Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

comparison of efficacy of metacognitive therapy and drug treatment in the frequency and severity of physical symptoms, psychological symptoms and quality of life in patients with functional dyspepsia

Protocol summary

Study aim

comparing the effect of metacognitive and medication on somatic symptoms, psychological symptoms, and quality of life in functional dyspeptic patient

Design

A randomized clinical trial study with the control group in Phase 3, including metacognitive, Nortriptyline and control groups with a sample of 160 patients. Sampling at first was available and simple random assignment was used.

Settings and conduct

160 patients with functional dyspepsia were selected during their visit to gastroenterology clinics. After filling consent form, they were randomly assigned to two groups; i.e., drug treatment with Nortriptyline 25 mg and 10 sessions metacognitive psychotherapy. Then, the patients were assessed clinically at pre-/post-treatment and a follow-up after 3, 6 months.

Participants/Inclusion and exclusion criteria

The inclusion criteria include: Having functional dyspepsia without comorbid diseases such as IBS or other digestive diseases, Not having a variety of chronic somatic disease, Non simultaneous use of other psychiatric drugs, Non dependency or abusing of substance, Absence of severe psychiatric disorders, Age range from 18 to 55, Having reading and writing skills. The exclusion criteria include: Unwillingness to participate in the research work for any reason, The inability of the patient to access the medical center Patients need to take any medicine other than the prescribed drugs in the study during the study.

Intervention groups

Intervention group 1: 10-session metacognitive therapy protocol based on anxiety therapy with common medical treatment in control group; Intervention Group 2: Nortriptyline, 25 mg once daily for 10 weeks along with common medical treatment in control group; Control Group: common medical treatment (20 mg omeprazole 10 mg domperidone, both once daily for 10 weeks), diet and regular exercise.

Main outcome variables

Functional dyspepsia symptoms, quality of life

General information

Reason for update

the extension of study in order to the sample size and extended follow-ups.

Acronym

IRCT registration information

IRCT registration number: **IRCT20190312043036N1**
Registration date: **2019-10-13, 1398/07/21**
Registration timing: **retrospective**

Last update: **2020-01-28, 1398/11/08**
Update count: **1**

Registration date

2019-10-13, 1398/07/21

Registrant information

Name
Sepideh Batebi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-22, 1398/01/02

Expected recruitment end date
2019-08-25, 1398/06/03
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
comparison of efficacy of metacognitive therapy and drug treatment in the frequency and severity of physical symptoms, psychological symptoms and quality of life in patients with functional dyspepsia

Public title
effect of metacognitive therapy on patients with functional dyspepsia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having functional dyspepsia without comorbid disease such as IBS or other digestive disease Not having any variety of chronic somatic diseases No simultaneous use of other psychiatric drugs No dependency on or abusing substance Partial adherence to diet and exercise Absence of severe psychiatric disorders Age range between 18 and 55 Having reading and writing skills
Exclusion criteria:
Unwillingness to participate in the research for any reason Inability of the patient to access the medical center Having chronic physical impairment or physical inability Having a severe mental disorder Substance use or dependence Patients need to take any medicine other than the prescribed drugs in the study during the study
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
At first, the available sample was selected from those who referred to the gastroenterology clinic of Taleghani Hospital and the affiliated centers. Finally, based on the simple random sampling by throwing a dice, the outcomes 1 and 2 were considered for assigning the patients to the metacognitive therapy group, the outcomes 3 and 4 for assigning the patients to the drug treatment group and the outcomes 5 and 6 for the 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 Shahid Beheshti university of medical science
Street address
Velenjak st
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Province
Tehran
Postal code
1985717443
Approval date
2018-01-16, 1396/10/26
Ethics committee reference number
IR.SBMU.MSP.REC.1396.756

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
Symptoms of functional dyspepsia
Timepoint
Pre test, post test and follow up
Method of measurement
Leeds dyspepsia questionnaire and clinical interview based on Rome IV

2

Description
depression
Timepoint
Pre test, post test and follow up three months after treatment
Method of measurement
Hamilton depression questionnaire

3

Description
anxiety
Timepoint
Pre test, post test and follow up three months after treatment
Method of measurement
Hamilton anxiety questionnaire

4

Description
quality of life
Timepoint
Pre test, post test and follow up three months after treatment
Method of measurement
Nepean dyspepsia index for quality of life

Secondary outcomes

1

Description
cortisol
Timepoint
Pre test, post test and follow up three months after treatment
Method of measurement
Blood Cortisol Test

2

Description
Emotional regulation
Timepoint
Pre test, post test and follow up three months after treatment
Method of measurement
Questionnaire for difficulty in emotional regulation

3

Description
emotional processing
Timepoint
Pre test, post test and follow up three months after treatment
Method of measurement
Baker's emotional processing questionnaire

Intervention groups

1

Description
Intervention group 1: metacognitive therapy, 10-session 45-minute treatment based on the Adrian Wells protocol approach to metacognitive therapy focused on anxiety protocol; First session: Formulation; Second session: Mindfulness training; Third to sixth sessions: Working on negative metacognitive beliefs; sessions 7 and 8: Challenging Positive metacognitive beliefs; sessions 9 and 10: New processing style training and relapse prevention training with common treatment: omeprazole and domperidone 25 mg for 10 weeks, once daily (made by Sobhan company) plus adhering to recommended diet and regular exercise.
Category
Behavior

2

Description
Intervention group 2: 25 mg Nortriptyline for 10 weeks, once daily, Sobhan manufacturer with usual treatment: omeprazole 20 mg and domperidone 10 mg for 10 weeks, once daily, Sobhan manufacturer, and adhering to recommended diet and regular exercise.
Category
Treatment - Drugs

3

Description
Control group: usual treatment by omeprazole (20 mg, once daily, Sobhan Darou) and domperidone (motidon, 10 mg, once daily, Abidi co.) for 10 weeks, and recommended diet and regular exercise.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Gastroenterology and Liver Diseases Research Center, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr.Mohamad Reza Zali
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Sponsors / Funding sources

1

Sponsor

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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
abbas masjedi arani
Position
Assistant professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

results, tables and treatment protocol

When the data will become available and for how long

6 months after publication

To whom data/document is available

Qualified applicants (graduates of medical, specialty and fellowship, psychiatrists, clinical and health psychologists)

Under which criteria data/document could be used

Repeated measure analysis

From where data/document is obtainable

Sepideh Batebi s.batebi@sbmu.ac.ir

What processes are involved for a request to access data/document

The applicants must first submit their application by an academic email to the correspondent, and then, the requests will be checked within one week and if approved the data will be sent.

Comments