Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of Intensive Short term Dynamic Psychotherapy (ISTDP) on the Difficulty in Emotion Regulation, Defense Mechanisms, Quality of Life and Outcome of Treatment in Patients with Irritable Bowel Syndrome

Protocol summary

Study aim
Effectiveness of Intensive Short term Dynamic Psychotherapy (ISTDP) Patients with Irritable Bowel Syndrome

Design
Clinical trial, with control and experimental groups, parallel, one-sided blind, randomized, on 36 patients. A randomization table is used for randomization

Settings and conduct
Gastroenterology Clinic of Rasoul Akram Hospital

Participants/Inclusion and exclusion criteria
Having irritable bowel syndrome based on the diagnosis of a gastroenterologist affected from Severe physical illness

Intervention groups
In the experimental group, short-term psychodynamic psychotherapy will be used based on John Frederickson's protocol. Both experimental and control groups will complete these questioners before and after the treatment and three months after the treatment : Bowel symptoms severity-frequency scale (BSS-FS) Irritable Bowel Syndrome Quality of Life Instrument (IBS-QOL) Difficulties in Emotion Regulation Scale (DERS) Defensive Styles Questionnaire

Main outcome variables
Irritable bowel syndrome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221101056369N1**
Registration date: **2023-07-25, 1402/05/03**
Registration timing: **retrospective**

Last update: **2023-07-25, 1402/05/03**
Update count: **0**

Registration date
2023-07-25, 1402/05/03

Registrant information

Name
Faezeh Shafiei

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-07, 1400/07/15

Expected recruitment end date
2022-03-11, 1400/12/20

Actual recruitment start date
2021-10-12, 1400/07/20

Actual recruitment end date
2022-05-15, 1401/02/25

Trial completion date
2023-02-11, 1401/11/22

Scientific title
Effectiveness of Intensive Short term Dynamic Psychotherapy (ISTDP) on the Difficulty in Emotion Regulation, Defense Mechanisms, Quality of Life and Outcome of Treatment in Patients with Irritable Bowel Syndrome

Public title
Effectiveness of Intensive Short term Dynamic Psychotherapy (ISTDP) on the irritable bowel syndrome

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having irritable bowel syndrome based on the diagnosis of gastroenterologists and Rome III diagnostic criteria age between 20-50 education level at least diploma
Exclusion criteria:
Having a significant physical illness based on the interview and history taking from the person Having a severe psychiatric disorder according to the fifth edition of the Diagnostic and Statistical Manual of Mental Illnesses DSM-5 Absence of more than two sessions in treatment
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **15**
Actual sample size reached: **15**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the Restricted Randomization method of block randomization will be used. Blocking is usually used to balance the number of samples assigned to each of the study groups. This feature helps researchers to equate the number of samples assigned to each of the study groups in cases where intermediate analyzes are required during the sampling process, so that the number of samples assigned to each of the study groups become equal and in this study, we will have 4 blocks. Random allocation software is used that this random sequence generation software in addition to simple randomization are able to generate random sequence by blocking method. Allocation concealment is also used, which is the method used to execute a random sequence on study participants. In such a way that the assigned group is not known before the individual is assigned. Using Sequentially numbered, sealed, opaque envelopes, each random sequence created is recorded on a card. And the cards are placed in the envelopes of the letter, respectively. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.
Blinding (investigator's opinion)
Single blinded
Blinding description
Evaluator and statistical analysts are blind to the research process. Statistical analyst is blind to research so that data analysis can be done without bias
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran university of Medical Sciences
Street address
Iran Univesity of Medical Sciences fifth floor
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2021-09-21, 1400/06/30
Ethics committee reference number
IR.IUMS.REC.1400.566

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
Difficulties in emotion regulation
Timepoint
before the intervention, last session 3 months after the intervention
Method of measurement
Difficulties in Emotion Regulation Scale

2

Description
Irritable bowel syndrome
Timepoint
before the intervention, last session 3 months after the

intervention

Method of measurement

Irritable bowel symptoms severity and frequency scale

3

Description

Defense mechanisms

Timepoint

before the intervention, last session 3 months after the intervention

Method of measurement

Defensive Styles Questionnaire

4

Description

Quality of life questionnaire

Timepoint

before the intervention, last session 3 months after the intervention

Method of measurement

Quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Short-term psychodynamic Psychotherapy based on the John Frederickson protocol: At first participants will complete the questionnairs as a pretest. Then they enter the treatment based on the mentioned approach for 6 months. Individual sessions are held weekly. participants will then complete the questionnaires as a post-test. in follow-up phase participants will complete the research questionnaire after 3 months.

Category

Treatment - Other

2

Description

Control group: First, the participants complete the research questionnaires as a pre-test. The control group received no intervention. After 6 months, they will complete the questionnaires as a post-test. In the follow-up phase, after 3 months, the participants will complete the research questionnaires again.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat rasol akram hospital

Full name of responsible person

Faezeh Shafiei

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Sponsors / Funding sources

1

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Name of organization / entity

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

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
Iran University of Medical Sciences

Full name of responsible person
Dr Hossein Keyvani

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Virology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable