Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing the effectiveness of unified transdiagnostic versus cognitive behavioral group therapy on treatment outcomes in adolescents with functional gastrointestinal disorders and determination of the mechanisms of change

Protocol summary

Study aim
Comparing the effectiveness of unified transdiagnostic versus cognitive behavioral group therapy on treatment outcomes in adolescents with functional gastrointestinal

Design
A controlled clinical trial with parallel groups, triple-blinded, randomized, phase 3, conducted on 30 patients, utilizing a random number table for randomization.

Settings and conduct
Pediatric Gastroenterology Specialty Clinic This research will be conducted in two parts: quantitative and qualitative, using a pre-test and post-test design with two experimental groups and a comparison. the blinding of participants, the assessment of treatment outcomes and data analysis will be conducted.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Diagnosis of at least one functional gastrointestinal disorder. Age range of 12 to 18 years. Currently enrolled in an educational level appropriate for their age. If there is a concurrent diagnosis of Attention Deficit/Hyperactivity Disorder (ADHD), the individual must be under medication treatment. At least one parent must participate. Exclusion Criteria: Concurrent diagnosis of autism spectrum disorder or bipolar disorder. Requirement for initiation of pharmacotherapy for emotional disorders. Simultaneous participation in other psychological treatments. Students from special education schools.

Intervention groups
The two treatment groups, unified transdiagnostic therapy and cognitive behavioral therapy, focus on key aspects of processing, emotional regulation, and the teaching of cognitive and behavioral skills, along with practice in real-life situations and parental involvement.

Main outcome variables
Gastrointestinal symptoms; anxiety symptoms; emotional regulation; quality of Life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250311065031N1**
Registration date: **2025-05-13, 1404/02/23**
Registration timing: **prospective**

Last update: **2025-05-13, 1404/02/23**
Update count: **0**

Registration date
2025-05-13, 1404/02/23

Registrant information

Name
Ensiyeh Najjari

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
2025-06-22, 1404/04/01

Expected recruitment end date
2025-09-22, 1404/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of unified transdiagnostic versus cognitive behavioral group therapy on treatment outcomes in adolescents with functional gastrointestinal disorders and determination of the mechanisms of change

Public title
"Effect of unified transdiagnostic group therapy in adolescents with functional gastrointestinal disorders"
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of at least one functional gastrointestinal disorder by a pediatric gastroenterologist based on the ROME diagnostic criteria Age range of 12 to 18 years Currently enrolled in an educational level appropriate for their age If a comorbid diagnosis of Attention Deficit/Hyperactivity Disorder (ADHD) is made, the adolescent must be receiving pharmacological treatment for symptoms At least one parent must be able to participate in the parent-specific sections of the therapeutic program
Exclusion criteria:
Concurrent diagnosis of Autism Spectrum Disorder or Bipolar Disorder Requirement to initiate pharmacotherapy for emotional disorders (if pharmacological treatment is stabilized, it does not preclude entry into therapy) Simultaneous participation in other psychological treatments Students from special education schools
Age
From **12 years** old to **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, simple randomization is used to allocate participants to treatment groups. This method allows each individual in the study to be assigned to one of the treatment groups randomly and without bias. To generate random allocations, a table of random numbers is used. This table contains randomly generated numbers that are employed to assign each participant to one of the groups. All randomization steps are carefully documented and recorded to maintain transparency in the allocation process and ensure traceability
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, a three-blinded method is used to prevent bias and enhance the validity of the results. In this trial, all stages of blinding are carefully implemented to ensure that none of the individuals involved in the study can influence the results. These individuals include: the participants of the study, who are unaware of the type of intervention they are receiving; the outcome assessors, who collect the data related to the treatment outcome variables; and the data analysts, who analyze the collected data. Outcome assessors will be individuals outside the research team who will administer the questionnaires to participants during post-test, pre-test, and follow-up stages. The person responsible for delivering the intervention will not be involved in this process. These individuals will possess at least a master's degree and will receive sufficient information regarding the tools used and the procedures for their administration. Participants, who are randomly assigned to either the experimental or control group, will only be informed about their group allocation and will not be provided with any additional details about the research. Data analysts will receive the coded dataset files without knowledge of participants' names or group assignments, with groups coded as 1 and 2.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences (IUMS), Shahid Hemmat Highway, Tehran 14
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1445613111
Approval date
2025-02-23, 1403/12/05
Ethics committee reference number
IR.IUMS.REC.1403.1030

Health conditions studied

1

Description of health condition studied
functional gastrointestinal disorders
ICD-10 code
K58-K59
ICD-10 code description
Irritable bowel syndrome - Other functional intestinal disorders

Primary outcomes

1

Description
Functional Gastrointestinal Disorders: These disorders typically include symptoms such as abdominal pain, bloating, changes in bowel habits (such as diarrhea or constipation), and discomfort in the digestive area
Timepoint
One week before the pre-test and one week after the post-test, and three months after the intervention (follow-up)
Method of measurement
Gastrointestinal Symptoms Rating Scale

2

Description
Anxiety Symptoms: Anxiety is described as "a feeling of tension and worry" that may be associated with specific behaviors such as avoiding stressful situations and fear. These feelings and behaviors can become disruptive patterns, especially if their intensity and duration negatively affect an individual’s daily functioning
Timepoint
One week before the pre-test and one week after the post-test, and three months after the intervention (follow-up)
Method of measurement
the Screen for Child Anxiety Related Emotional Disorders

3

Description
Quality of Life: Quality of life is typically regarded as a multidimensional concept that encompasses various aspects, including physical health, mental health, social interactions, and environmental influences
Timepoint
One week before the pre-test and one week after the post-test, and three months after the intervention (follow-up)
Method of measurement
Pediatric Quality of Life Inventory TM 4.0

4

Description
Emotion Regulation: Emotion regulation refers to the processes that individuals use to manage and control their emotions, which include identifying, assessing, and modifying feelings in a way that aids adaptation and improves an individual's quality of life
Timepoint
One week before the pre-test and one week after the post-test, and three months after the intervention (follow-up)
Method of measurement
Emotion Regulation Questionnaire for Children and Adolescents

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, the adolescent group therapy protocol (UP-A) designed by Ehrenreich (2018) is used. This therapeutic protocol consists of eight modules with flexibility in the number of sessions, targeting key aspects of emotional processing, regulation, and emotional experiences. It includes present-moment emotional awareness, cognitive flexibility, emotional avoidance, emotion-driven behaviors, awareness and tolerance of bodily feelings, and both endogenous and situational emotional exposure. In this protocol, sessions with parents are held to encourage their participation in the treatment. The number of sessions in the present study is 10 to 12 sessions
Category
Treatment - Other

2

Description
Control group: In this study, a cognitive-behavioral therapy protocol for anxiety in adolescents is used, with session topics including assessment and identification of anxiety problems and setting treatment goals, cognitive skills training (cognitive techniques such as identifying negative thoughts and challenging them), behavioral skills training (including exposure therapy, where adolescents gradually face fearful situations), real-life practice (where adolescents are encouraged to apply the skills learned in real-life situations and review their progress), and parental involvement (including sessions to educate parents on how to support their child). The number of sessions in the present study is 10 to 12 sessions
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

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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
Iran 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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
The SPSS file contains participant information in the form of defined codes, as well as the variables related to the research and their scoring in the data file
When the data will become available and for how long
Year 2026
To whom data/document is available
Researchers and academic institutions for use in scientific studies
Under which criteria data/document could be used
Submission of logical and scientific requests by individuals whose identities are known
From where data/document is obtainable
Ensiyeh najjari email: ensiyehnajjary@gmail .com
What processes are involved for a request to access data/document
Researchers who submit their requests with logical and scientific reasons, including supplementary analyses, advanced data analyses, or data aggregation in the form of a meta-analysis, can contact me via email (ensiyehnajjary@gmail.com) to introduce themselves and specify the objectives of their study. After receiving the request, the data will be provided to them within two to three weeks.
Comments