Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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)

Phone

+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 Commitee 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/د

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 Scienses

Full name of responsible person

Shahrzad 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