

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The impact of management training on self-efficacy and quality of life of patients with Ulcerative colitis

Protocol summary

Summary

The effect of self- management training on self- efficacy and quality of life of patients with Ulcerative colitis: A total of 84 patients with a confirmed diagnosis of Ulcerative colitis will enroll in this study. The experiment will be done in Motahari Clinic in Shiraz, using a clinical trial. First, the study sample will be selected based on convenient sampling. Then, it will be randomized to one group that will receive the intervention being studied (the experimental group) and another group that will not receive the intervention (the control group). The intervention group will receive self-management training in six 90-minute sessions for a month. Training sessions include familiarity with the disease, ways to control the symptoms, the correct principles of nutrition, medication, cognitive therapy techniques, problem solving, decision-making and strengthen the positive abilities. After the intervention, the intervention group will use self-management training for a month. During this time, researcher will has four telephone consultation with them. Information will be collected via SUPPH questionnaire and Inflammatory Bowel Disease Questionnaire-9 (IBDQ-9). Two groups will be formed by questionnaires before, immediately after and four weeks after the intervention. Inclusion criteria: The definitive diagnosis of Ulcerative colitis by a specialist, and colonoscopy results; Age greater than 18 and less than 65 years; Having the ability to understand the language of Farsi; The possibility of making a phone call with patients; Willingness to participate in research; No other chronic diseases; Residence in Shiraz or the possibility of attending meetings; Lack of mental disease has been confirmed (according to the patient and family talk) Exclusion criteria: Conditions acute illness; Lack of presence in over two sessions; patient's lack of cooperation during the investigation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092429823N1**

Registration date: **2016-11-09, 1395/08/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-09, 1395/08/19

Registrant information

Name

Sakine Jaafari

Name of organization / entity

Hazrat-e-Fatemeh nursing and midwifery college

Country

Iran (Islamic Republic of)

Phone

+98 71 3622 0235

Email address

stud2280469413@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research , Shiraz University of Medical Sciences

Expected recruitment start date

2016-10-27, 1395/08/06

Expected recruitment end date

2016-11-26, 1395/09/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of management training on self-efficacy and quality of life of patients with Ulcerative colitis

Public title

The impact of self-management education for patients with Ulcerative colitis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The definitive diagnosis of Ulcerative colitis by a specialist, and colonoscopy results; Age greater than 18 and less than 65 years; Having the ability to understand the language of Farsi; The possibility of making a phone call with patients; Willingness to participate in research; No other chronic diseases; Residence in Shiraz or the possibility of attending meetings; Lack of mental disease has been confirmed (according to the patient and family talk)
Exclusion criteria: Conditions acute illness; Lack of presence in over two sessions; patient's lack of cooperation during the investigation

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Simple randomization is used in this study.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical sciences, Zand Street, Shiraz

City

Shiraz

Postal code

14336-71348

Approval date

2016-07-17, 1395/04/27

Ethics committee reference number

IR.SUMS.REC.1395.87

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

Timepoint

Before training (intervention), immediately after training and one month after training

Method of measurement

Strategies Used by People to Promote Health

2**Description**

Quality of Life

Timepoint

Before training (intervention), immediately after training and one month after training

Method of measurement

Inflammatory Bowel Disease Questionnaire-9 (IBDQ-9)

Secondary outcomes

empty

Intervention groups**1****Description**

The intervention group will receive self-management training in six 90-minute sessions for a month. Training sessions include familiarity with the disease, ways to control the symptoms, the correct principles of nutrition, medication, cognitive therapy techniques, problem solving, decision- making and strengthen the positive abilities. After the intervention, the intervention group will use self-management training for a month. During this time, researcher will has four telephone consultation with them.

Category

Other

2

Description

The control group will not receive training, at the end of study, training manual given to them.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Motahari Clinic

Full name of responsible person

Sakine Jaafari; Master of Science Nursing Student

Street address

Shiraz Motahari Clinic; Namazi Square; Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research , Shiraz University of Medical Sciences

Full name of responsible person

Seyyed Basir Hashemi

Street address

Vice chancellor for research, 7th floor , Central Building of Shiraz University of Medical Sciences,Zand Street, Shiraz

City

Shiraz

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for research , Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences-Hazrat-e-Fatemeh nursing and midwifery college

Full name of responsible person

Sakine Jaafari

Position

Master of Science Nursing Student

Other areas of specialty/work

Street address

Hazrat-e-Fatemeh nursing and midwifery college, Namazi hospital, Namazi Squer, Shiraz

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Master of Science Nursing Student

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty