

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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**

ruminatio

**Timepoint**

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

**Method of measurement**

ruminatio 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**

Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

3919715179

**Phone**

+98 86 4243 3342

**Email**

nfouladi1@gmail.com

**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

**City**

Saveh

**Province**

Markazi

**Postal code**

3919715179

**Phone**

+98 86 4243 3342

**Email**

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

**Street address**

Shahid Fahmideh Blvd., Shahid Beheshti Blvd

**City**

Saveh

**Province**

Markazi

**Postal code**

3919715179

**Phone**

+98 86 4243 3342

**Email**

nfouladi1@gmail.com

## Person responsible for scientific 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

**Street address**

Shahid Fahmideh Blvd., Shahid Beheshti Blvd

**City**

Saveh

**Province**

Markazi

**Postal code**

3919715179

**Phone**

+98 86 4243 3342

**Email**

nfouladi1@gmail.com

## Person responsible for updating data

### 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

**Street address**

Shahid Fahmideh Blvd., Shahid Beheshti Blvd

**City**

Saveh

**Province**

Markazi

**Postal code**

3919715179

**Phone**

+98 86 4243 3342

**Email**

nfouladi1@gmail.com

## 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