Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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 inthe third group, no intervention will be performed.

Main outcome variables
Depression, self-care behaviors, and quality of life

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
Hormozgan

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
Deppression

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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Isfahan
Province
Isfehan
Postal code
8183693311
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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, Kish Island.
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Kish
Province
Hormozgan
Postal code
7941775883
Phone
+98 76 4442 2720
Email
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

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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