

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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

Name

Marzieh sadat Sajadinejad

Name of organization / entity

University of Isfahan

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Science , Behavioral Medicine Research 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

effectiveness of psychological intervention on ulcerative colitis

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: diagnosis of ulcerative colitis based on gastroenterologist's idea and endoscopic, histologic and radiologic criteria; age between 18-65; minimal education level on diploma; nonconsumption psychiatric drugs or no participation in psychological intervention on past 6 months; satisfaction about participation in this project
exclusion criteria: age less than 18 or more than 65 years old; consumption psychiatric drugs or participation in psychological intervention on past 6 months; education level under diploma; 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 months next

Method of measurement

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

Secondary outcomes

1

Description

somatic symptom

Timepoint

pretreatment, post treatment and 6 months next

Method of measurement

physician idea, Lichtiger colitis activity index (CAI)

2

Description

IL6, IL10, TNF, INF, Cortisol

Timepoint

pretreatment, post treatment and 6 months 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 gastroenterologist clinic

Full name of responsible person

Peyman Adibi

Street address

Mohtasham Kashani street, Isfahan

City

Isfahan

2

Recruitment center

Name of recruitment center

Noor Medical Center

Full name of responsible person

Reza Bagherian

Street address

Noor Medical Center, Ostandari Street, Isfahan

City

Isfahan

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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Isfahan

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

Contact

Name of organization / entity

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Full name of responsible person

Marzieh sadat Sajadinejad

Position

student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Marzieh sadat Sajadinejad

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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