the doctor's appointment with the nurse, educating the patient and providing various educational resources and psychosocial support Through conversations with peers, answering patients' questions is based on the results of recent studies in the field of ulcerative colitis and attention to their preferences for decisions about treatment and care and electronic recording of patient information and history.

Category

Lifestyle

2

Description

Control group: the control group will have only regular visits to the doctor as usual.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Poursina Hakim clinic

Full name of responsible person

Abdolmehdi Baghaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Esfahan 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

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Sedigheh Farzi

Position

Faculty of Isfahan University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
By maintaining the confidentiality of participants' personal characteristics, the results of the study are shared based on the objectives of the study.
When the data will become available and for how long
Access will start immediately after the results are published in reputable journals
To whom data/document is available
If a request is sent to the responsible author of the article, due to the confidentiality of the participants' information, the decision on access to the results will be made.
Under which criteria data/document could be used
If a request is sent to the responsible author of the article, due to the confidentiality of the participants' information, the use of the data will be decided.
From where data/document is obtainable
people can correspond with the responsible author via the email contained in the article to receive data.
What processes are involved for a request to access data/document
A request can be made by correspondence with the responsible author of the article via email.
Comments