Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

2018-07-21, 1397/04/30

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
Street address
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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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3919715179
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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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Person responsible for updating data

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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