

# 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)

##### Phone

+98 21 8670 5503

##### Email address

ali\_bakhshi110@yahoo.com

##### 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

##### **Street address**

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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1748873673

##### **Phone**

+98 21 3305 5284

##### **Email**

ali\_bakhshi110@yahoo.com

## **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

##### **City**

Birjand

##### **Province**

South Khorasan

##### **Postal code**

1234567890

##### **Phone**

+98 56 3234 5591

##### **Email**

ali\_bakhshi110@yahoo.com

**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  
**Full name of responsible person**  
Ali Bakhshi  
**Position**  
Psychologist  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Psychology  
**Street address**  
No. 77, Hadadi Alley, Shiva St., Dolab Head Mill.  
second floor  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1764873673  
**Phone**  
+98 21 3305 5284  
**Email**  
ali\_bakhshi110@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Ali Bakhshi  
**Position**  
Psychologist  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Psychology  
**Street address**

No. 77, 2nd Floor, Hadadi Alley, Shiva Alley, Doolab Mill Square  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1764873673  
**Phone**  
+98 21 3305 5284  
**Email**  
ali\_bakhshi110@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Ali Bakhshi  
**Position**  
Psychologist  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Psychology  
**Street address**  
No. 77, 2nd Floor, Hadadi Alley, Shiva Alley, Doolab Mill Square  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1764873673  
**Phone**  
+98 21 3305 5284  
**Email**  
ali\_bakhshi110@yahoo.com

## 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