Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Efficacy Of The Unified Protocol For Transdiagnostic Treatment On Anxiety, Stress, Depression And Emotion Regulation Of Patient With Irritable Bowel Syndrome (IBS)

Protocol summary

Summary

(1) Objective: The aim of this study is the effectiveness of unified transdiagnostic treatment of anxiety, stress, depression and emotion regulation in patients with irritable bowel syndrome at Kashan. (2) Design: General plan of this study consists of experimental pre and post-test with a control group and follow-up period. (3) Setting and conduct: 64 subjects who met the inclusion criteria are selected and randomly divided into two groups (transdiagnostic treatment and control groups). All participants completed Depression, Anxiety and Stress Scale (DASS-42) and Emotion Regulation Questionnaire (ERQ). Then, two groups of people randomly assign either experimental or control group based on a random numbers table point. Then, experimental group will receive transdiagnostic treatment and the control group receive only drug therapy and psychoeducation sessions. After the intervention, two groups will complete DASS-42 and ERQ again. then, data will analyze by SPSS-22 and use the t-test and MANCOVA statistical methods. (4) Inclusion criteria: Having IBS diagnosis based on Rome III. Exclusion criteria: received psychological treatment interventions in the last year and time of the study. (5) Interventions: The unified transdiagnostic treatment protocol Barlow consisted of eight module Which in this study during the 12 sessions about 60 minutes (6) The main outcome variables include depression, anxiety, stress and emotion regulation.

General information

Acronym

irritable bowel syndrome

IRCT registration information

IRCT registration number: **IRCT2017010431765N1**
Registration date: **2017-05-30, 1396/03/09**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-05-30, 1396/03/09

Registrant information

Name

hamid mohsenabadi

Name of organization / entity

Kashan University of Medical Sciences and Health Services

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Kashan University of Medical Sciences and Health Services

Expected recruitment start date

2016-12-08, 1395/09/18

Expected recruitment end date

2017-03-17, 1395/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficacy Of The Unified Protocol For Transdiagnostic Treatment On Anxiety, Stress, Depression And Emotion Regulation Of Patient With Irritable Bowel Syndrome (IBS)

Public title
The Efficacy Of The Unified Transdiagnostic Treatment for Irritable Bowel Syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: diagnosis IBS based on the criteria of Rome III; aged between 18 and 40 years; satisfaction and commitment to participate in the study Exclusion criteria: get interventions psychological treatment in the past year and the time of the study; history of alcohol abuse or drugs; two sessions of absence for each patient.
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences and Health Services
Street address
Ethics committee, Vice chancellor for research of Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan
City
Kashan
Postal code
Approval date
2016-12-06, 1395/09/16
Ethics committee reference number
IR.KAUMS.REC.1395.100

Health conditions studied

1

Description of health condition studied
Irritable bowel syndrome
ICD-10 code
K58
ICD-10 code description
irritable colon

Primary outcomes

1

Description
Depression
Timepoint
Before intervention, After intervention, One month after intervention
Method of measurement
subscale depression dass-42

2

Description
Anxiety
Timepoint
Before intervention, After intervention, One month after intervention
Method of measurement
subscale anxiety dass-42

3

Description
Stress
Timepoint
Before intervention, After intervention, One month after intervention
Method of measurement
subscale stress dass-42

4

Description
Emotion regulation
Timepoint
Before intervention, After intervention, One month after intervention
Method of measurement
emotion regulation questionnaire

5

Description
Severity of symptoms in patients with irritable bowel syndrome
Timepoint
Before intervention, After intervention, One month after intervention
Method of measurement
IBS Symptom Severity Scoring

Secondary outcomes

empty

Intervention groups

1

Description
Transdiagnostic treatment for 12 sessions of 2 hours on the intervention group
Category
Behavior

2

Description
Drug therapy along with psychological training for 12 sessions of two hours for control group
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashan Shahid Beheshti Hospital
Full name of responsible person
Hamid Mohsenabadi
Street address
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Kashan University of Medical Sciences and Health Services
Full name of responsible person
Dr Qolam Ali Hamidi
Street address
Vice chancellor for research of Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan
City
Kashan
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 of Kashan University of Medical Sciences and Health Services
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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Position
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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