

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The Effectiveness of Integrative Therapy, Acceptance and Commitment-Based Therapy, Short-term Psychoanalysis in Alexithymia, Distress and Psychosomatic Symptoms in Gastrointestinal Disorder Patients with High Score in the personality type D

Protocol summary

Study aim

The effectiveness of various treatments in reducing psychosomatic symptoms in patients with gastrointestinal dysfunction type D

Design

A clinical trial with a control group, with parallel, randomized groups, on 48 patients.

Settings and conduct

The statistical population in this study was among all patients with gastrointestinal dysfunction (FGID) who had referred to Hamrah Psychological Institute from September to March.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient cooperation to participate in the research, and complete the consent form, First referral, Minimum 9 years education, Age 60-18 years, Patients with gastrointestinal dysfunction according to ROME III criteria by a gastroenterologist for referral patients, Diagnosis of gastrointestinal dysfunction (IBS), functional indigestion (FD), or both. Do not take psychiatric drugs with the main purpose of reducing emotions (anxiety, etc.). Exclusion criteria: A history of substance abuse or dependence is currently on record during the four months before treatment, Use of any type of psychiatric medication based on the record in the four months before the first treatment session, Use of any kind of psychological and counseling services for any mental disorder I and II,

Intervention groups

Three treatment groups (integrated therapy), (acceptance and commitment therapy) and (short-term psychoanalysis) and a control group were assigned. First, Alexithymia (Toronto-20 Alexithymia Questionnaires), distress (mental distress with general health questionnaire), and assessment of psychosomatic symptoms (Takata and Sakata Psychosomatic

Complaints Scale) completed, and then interventions were performed.

Main outcome variables

Anxiety; psychosomatic symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201107049294N1**

Registration date: **2021-07-20, 1400/04/29**

Registration timing: **retrospective**

Last update: **2021-07-20, 1400/04/29**

Update count: **0**

Registration date

2021-07-20, 1400/04/29

Registrant information

Name

Ali Bakhshi Bejestani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8670 5503

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-05, 1399/06/15

Expected recruitment end date

2021-03-05, 1399/12/15
Actual recruitment start date
2020-09-10, 1399/06/20
Actual recruitment end date
2021-03-10, 1399/12/20
Trial completion date
2021-04-30, 1400/02/10

Scientific title

The Effectiveness of Integrative Therapy, Acceptance and Commitment-Based Therapy, Short-term Psychoanalysis in Alexithymia, Distress and Psychosomatic Symptoms in Gastrointestinal Disorder Patients with High Score in the personality type D

Public title

The effectiveness of various treatments in reducing psychosomatic symptoms in patients with gastrointestinal dysfunction type D

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient cooperation to participate in the research complete the consent form First referral Minimum cycle education Age 60-18 years Patients with gastrointestinal dysfunction according to ROME III criteria by a gastroenterologist for patients referred to a psychiatric clinic Diagnosis of gastrointestinal dysfunction with irritable bowel syndrome (IBS) dyspepsia (FD) or both Do not take psychiatric drugs with the main purpose of reducing emotions (anxiety, etc.)

Exclusion criteria:

A history of substance abuse or dependence is currently on record during the four months prior to treatment Use of any type of psychiatric and psychiatric medication based on the record in the four months before the first treatment session Use of any kind of psychological and counseling services for any mental disorder I and II

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Actual sample size reached: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

All 48 participants were sorted alphabetically into a list of 48 people by surname and first name, then using one of the eight random blocks, among possible compositions, which were selected randomly, assigned individuals to 4 groups (three treatment groups and one control group).

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 Birjand University of Medical Sciences

Street address

South Khorasan Province, Birjand County, Ayatollah Ghaffari St., University of Medical Sciences

City

Birjand

Province

North Khorasan

Postal code

9717853577

Approval date

2020-07-11, 1399/04/21

Ethics committee reference number

IR.BUMS.REC.1399.163

Health conditions studied

1

Description of health condition studied

Diseases of oesophagus, stomach and duodenum

ICD-10 code

K20-K31

ICD-10 code description

Diseases of oesophagus, stomach and duodenum

Primary outcomes

1

Description

Alexithymia

Timepoint

Before starting, after finishing, two months after finishing.

Method of measurement

Toronto Alexithymia Scale

2

Description

Stress-Anxiety

Timepoint

Before starting, after finishing, two months after finishing.

Method of measurement

DASS-21 Stress-Anxiety-Depression Inventory

3

Description

Psychosomatic Symptoms

Timepoint

Before starting, after finishing, two months after finishing.

Method of measurement

Takata and Sakata Psychosomatic Complaints Scale

4

Description

Gastrointestinal Dysfunction

Timepoint

Before starting, after finishing, two months after finishing.

Method of measurement

ROME-III questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First group therapy (integrated treatment). Integrated protocol by integrated protocol by Mollajafar et al. (2017) which is a combination of three therapies (cognitive-behavioral, spiritual therapy and therapy based on acceptance and commitment), in eight sessions of one and a half hours and two sessions per week for A month is formed. The following are the steps of the treatment separately for the training sessions.

Category

Behavior

2

Description

Intervention group: Intervention group: Second group therapy (acceptance and commitment based therapy). For acceptance-based behavior therapy, a therapeutic guide was used in the book Acceptance-Based Behavior Therapy by Hysacleton, Roemer, and Arsillo (2011). The treatment sessions consisted of 8 sessions (two sessions per week). The first 4 sessions were aimed at guiding and placing clients in the path of the treatment model, with a time of 90 minutes. The remaining 4 sessions were one hour.

Category

Behavior

3

Description

Intervention group: Intervention group: Third group therapy (short-term psychoanalysis). The content of the

sessions according to the short-term psychotherapy psychotherapy guideline, ie the seven stages of questions about problems, pressure, challenge, transfer resistance, direct access to the unconscious, transfer analysis, and scanning in the unconscious (Fooladi et al., 2017), are described in Table 4. Is. These sessions were held for two months (two sessions per week).

Category

Behavior

4

Description

Control group: Only support counseling program

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Institute of Psychology Hamdam Hamrah

Full name of responsible person

Bakhshi

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Tehran - Dolab Head Mill Square. Shiva Street. Haji Amiri Alley. No. 77. The second unit

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Majid Aliabadi

Street address

South Khorasan, Birjand city, at the end of Ayatollah Ghaffari Boulevard

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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
Islamic Azad University
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
Islamic Azad University
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Ali Bakhshi
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable