

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of hypnotherapy on gastrointestinal symptoms severity, anxiety scores and quality of life in patients with irritable bowel syndrome.

Protocol summary

Summary

The aim of this research was to determine the effect of hypnotherapy on the severity of gastrointestinal symptoms, anxiety score and quality of life in patients with irritable bowel syndrome. The inclusion criteria were having at least three months history of suffering from irritable bowel syndrome and exclusion criteria were also suffering from other gastrointestinal disease or recognized psychical disease. In the clinical trial study, 100 patients referred to the Shahid Faghihi and Motahari clinics divided randomly into groups of control and experimental. Hypnotism was done by scientific method for 3 sessions of 1 hour each during 15 weeks for patients of experimental group. Before and after each time hypnotism, the questionnaire of determining the severity of gastrointestinal symptoms, anxiety scores and quality of life of patients with IBS was completed. Of course, self-hypnosis was also done by patients in between sessions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102264775N2**

Registration date: **2015-06-15, 1394/03/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-15, 1394/03/25

Registrant information

Name

Zinat Mohebibi

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology, Shiraz University of Medical Sciences

Expected recruitment start date

2010-12-30, 1389/10/09

Expected recruitment end date

2011-12-30, 1390/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of hypnotherapy on gastrointestinal symptoms severity, anxiety scores and quality of life in patients with irritable bowel syndrome.

Public title

The effect of hypnotherapy on irritable bowel syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: having ages between 20 to 60 years; possessing the literacy of at least primary fifth class; IBS diagnosis by gastroenterologist; having at least three months history of suffering from IBS disease and being under the IBS usual therapeutic program; showing

propensity of participating in hypnotherapy sessions and filling the written letter of satisfaction. Exclusion criteria: suffering from other gastrointestinal diseases or recognized psychological disease; being under other therapeutic programs like homeopathy, relaxation etc.; having the symptoms of reflux and functional dyspepsia; cancer history in individual or family; having anemia and positive stool test for parasite or blood

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Vice Chancellor for research and technology, Shiraz University of Medical Sciences

Street address

Central Building Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Postal code

713451978: صندوق پستی

Approval date

2010-12-29, 1389/10/08

Ethics committee reference number

89,241877

Health conditions studied

1

Description of health condition studied

Irritable Bowel Syndrom

ICD-10 code

K58.0

ICD-10 code description

irritable bowel syndrome

Primary outcomes

1

Description

Gastrointestinal symptoms included abdominal pain, feeling cramp above abdomen, nausea and vomiting, borborygmus, abdominal distension, constipation, diarrhea, loose stool, solid stool, feeling urgent defecation and feeling tenesmus.

Timepoint

3 weeks before intervention, The beginning of fourth week, The beginning of sixth week, The beginning of fifth week.

Method of measurement

Gastrointestinal Symptom Rating Scale

2

Description

Quality of Life

Timepoint

3 weeks before intervention, The beginning of fourth week, The beginning of sixth week, The beginning of fifth week.

Method of measurement

IBS specific quality of life

3

Description

Anxiety

Timepoint

3 weeks before intervention, The beginning of fourth week, The beginning of sixth week, The beginning of fifth week.

Method of measurement

Spielberger State Trait Anxiety Inventory (SSTAI)

Secondary outcomes

empty

Intervention groups

1

Description

After obtaining the written letter of satisfaction to take part in the research and completing demographic questionnaire by physician, the usual treatment (drug-therapy) was started for patients and then was introduced to researchers. Thereafter, these patients were divided into two control and intervention groups as Block randomization. At the next stage, three weeks from beginning of treatment and introducing patient to researcher, the Hypnotism of patient was carried out in sessions of one hour and in the presence of third person (except Hypnotizer and patient) for the intervention group. The first Hypnotherapy was carried out in the beginning of fourth week of research and again it was

done in the beginning of sixth week by scientific method. In these sessions, creating fatigue in eyes and muscular relaxation, creating concentration and Hypnotism, going deep into Hypnotism via reinforcement of imaginations and mental incarnation, giving positive and effective inculcations were educated. Lightening the Hypnotism and sending patient out of it was finally taken place.

Category

Other

2**Description**

Hypnotherapy did not carry out for control group.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Motahari Clinic of Shiraz

Full name of responsible person

Zinat Mohebbi

Street address

Shahid Motahari Clinic, Namazi Squer

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Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

University of Medical Sciences Shiraz

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Central Building Shiraz University of Medical Sciences,
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City

Shiraz

Grant name

بودجه رديف طرحهاي پژوهشي

Grant code / Reference number

89-5340

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

Yes

Title of funding source

University of Medical Sciences Shiraz

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**

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Full name of responsible person

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Web page address**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