

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 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 $0.05 = \alpha$, $0.8 = \beta$, $10.52 = \sigma$, $d = 7.5$) 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

Name

Ali Kamkar

Name of organization / entity

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

Central 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

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Ali Kamkar

Position

MS.PhD candidate/Financial Administrative Assistant of University

Other areas of specialty/work

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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