

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

the investigation of Impact of psycho educational intervention on physical and psychological symptoms in patients with inflammatory bowel disease

Protocol summary

Summary

The impact of psycho-educational intervention on physical and psychological symptom in patients with inflammatory bowel disease . A total of 60 patients with a confirmed diagnosis of inflammatory bowel disease will enroll in this study. The experiment will be done in Faghihi 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 experimental group will receive regular psychoeducational treatment, including healthy diet plans, regular exercise and stress, anxiety, and depression prevention and management for one month, one day a week for 90 minutes. A series of assessments will be administered before patients begin treatment, after 4 weeks, and after 8 weeks. All the information will be collected via HADS questionnaire, SCCI index and CDAI index. Inclusion criteria for this study will be patients with 18 years old and above, the patients that are diagnosed with "IBD" disease and are in the active phase of the disease, the patients that are able to perform physical activity and the patients with no chronic illnesses. The exclusion criteria of the experiment will be the patient's lack of cooperation during the investigation. It is expected that the experimental group, who has received psychoeducation, shows significantly more symptom's improvement than the control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015041921850N1**
Registration date: **2016-01-12, 1394/10/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-12, 1394/10/22

Registrant information

Name

Fateme Pashootan Yalame

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 3647 4554

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pashootan@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research , Shiraz University of Medical Sciences

Expected recruitment start date

2015-08-16, 1394/05/25

Expected recruitment end date

2015-09-01, 1394/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the investigation of Impact of psycho educational intervention on physical and psychological symptoms in

patients with inflammatory bowel disease

Public title

impact of psychoeducational intervention on patient with inflammatory bowel disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:Willingness to participate in the study;
Age over 18 years Patients diagnosed with the disease;
Patients in the active phase of the disease Ability to perform physical activity; Not with other chronic illnesses
Exclusion criteria: patient's lack of cooperation during the investigation

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

block randomization is used in this study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Shiraz University of Medical Sciences

Street address

Central Building of Medical sciences, Zand Street, Shiraz

City

Shiraz

Postal code

71348-14336

Approval date

2014-10-29, 1393/08/07

Ethics committee reference number

CT-9372-7182

Health conditions studied

1

Description of health condition studied

inflammatory bowel disease

ICD-10 code

k50- k51

ICD-10 code description

crohn disease[reginal enteritis]-ulceritive colitis

Primary outcomes

1

Description

Physical symptom

Timepoint

before the intervention and 4 weeks and 8 weeks after intervention

Method of measurement

Crohn's Disease Activity Index,Clinical Scoring System for the CLINICAL colitis Activity Index

2

Description

psychological intervention

Timepoint

before the intervention,4 weeks after intervention,8 weeks after intervention

Method of measurement

HADS Questionary

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group training classes for 4 meeting will be held within one month, training include: training, diet, exercise, stress management, anxiety, depression, learning ways to deal with and get instruction for use drug and receive training booklet and patient follow-up by phone

Category

Other

2

Description

The control group did not receive the intervention at the end of the training manual given to them.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Shahid Faghihi Clinic

Full name of responsible person

Molazem Zahra

Street address

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

City

Shiraz

Other areas of specialty/work

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research , Shiraz University of
Medical Sciences

Full name of responsible person

Dr.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

Full name of responsible person

Zahra Molazem

Position

PHD in nursing

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Molazem

Position

master of nursing

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Fatemeh Pashootan Yalameh

Position

M.Sc.Nursing Student

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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