Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Comparative efficacy of unified protocol of transdiagnostic psychotherapy, metacognitive therapy, and mirtazapine treatment in the frequency and severity of physical symptoms, psychological symptoms, and quality of life in functional dyspepsia disorder

Protocol summary

Study aim
Comparison the efficacy of psychotherapy between pharmacotherapy in patients with functional dyspepsia

Design
Randomized control trial consisted of parallel groups, single blind

Settings and conduct
This research conducted in Gastroenterology and Liver Diseases Research Center, Shahid Beheshti University of Medical Sciences, in a randomized clinical trial with single-blinding of patients.

Participants/Inclusion and 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 years old; reading and writing skills. Exclusion criteria: unwillingness to participate in the research for any reason Inability of the patient to access the medical center; chronic physical impairment or physical inability; severe mental disorder; substance abuse or dependence; patients need to take any medicine other than the prescribed drugs in the study during the study.

Intervention groups
Unified protocol transdiagnostic psychotherapy consisted of 12, 45-minute individual treatment sessions based on Barlow protocol to target key aspects of emotional processing and regulation of emotional experiences, metacognitive therapy 10-session 45-minute treatment based on the Adrian Wells protocol approach to metacognitive therapy focused on anxiety protocol, mirtazapine 7.5 ml per day over 12 weeks.

Main outcome variables
Functional dyspepsia symptoms; cortisol, serotonin; depression and anxiety

General information

Reason for update

Acronym
UP, MCT,

IRCT registration information
IRCT registration number: **IRCT20190312043036N2**
Registration date: **2021-05-07, 1400/02/17**
Registration timing: **prospective**

Last update: **2021-05-07, 1400/02/17**
Update count: **0**

Registration date
2021-05-07, 1400/02/17

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
2021-05-22, 1400/03/01

Expected recruitment end date
2023-02-20, 1401/12/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative efficacy of unified protocol of transdiagnostic psychotherapy, metacognitive therapy, and mirtazapine treatment in the frequency and severity of physical symptoms, psychological symptoms, and quality of life in functional dyspepsia disorder

Public title
Comparative efficacy of unified protocol of transdiagnostic psychotherapy, metacognitive therapy, and mirtazapine in functional dyspepsia disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Suffering functional dyspepsia without comorbid diseases such as IBS or other digestive diseases if IBS was comorbid, the onset of functional dyspepsia symptoms would be prior to IBS 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 6 months lasted from the definite diagnosis of functional dyspepsia for all patients All patients had not taken any psychiatric drug and psychotherapy during the last 3 months ago 80-90% adherence to the targeted treatments and treatment as usual in any groups
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 Infected to H-pylori Being pregnant Having any physiopathology in Endoscopy Having any severe and intolerable side effects 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

- Participant

Sample size
Target sample size: **220**
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, patients refer in odd days from 8 to 13 hour recruited in the up group, patients refer in odd days from 14- 19 hours recruited the metacognitive group, patients patient refer in even days from 8 to 13 hour recruited in mirtazapine treated group, patients refer in even days from 14- 19 hours recruited the placebo group
Blinding (investigator's opinion)
Single blinded
Blinding description
All the patients were single-blinded according to the treatments offering to them
Placebo
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 Sciences
Street address
Shahid Beheshti University of Medical Sciences, Velenjak St.
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1985717443
Approval date
2021-02-15, 1399/11/27
Ethics committee reference number
IR.SBMU.RIGLD.REC.1399.066

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

Secondary outcomes

1

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

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: the second intervention: unified protocol of transdiagnostic treatment, 12 sessions 45 minutes psychotherapy based on the manual based approach of unified transdiagnostic psychotherapy by David Barlow, the aims of the session: 1:increasing present-focused emotion awareness, 2: increasing cognitive flexibility, 3: identifying and preventing patterns of emotion avoidance and maladaptive emotion-driven behaviors (EDBs), 4: increasing awareness and tolerance of emotion-related physical sensations, and 5: interoceptive and situation-based emotion-focused exposure.
Category
Behavior

3

Description
Intervention group 3: 7.5 mg Mirtazapine for 12 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

4

Description
Control group: usual treatment by omeprazole (20 mg, once daily, Sobhan Darou) and domperidone (motidon, 10 mg, once daily, Abidi co.) for 12 weeks, and recommended diet and regular exercise.
Category
Placebo

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

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

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
Amir Sadeghi

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Physical Medicine

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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