

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

Iran (Islamic Republic of)

Phone

+98 31 5554 2305

Email address

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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

Kashan University of Medical Sciences and Health Services

Full name of responsible person

Hamid Mohsenabadi

Position

M.Sc Candidate in Clinical Psychology

Other areas of specialty/work

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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