Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparison of the effectiveness of cognitive-behavioral stress management and optimism training on psychological adjustment, immunological markers and somatic symptoms in female Ulcerative Colitis patients

Protocol summary

Summary

The aim of this study was comparison of cognitive-behavioral stress management and optimism training on psychological adjustment, immunological markers and somatic symptoms in female Ulcerative Colitis patients. Statistical population of this project were the whole female Ulcerative Colitis patients, that referred to Noor Medical center and private gastrointestinal clinic. Among this patients, 60 patients, based on histological, endoscopic and radiologic criteria, diagnosed Ulcerative Colitis and were between 18-65 years old, at least diploma that inclined to participation in the project, were selected randomly. These patients were assigned in 3 groups, by random. First group exposed to cognitive-behavioral stress management plus common medical treatment, second group exposed to optimism training plus common medical treatment, and third group exposed to common medical treatment, only. Two interventional groups, exposed to 8 week cognitive-behavioral stress management or optimism training. Every groups, pre and post intervention completed psychological inventories and somatic symptoms and blood samples, too. Inventories and blood samples was compared among groups, then.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011295278N1**
Registration date: **2011-07-21, 1390/04/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-07-21, 1390/04/30

Registrant information

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Marzieh sadat Sajadinejad
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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Science , Behavioral Medicine Researche Center

Expected recruitment start date

2010-12-22, 1389/10/01

Expected recruitment end date

2011-05-20, 1390/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effectiveness of cognitive-behavioral stress management and optimism training on psychological adjustment, immunological markers and somatic symptoms in female Ulcerative Colitis patients

Public title

efectiveness of psychological intervention on ulcerative colitis

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: diagnosis of ulcerative colitis based on gastroentrologist,s idea and endoscopic, histologic and raidiologic criteria; age between 18-65; minimal education level on dyploma; nonconsumption psychiatric drugs or no participation in psychological intervention on past 6 mounth; satisfaction about participation in this project exclusion criteria: age less 18 or more 65 yaers old; consumption psychiatric drugs or participation in psychological intervention on past 6 mounth; education level under dyploma; no satisfaction about participation in this project

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Science

Street address

Isfahan University of Medical Science,Hezarjarib Avenue, Isfahan

City

Isfahan

Postal code

81745-319

Approval date

2011-01-31, 1389/11/11

Ethics committee reference number

12/4/115943/پ

Health conditions studied

1

Description of health condition studied

ulcerative colitis

ICD-10 code

k51.9

ICD-10 code description

postprocedural disorders of digestive system

Primary outcomes

1

Description

psychological adjustment

Timepoint

pretreatment, post treatment and 6 mounth next

Method of measurement

Hospital Anxiety and Depression Scale, Precived Stress Scale, Coping Strategies Inventory

Secondary outcomes

1

Description

somatic symptom

Timepoint

pretrreatment, post treatment and 6 mounth next

Method of measurement

physician idea, Lichtiger colitis activity index (CAI)

2

Description

IL6,IL10,TNF,INF,Cortisol

Timepoint

pretrreatment, post treatment and 6 mounth next

Method of measurement

blood sample

Intervention groups

1

Description

in intervention group: cognitive-behavioral stress management

Category

Behavior

2

Description

in intervention group: optimism training

Category

Behavior

3

Description
in control group: common medical treatment
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
private gastroentrologist clinic
Full name of responsible person
Peyman Adibi
Street address
Mohtasham Kashani street, Isfahan
City
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2

Recruitment center
Name of recruitment center
Noor Medical Center
Full name of responsible person
Reza Bagherian
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Noor Medical Center, Ostandari Street, Isfahan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Behavioral Sciences Research Centre,Isfahan University Medical Science
Full name of responsible person
Reza Bagherian
Street address
Noor Medical Centre, Ostandari Street, Isfahan
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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
Behavioral Sciences Research Centre,Isfahan University Medical Science
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

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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