

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Comparing the effectiveness of dialectical behavior therapy and anti-anxiety medication on anxiety and symptoms of patient with functional dyspepsia

#### Protocol summary

##### Study aim

The aim of the study is to determine the comparison of dialectical behavior therapy and anti-anxiety medication on anxiety symptoms of patients with functional dyspepsia

##### Design

In this research, 60 eligible patients with irritable bowel syndrome referring to gastrointestinal clinic were chosen purposefully and were randomly divided into three groups of interventions with behavior therapy, anti anxiety medication and control by closed packets.

##### Settings and conduct

This study which will be conducted in gastrointestinal clinic of Valiasr hospital birjand. patients will be divided into three groups randomly with 20 members and in the end of interventions, efficacy will be evaluated with patient assessment of upper gastrointestinal symptom (PAGI-SYM) and beck anxiety inventory.

##### Participants/Inclusion and exclusion criteria

Patients aged between 18 and 50 years old! patients who accepted to participate in the study after explaining the purposes of the study and advantages and disadvantages of the interventions! Patients who do not have any other anatomical or functional gastrointestinal disorders

##### Intervention groups

60 eligible patients with functional dyspepsia were randomly divided into three groups of interventions with behavior therapy, anti anxiety medication and control by closed packets.

##### Main outcome variables

Functional dyspepsia severity; Anxiety severity

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20171022036938N2**

Registration date: **2018-04-16, 1397/01/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-04-16, 1397/01/27**

Update count: **0**

#### Registration date

2018-04-16, 1397/01/27

#### Registrant information

##### Name

**Name of organization / entity**

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3212 5073

##### Email address

dr.mas.hosseyni@bums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2018-04-04, 1397/01/15

#### Expected recruitment end date

2018-05-05, 1397/02/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparing the effectiveness of dialectical behavior therapy and anti-anxiety medication on anxiety and symptoms of patient with functional dyspepsia

**Public title**

Efficacy of dialectical behavior therapy and anti-anxiety drugs on functional dyspepsia

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients aged between 18 and 50 years old Patients who accepted to participate in the study after explaining the purposes of the study and advantages and disadvantages of the interventions There should be the possibility to keep the type and dose of the medications fixed during the study Having at least diploma education

**Exclusion criteria:**

Patients who do have psychotic or other simultaneous digestive disorders Having full criteria of personality disorders Patients who do not have alarm signs including gastrointestinal bleeding, blood in stool, fever, weight loss, anemia, diarrhea at night, severe abdominal pain and so on

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple Randomization by sealed envelope

**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**

Faculty of medicine, Birjand University of Medical Sciences, Ghaffari street, Birjand

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9187874151

**Approval date**

2017-06-25, 1396/04/04

**Ethics committee reference number**

lr.bums.REC.1396.83

**Health conditions studied****1****Description of health condition studied**

Functional dyspepsia

**ICD-10 code**

K30

**ICD-10 code description**

Functional dyspepsia

**Primary outcomes****1****Description**

Functional dyspepsia severity

**Timepoint**

Before and right after the end of intervention

**Method of measurement**

Patient assessment of upper gastrointestinal symptom (PAGI-SYM) designed by Rentz in 2004; Made of 20 items, according to 6 degree classification 0 to 5 (no symptoms to very severe symptoms): no symptoms(0 to 20)- mild(21 to 40)- moderate(41 to 60)- sever(61 to 80)- very sever(81 to 100)

**Secondary outcomes****1****Description**

Anxiety severity

**Timepoint**

Before and right after the end of intervention

**Method of measurement**

Anxiety score from beck anxiety inventory

**Intervention groups****1****Description**

Intervention in the first intervention group:dialectical behavior therapy:an Interventional behavior therapy including discussion and practice in each meetings and also at home in order to reach mental skills, notifications and excitement control. Meetings will be held once a week, there are eight meetings,each meetings duration are 90 minutes, include aims and relative titles, discussion and practice.a first meeting is justification of dialectical behavior therapy for participants and each next meetings are based on a five minutes mental

practice and comprehensive notice by breathing and then review the previous meetings. Patient assessment of upper gastrointestinal symptom (PAGI-SYM) designed by Rentz in 2004; Made of 20 items, according to 6 degree classification 0 to 5 (no symptoms to very severe symptoms)

**Category**

Behavior

**2**

**Description**

Intervention in the second intervention group: Anti-anxiety treatment: Sertraline, 100 mg orally once a day for eight weeks

**Category**

Treatment - Drugs

**3**

**Description**

Control group: Symptomatic treatment with pantoprazole 40 mg orally daily for eight weeks

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Gastroenterology clinic, Vali-e-Asr hospital, birjand

**Full name of responsible person**

Dr Tavakoli Tahmine assistant professor and gastroenterologist

**Street address**

Gastroenterology clinic, Vali-e-Asr hospital, birjand

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9187874151

**Phone**

+98 51 6845 0050

**Email**

masoud60h@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Vice Chancellor for research of Birjand University of Medical Sciences

**Street address**

Faculty of medicine, Birjand University of Medical Sciences

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9187874151

**Phone**

+98 51 6845 0050

**Email**

masoud60h@yahoo.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Birjand 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**

Birjand University of Medical Sciences

**Full name of responsible person**

Hosseini Masoud

**Position**

Internist

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Faculty of medicine, Birjand University of Medical Sciences, Ghaffari street, Birjand

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9187874151

**Phone**

+98 51 3761 3026

**Email**

masoud60h@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Tavakoli Tahmine

**Position**

Assistant professor and gastroenterologist

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Faculty of medicine, Birjand University of Medical Sciences, Ghaffari Street, Birjand

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9187874151

**Phone**

+98 51 3761 3026

**Email**

Tahminetavakoli95238@yahoo.com

Number 97, Mina 2 avenue, Bahar10 avenue, Sajjad bolvar, Mashhad

**City**

Masshad

**Province**

Razavi Khorasan

**Postal code**

9187874151

**Phone**

+98 38781846

**Email**

Faezeh.vaezin@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**

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

**Data Dictionary**

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

**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Tabrizi Sanaz

**Position**

دستیار داخلی

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**