

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of brief psychodynamic psychotherapy with emphasis on Core conflict Relationship Theme on the improvement of physical and psychological health indexes in functional dyspepsia patients

Protocol summary

Summary

The aim of this study is to investigate the effects a brief psychodynamic psychotherapy of Core conflict relationship theme (CCRT) on improvement of physical and psychological symptoms in patients with functional dyspepsia. A total of 30 women, aged 20-40 years old and diagnosed functional dyspepsia according to Rome III criteria are randomly assigned into experimental or control group. The participants of control group are taken standard pharmacotherapy for 6 weeks. The participants of experimental group are taken standard pharmacotherapy as well as attending in individual psychotherapy method of CCRT during 4 months (16 sessions, 50 minutes, once weekly). The patient's assessment questionnaire of upper gastrointestinal disorder-symptom severity index, the Persian version of the twenty-item Toronto Alexithymia scale, and SCL90-R will be completed at the beginning and at the end and 1-month after interventions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102285931N1**
Registration date: **2011-03-30, 1390/01/10**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-03-30, 1390/01/10

Registrant information

Name

Mahbobeh Faramarzi

Name of organization / entity

Babol University of medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tarbiat Modaress University

Expected recruitment start date

2011-01-13, 1389/10/23

Expected recruitment end date

2011-08-20, 1390/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of brief psychodynamic psychotherapy with emphasis on Core conflict Relationship Theme on the improvement of physical and psychological health indexes in functional dyspepsia patients

Public title

The effect of brief psychodynamic psychotherapy with emphasis on Core conflict Relationship Theme on the improvement of physical and psychological health indexes in functional dyspepsia patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Women 20-40 and education diploma or above with normal test of endoscopy, sonography,

and routine blood tests Exclusion criteria: Irritable bowel syndrome, Paranoid personality, Schizoid personality

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Tarbiat Modares University

Street address
AL-E-Ahmad highways, Chamran Intercection, Tehran

City
Tehran

Postal code

Approval date
2011-01-12, 1389/10/22

Ethics committee reference number
85387/60

Health conditions studied

1

Description of health condition studied
Functional dyspepsia

ICD-10 code
K30

ICD-10 code description
Dyspepsia

Primary outcomes

1

Description

Symptoms of functional dyspepsia

Timepoint
before and after treatment and 1 month after treatment

Method of measurement
Patient assessment of upper gastrointestinal disorder – symptom severity index,

Secondary outcomes

1

Description
psychological symptoms

Timepoint
before tratment, after treatment, and 1 month after treatment

Method of measurement
ScL-90

Intervention groups

1

Description
Intervention group: The patients with positive H. pylori will receive a combination of bismuth subcitrate (3×500 mg), metronidazole (3×250 mg), amoxicillin (3×500 mg) and either omeprazole (2×20 mg) (2×150 mg) for 2 weeks and continue omeprazole (2× 20 mg) (2 ×150 mg) only for 4 weeks. Patients with negative for H. pylori will receive omeprazole (2×20 mg) for 6 weeks as well as attending in individual psychotherapy for 16 sessions (50 minutes) every a week

Category
Behavior

2

Description
Control group: The patients with positive H. pylori will receive a combination of bismuth subcitrate (3×500 mg), metronidazole (3×250 mg), amoxicillin (3×500 mg) and either omeprazole (2×20 mg) (2×150 mg) for 2 weeks and continue omeprazole (2× 20 mg) (2 ×150 mg) only for 4 weeks. Patients with negative for H. pylori will receive omeprazole (2×20 mg) for 6 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Rohani hospital

Full name of responsible person
Dr. Hassan Taheri

Street address
Ayatillah Rohani hoasptial- Gang Afroz street- Babol

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Parviz Azadfallah

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AL-E-Ahmad highways, Chamran Intercection, Tehran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tarbiat Modares University

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**

Babol University of Medical Sciences

Full name of responsible person

Mahbobeh Faramarzi

Position

Faculty of member of Babol University of Medical Sciences- PhD student of Tarbiat modares university

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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