

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Comparison of self-efficacy theory and self-compassion therapy on depression, self-care behaviors and quality of life of patients with irritable bowel syndrome

Protocol summary

Depression, self-care behaviors, and quality of life

Study aim

Comparison of the effectiveness of self-efficacy theory training and compassion-focused therapy on depression, self-care behaviors and quality of life in patients with irritable bowel syndrome

Design

A randomized controlled clinical trial with parallel groups, without blinding

Settings and conduct

The statistical population includes all patients with irritable bowel syndrome referred to Khorshid hospital in Isfahan. The study sample consisted of 45 patients with irritable bowel syndrome who were randomly divided into two equal intervention groups and one control group. The sampling method in this study is purposive. The intervention duration will be 6 months and the intervention group will be randomly divided into two groups of 15 each. Patients in all three groups will receive routine treatment of gastrointestinal irritable bowel syndrome, but the intervention group will undergo self-efficacy and compassion-focused therapy programs designed in an executive protocol in addition to routine treatment. It took.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of irritable bowel syndrome based on Rome II criteria was diagnosed by a gastroenterologist with no psychiatric treatment during the past three months. Exclusion criteria: Symptoms such as gastrointestinal bleeding, fecal hemorrhage, fever, 1% weight loss in the past 6 months, family history of colon cancer, severe psychiatric illness, and first-degree relatives or they were neighbors.

Intervention groups

For the first group of Self-efficacy theory training, For the second group Compassion-focused treatment and in the third group, no intervention will be performed.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191217045761N1**

Registration date: **2020-02-08, 1398/11/19**

Registration timing: **retrospective**

Last update: **2020-02-08, 1398/11/19**

Update count: **0**

Registration date

2020-02-08, 1398/11/19

Registrant information

Name

Fakhrialsadat Khalifesoltani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3337 5332

Email address

psrc@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-15, 1398/05/24

Expected recruitment end date

2020-01-08, 1398/10/18

Actual recruitment start date

2019-08-15, 1398/05/24

Actual recruitment end date

2020-01-08, 1398/10/18

Trial completion date

2020-01-08, 1398/10/18

Scientific title

Comparison of self-efficacy theory and self-compassion therapy on depression, self-care behaviors and quality of life of patients with irritable bowel syndrome

Public title

Comparison of self-efficacy theory and self-compassion therapy on depression, self-care behaviors and quality of life

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of irritable bowel syndrome based on Rome II criteria with diagnosis of gastroenterologist no psychiatric treatment for the past three months

Exclusion criteria:**Age**

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 45

Actual sample size reached: 45

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization

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 Hormozgan University of Medical Sciences (HUMS)

Street address

Sana Complex, No. 1, Kashani St., Isfahan.

City

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Province

Hormozgan

Postal code

3259874168

Approval date

2019-12-07, 1398/09/16

Ethics committee reference number

IR.HUMS.REC.1398.311

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**

Depression

Timepoint

At the beginning of the study (before the intervention), and one and a half months after the intervention

Method of measurement

Beck Depression Inventory

2**Description**

Self-care

Timepoint

At the beginning of the study (before the intervention), and one and a half months after the intervention

Method of measurement

Self-Care Questionnaire Alizadeh et al. (2016)

3**Description**

Quality of Life

Timepoint

At the beginning of the study (before the intervention), and one and a half months after the intervention

Method of measurement

Ware & Sherbourne Quality of Life Questionnaire (1996)

Secondary outcomes

empty

Intervention groups**1****Description**

Self-efficacy theory training

Category

Treatment - Other

2

Description

Compassion-focused treatment

Category

Treatment - Other

3

Description

Control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorshid Hospital

Full name of responsible person

Amin Rafiepour

Street address

Noor Medical Center, Ostandari St.

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bsrc@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Alireza Roosta

Street address

Islamic Azad University of Kish International Branch,
Free Zone Organization Square, Sana'i Boulevard,
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Info@laukishInt.Ac.Ir

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

20

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

Fakhrialsadat Khalifesoltani

Position

Reasearch expert

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for updating data

Contact

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Islamic Azad University
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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

All potential data can be shared after unidentifiable people

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

It will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any statistical analysis of the data is permitted.

From where data/document is obtainable

Fakhrialsadat Khalifesoltani Email: Psrc@mui.ac.ir Tel: 03133375332 Mobile: 09132196260

What processes are involved for a request to access data/document

Email request to Psrc@mui.ac.ir

Comments