

# 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)

###### Phone

+98 71 3647 4554

###### Email address

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

**Street address**

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

**City**

Shiraz

**Postal code**

1978-71345

**Phone**

+98 71 3647 4254

**Fax**

**Email**

Molazemzah@yahoo.com

**Web page address**

www.sums.ac.ir

## 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**

**Street address**

Hazrat-e- Fatemeh nursing and midwifery college,  
Namazi Hospital, Namazi squer, Shiraz

**City**

Shiraz

**Postal code**

1978-71345

**Phone**

+98 71 3647 4254

**Fax**

**Email**

Molazemzah@yahoo.com

**Web page address**

www.sums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Fatemeh Pashootan Yalameh

**Position**

M.Sc.Nursing Student

**Other areas of specialty/work**

**Street address**

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

**City**

Shiraz

**Postal code**

**Phone**

+98 71 3621 6083

**Fax**

**Email**

pashootanfatima@yahoo.com

**Web page address**

## **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*