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: 0
Update count: 0
Registration date: 2016-01-12, 1394/10/22
Registrant information
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Name of organization / entity
Shiraz University of Medical Sciences
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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]-ulcerive colitis

Primary outcomes

1

Description
Physicall 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

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

Other areas of specialty/work
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Hazrat-e- Fatemeh nursing and midwifery college, Namazi Hospital, Namazi Squer, Shiraz
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Person responsible for general inquiries

Contact
Name of organization / entity
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Full name of responsible person
Zahra Molazem
Position
PHD in nursing

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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