

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effect of instructional program of self-care on severity of symptoms and quality of life in patients with irritable bowel syndrom

Protocol summary

Summary

This study is a Randomized Clinical Trial study with two arms. The goal is to determine the effect of an educational program on severity of symptoms and quality of life. The study population includes patients with IBS who have been referred to specialist clinic in Arak. Inclusion criteria: age 18-65 years old; be able to read Persian; having the sign and symptom of Rome III ; mild till moderate diagnosis of IBS. Exclusion criteria: diagnosis of any other disease during study which have signs and symptoms similar to IBS; not cooperative patient. There were two intervention and control groups. Subjects were allocated to the groups randomly. the sample was 44 patients in each group and attrition rate of 10 %. which was calculated based on specific formula and on the whole 100 patients were recruited for both groups. All participants signed an informed consent. Both groups will receive the treatment for IBS but the intervention group will receive the educational program and the quality of life and the severity of sign and symptoms will be measured by standard instruments in two phases before giving and 8 weeks after giving education (IBS-QOL & IBS-SSS) in the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310195987N7**

Registration date: **2014-01-20, 1392/10/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-20, 1392/10/30

Registrant information

Name

Shahrzad Ghiyasvandian

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 6692 7171

Email address

shghiyas@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2013-10-23, 1392/08/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of instructional program of self-care on severity of symptoms and quality of life in patients with irritable bowel syndrom

Public title

The effect of instructional program of self-care on severity of symptoms and quality of life in patients with irritable bowel syndrom

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age 18-65 years old; be able to read persian; having the sign and symptom of Rome III ; mild

till moderate diagnosis of IBS. Exclusion criteria:
Determining any disease during study which sign and symptoms are similar to IBS; not cooperative patient.

Age

From **18 years** old to **65 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)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University Medical Science

Street address

6th floor, Tehran University of Medical Sciences' central building, Ghods St., Keshavarz Boulevard

City

Tehran

Postal code

Approval date

2013-10-22, 1392/07/30

Ethics committee reference number

130/1554/92/3

Health conditions studied

1

Description of health condition studied

Irritable Bowel Syndrom

ICD-10 code

K58

ICD-10 code description

irritable colon

Primary outcomes

1

Description

The severity of symptoms of IBS

Timepoint

Before and 8 weeks after RCT

Method of measurement

IBS-SSS

2

Description

The quality of life of patients with IBS

Timepoint

Before and 8 weeks after RCT

Method of measurement

IBS-QOL

Secondary outcomes

empty

Intervention groups

1

Description

The case group: giving educational package to patients which contains a booklet of IBS and a relaxation CD. The education will be given during an individual meeting, two telephone calls and a group meeting.

Category

Other

2

Description

The control group: will receive the treatment of IBS.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastrointestinal Specialist Clinic

Full name of responsible person

Street address

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of

Medical Sciences

Full name of responsible person

Masod Yonesian

Street address

6th floor, Tehran University of Medical Sciences'
central building, Ghods St., Keshavarz Boulevard

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Shahrazad Ghiyasvandian

Position

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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