

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effectiveness of Cognitive Behavioral Therapy (CBT), Hypnotherapy and drug Therapy on Symptoms Intensity, Quality of Life, Self-focused Attention and Rumination- Reflection in Patients with Irritable Bowel Syndrome

Protocol summary

Study aim

the present study was conducted to formulate individual treatment protocols of hypnotherapy and cognitive behavioral therapy in patients with irritable bowel syndrome and examine their effectiveness in the severity of IBS symptoms, quality of life, Self-focused attention and rumination in patients with IBS and compare the effectiveness of these two treatments in improving the above-mentioned variables.

Design

controlled clinical trial, parallel group, not blinded, randomized

Settings and conduct

The present study is with pre-test, post-test and follow-up and not blinded research. The samples include 48 patients referred to Tehran Gastroenterology Clinics. The samples were randomly divided into three group of cognitive-behavioral therapy hypnotherapy and control group. In addition to drug therapy, the intervention groups were treated individually and separately during cognitive-behavioral and hypnotherapy treatments at 1 hour and half session during eight weeks, and the control group were only received the drug treatment

Participants/Inclusion and exclusion criteria

age between 20 to 50, degree of diploma, no history of mental illness, lack of any warning physical signs such as unusual weight loss, rectal bleeding, family history of colon cancer

Intervention groups

cognitive-behavioral therapy, hypnotherapy and control group

Main outcome variables

severity of IBS symptoms, quality of life, Self-focused attention and rumination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190121042437N1**

Registration date: **2019-02-23, 1397/12/04**

Registration timing: **retrospective**

Last update: **2019-02-23, 1397/12/04**

Update count: **0**

Registration date

2019-02-23, 1397/12/04

Registrant information

Name

Negar Fouladi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 4243 3342

Email address

nfouladi1@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-21, 1396/09/30

Expected recruitment end date

2018-05-20, 1397/02/30

Actual recruitment start date

2018-01-20, 1396/10/30

Actual recruitment end date

2018-07-21, 1397/04/30

Trial completion date

Scientific title

The effectiveness of Cognitive Behavioral Therapy (CBT), Hypnotherapy and drug Therapy on Symptoms Intensity, Quality of Life, Self-focused Attention and Rumination-Reflection in Patients with Irritable Bowel Syndrome

Public title

The effectiveness of Cognitive Behavioral Therapy (CBT) and Hypnotherapy on Irritable Bowel Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

age between 20 to 50 degree of diploma no history of mental illness lack of any warning physical signs such as unusual weight loss, rectal bleeding family history of colon cancer

Exclusion criteria:

having symptoms such as gastrointestinal bleeding, melena, fever, weight loss of 10 percent during the past six months. having a history of cancer of colon in the family. having a severe psychiatric disease. lack of willingness to participate in the plan.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

More than 1 sample in each individual

Number of samples in each individual: **1**

patients who were referred to Gastroenterology Clinic in Tehran

Actual sample size reached: **48**

More than 1 sample in each individual

Actual sample size in each individual: **1**

patients who were referred to Gastroenterology Clinic in Tehran

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were randomized using simple randomization to ensure equal group sizes.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Islamic Azad University, Science and Research Branch

Street address

Science and Research Branch, Daneshgah Blvd, Simon Bulivar Blvd, Tehran

City

Tehran

Province

Tehran

Postal code

1477893855

Approval date

2017-12-10, 1396/09/19

Ethics committee reference number

IR.IAU.SRB.REC.1396.76

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 symptoms

Timepoint

pre-test, a post-test and 3 months of follow up

Method of measurement

irritable bowel syndrome severity scoring system
Questionnaire

2**Description**

Irritable bowel syndrome quality of life

Timepoint

pre-test, a post-test and 3 months of follow up

Method of measurement

irritable bowel syndrome quality of life Questionnaire

3**Description**

focus of attention

Timepoint

pre-test, a post-test and 3 months of follow up

Method of measurement

focus of attention questionnaire

4

Description

rumination

Timepoint

pre-test, a post-test and 3 months of follow up

Method of measurement

rumination questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cognitive Behavior Therapy

Category

Treatment - Other

2

Description

Intervention group: hypnotherapy

Category

Treatment - Other

3

Description

Control group: only drug therapy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Gastroenterology Clinics

Full name of responsible person

Negar Fouladi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Anoosh Eghdami

Street address

Shahid Fahmideh Blvd., Shahid Beheshti Blvd

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alielyasi15@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Negar Fouladi

Position

PHD Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Publish as an article

When the data will become available and for how long

Publish as an article

To whom data/document is available

Publish as an article

Under which criteria data/document could be used

Publish as an article

From where data/document is obtainable

Publish as an article

What processes are involved for a request to access data/document

Publish as an article

Comments

Publish as an article