Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effectiveness of integrated transdiagnostic therapy(UP) and acceptance and commitment therapy(ACT) on rumination, life satisfaction, treatment citizenship, emotional disorders, gastrointestinal symptoms and perceived stress in patients with irritable bowel syndrome(IBS)

Protocol summary

Study aim
Determining the difference between the effectiveness of integrated transdiagnostic therapy with acceptance and commitment therapy on rumination, life satisfaction, treatment citizenship, emotional disorders, gastrointestinal symptoms and perceived stress in patients with irritable bowel syndrome

Design
The clinical trial study has two experimental groups, single blind, randomized and performed on 40 people. Simple randomization is used for randomization. The website https://www.Randomization.com is used online for random allocation. Numbered, sealed envelopes are used for blinding.

Settings and conduct
The present study is a clinical trial study with pre-test, post-test and follow-up that will be performed in patients diagnosed with irritable bowel syndrome in Taleghani Hospital. Samples are identified by a gastroenterologist after a definitive diagnosis and referred to a clinical psychologist. The clinical psychologist randomly places patients into two groups of 20, then treats each person individually online. Therapeutic intervention sessions are performed in a very similar manner and based on a single protocol.

Participants/Inclusion and exclusion criteria
Having a diagnosis of irritable bowel syndrome; age over 18 years old; having at least a third grade of secondary education; conscious satisfaction with conducting research

Intervention groups
Intervention group 1: includes patients with irritable bowel syndrome who receive integrated transdiagnostic treatment intervention in 10 sessions. Intervention group 2: includes patients with irritable bowel syndrome who receive the intervention of acceptance and commitment treatment in 8 sessions

Main outcome variables
Rumination; Life Satisfaction; Treatment Citizenship; Emotional Disorders; Gastrointestinal Symptoms; Perceived Stress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211223053494N2**
Registration date: **2022-06-27, 1401/04/06**
Registration timing: **prospective**

Last update: **2022-06-27, 1401/04/06**
Update count: **0**

Registration date
2022-06-27, 1401/04/06

Registrant information

Name
Jafar Sarani yaztappeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 17 1334 1894

Email address
sarani.jafar@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-27, 1401/05/05
Expected recruitment end date
2022-11-26, 1401/09/05
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of integrated transdiagnostic therapy(UP) and acceptance and commitment therapy(ACT) on rumination, life satisfaction, treatment citizenship, emotional disorders, gastrointestinal symptoms and perceived stress in patients with irritable bowel syndrome(IBS)

Public title
Comparison of the effectiveness of integrated transdiagnostic therapy (UP) and acceptance and commitment therapy (ACT) on rumination, life satisfaction, treatment citizenship, emotional disorders, gastrointestinal symptoms and perceived stress in patients with irritable bowel syndrome (IBS)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having a diagnosis of irritable bowel syndrome Age over 18 years old Conscious satisfaction with conducting research Having at least a third grade of secondary education
Exclusion criteria:
Three consecutive absences in treatment sessions Reluctance to continue the treatment process Incompleteness of one of the questionnaires, in which case the rest of the questionnaires related to that person will be deleted
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
In order to avoid the effect of restrictive variables, after randomly selecting the subjects and examining the criteria for entering the research, the samples of the two groups in terms of contextual variables (age, sex, education, marriage) try to be matched and thus They are included in the study and in each group, the treatment is performed as a single blind that patients are not aware of the treatment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Medicine - Shahid Beheshti University of Medical Sciences
Street address
School of Medicine, Shahid Beheshti University of Medical Sciences, next to the University Headquarters, Shahid Chamran Evin Highway,
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2022-04-12, 1401/01/23
Ethics committee reference number
IR.SBMU.MSP.REC.1401.005

Health conditions studied

1

Description of health condition studied
Irritable bowel syndrome
ICD-10 code
K58
ICD-10 code description
Irritable bowel syndrome

Primary outcomes

1

Description
Score of Intensity of Gastrointestinal Symptoms in questionnaire (GSRS)
Timepoint
At the beginning of the study (before the intervention), after the intervention and 3and 6 months after the intervention
Method of measurement
Questionnaire of Intensity of Gastrointestinal Symptoms (GSRS)

2

Description
Perceived Stress Score in Cohen Questionnaire
Timepoint
At the beginning of the study (before the intervention), after the intervention and 3and 6 months after the intervention
Method of measurement
Cohen Perceived Stress Questionnaire

3

Description
Adherence of Medication Score in Morisky scale
Timepoint
At the beginning of the study (before the intervention), after the intervention and 3and 6 months after the intervention
Method of measurement
Morisky Medication Adherence Scale

4

Description
Life Satisfaction Score in Diener Questionnaire
Timepoint
At the beginning of the study (before the intervention), after the intervention and 3and 6 months after the intervention
Method of measurement
Diener Life Satisfaction Questionnaire

5

Description
Rumination-Reflection Score in Nolen-Hoeksema and Morrow Scale
Timepoint
At the beginning of the study (before the intervention), after the intervention and 3and 6 months after the intervention
Method of measurement
Rumination-Reflection Scale

6

Description
Depression and Anxiety and Stress Score in Antony Scale DASS-21
Timepoint
At the beginning of the study (before the intervention), after the intervention and 3and 6 months after the intervention
Method of measurement
Depression and Anxiety and Stress Scale Antony (dass-21)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: includes patients with irritable bowel syndrome who receive integrated transdiagnostic treatment intervention in 10 sessions. The content of the first session includes increasing motivation to participate in treatment, motivational interview for patient participation and involvement, presenting the logic of treatment and setting treatment goals. Emotional experiences and AR model (history, responses, outcomes). The content of the third and fourth sessions includes teaching emotional awareness, learning to observe emotional experiences (emotions and reacting to emotions), especially using mindfulness techniques. The content of the fifth session includes re-evaluation and cognitive re-evaluation. Creating awareness of the impact and interrelationship between thoughts and emotions, identifying automatic maladaptive evaluations and cognitive re-evaluation and increasing flexibility in thinking. The content of the sixth and seventh sessions includes identifying patterns of emotion avoidance and examining emotion-induced behaviors. Familiarity and identification of emotion-induced behaviors and understanding their impact on emotional experiences, identifying maladaptive EDBS, and developing alternative action tendencies by coping with behaviors. The content of the eighth body includes awareness and tolerance of physical feelings. Increasing awareness of the role of physical feelings in emotional experiences, performing physiological visceral exposure or confrontation exercises in order to be aware of physical feelings and increase tolerance of these symptoms. The content of the ninth and tenth sessions includes visceral confrontation and confrontation with emotion based on situation, learning about the logic of emotional dreams, teaching how to prepare the hierarchy of fear and avoidance and designing repetitive and effective emotional confrontation exercises visually and objectively and inhibition. Avoid. Session 11 and 12: Prevention of recurrence. Overview of treatment concepts and discussion of the patient's recovery and therapeutic progress.
Category
Treatment - Other

2

Description
Intervention group 2: includes patients with irritable bowel syndrome who receive the intervention of acceptance and commitment treatment in 8 sessions.The content of the first session includes establishing a therapeutic relationship and an overall assessment.The content of the second session includes creative helplessness, exploring the world inside and out, and understanding that control is the problem, not the solution. The content of the third session includes identifying individual values, specifying values, practices, and barriers. The content of the fourth session includes

examining one's values and using relevant metaphors. The content of the fifth session includes examining fusion and faulting and performing exercises for faulting using metaphor.The content of the sixth session includes explaining the concepts, role and context, observing oneself as a context. The content of the seventh session includes emphasizing the present and presenting an instruction on the effective use of the present and the present.The content of the eighth session includes commitment training, reviewing life stories, identifying behavioral plans according to values, and summarizing.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Gastroenterology Department of Taleghani Hospital

Full name of responsible person
Amirsam Kianimghadam

Street address
Shahid Beheshti University of Medical Sciences - next to Taleghani Hospital - Yemen Street - Shahid Chamran Highway

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 2303 1548

Email
as.kianimoghadam@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afsin Zarghi

Street address
Vice-Chancellor of Research Affairs,Shahid Beheshti University of Medical Sciences, Next to Taleghani hospital, Erabi Ave., Chamran highway

City
Tehran

Province
Tehran

Postal code
1983963113

Phone
+98 21 2243 9770

Email
Intl-office@sbmu.ac.ir

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
Amirsam Kianimghadam

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Shahid Beheshti University of Medical Sciences - next to Taleghani Hospital - Yemen Street - Shahid Chamran Highway

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 2303 1548

Email
as.kianimghadam@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Amirsam Kianimghadam

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Shahid Beheshti University of Medical Sciences - next

to Taleghani Hospital - Yemen Street - Shahid Chamran Highway

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 2303 1548

Email
as.kianimghadam@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Jafar Sarani Yaztappeh

Position
Ph.D Student

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
Psychology Group, Floor4, Taleghani hospital, Erabi Ave., Yaman Ave., Chamran highway

City
Tehran

Province
Tehran

Postal code
1985711151

Phone
+98 21 2303 1548

Email
sarani.jafar@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