Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Efficacy of group method cognitive-behavioral stress management on reducing symptoms of patients with irritable bowel syndrome with and without co–morbidity of depression and anxiety and increase quality of life

Protocol summary

Summary
In this double-blind clinical trial, 50 patients with irritable bowel syndrome (assuming 0.05 = α, 0.8 = β, 10.52 = σ, d = 7.5) were selected randomly from study population contains all patients referred to GI clinic of Yasouj after diagnosis by a gastroenterologist based on clinical interview and examination criteria Diagnosis of Rome III. These objects were randomly allocated to two groups: drug therapy combined with cognitive behavioral stress management training and drug therapy alone. During two months of educational sessions of cognitive behavioral stress management therapy, 8 sessions for each group were held (each session 2 hours). Then questionnaire included demographic data, test strategies to deal Carver et al (1989), Quality of Life questionnaire in patients with irritable bowel, Patrick and Drasman (1998), Holmes and Rahe scale and severity of intestinal symptoms (BSS-FS) and Beck Anxiety & depression Scale were collected.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT201102195868N1**
Registration date: **2011-04-08, 1390/01/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2011-04-08, 1390/01/19

Registrant information
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Yasouj University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source
Yasouj University of Medical Sciences

Expected recruitment start date
2010-10-23, 1389/08/01

Expected recruitment end date
2010-12-21, 1389/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy of group method cognitive-behavioral stress management on reducing symptoms of patients with irritable bowel syndrome with and without co–morbidity of depression and anxiety and increase quality of life

Public title
Behavioural cognitive therapy of irritable bowel syndrome (IBS)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 1- diagnostic criteria for IBS based on

Rome III criteria; 2- No psychological treatment during the past three months; 3- desire and satisfaction of participating in the plan. Exclusion criteria: 1- having symptoms such as gastrointestinal bleeding, melena, fever, weight loss of 10 percent during the past six months, and anemia; 2- having a history of cancer of colon in the family; 3- having a severe psychiatric disease; 4- lack of willingness to participate in the plan. 5-lack of being first-degree relatives or neighbours of patients.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Yasouj University of Medical Sciences

Street address
Centeral Building of Yasouj University of Medical Sciences, Motahari Blvd.

City
Yasouj

Postal code

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
P/23/5/3465

Health conditions studied

1

Description of health condition studied
Irritable Bowel Syndrome

ICD-10 code
k58

ICD-10 code description
Irritable bowel syndrome

Primary outcomes

1

Description
severity of IBS symptoms

Timepoint
3 month

Method of measurement
scale rome III

2

Description
stress management

Timepoint
3 month

Method of measurement
Holmz & Rahe questionnaire & carver questionnaire

Secondary outcomes

1

Description
depression

Timepoint
3 months

Method of measurement
Beck depression scale

2

Description
anxiety

Timepoint
3 months

Method of measurement
Beck anxiety scale

3

Description
quality of life

Timepoint
3 months

Method of measurement
QOL-IBS questionnaire

Intervention groups

1

Description
Treatment group: behavioural cognitive therapy of stress management (8 sessions, each session 2 hours) and drug therapy

Category

Behavior

2

Description
control group: only drug therapy
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mofateh Clinic
Full name of responsible person
Street address
City
Yasouj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Dr.Mohammad Zoladl - University Research and Technology Deputy
Street address
Central Building of Yasouj University of Medical Sciences -Second Floor, Motahari Blvd.
City
Yasouj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj 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

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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