

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effectiveness of emotional schema therapy on the modification of emotional schemas and difficulties of emotional regulation in women with irritable bowel syndrome: single-subject design

Protocol summary

Summary

The method of research is of single-subject design type. It was used A-B schema with stepwise method. Generally, the first position (A) is the basic line, in second position (B) is performed a therapeutic intervention and then, dependent variable is evaluated. Statistical people included all women with irritable bowel syndrome that came to the office of a specialist in Isfahan in summer of 2016. Five people were selected as available sampling based on the participation willingness of individuals to the research and taking criteria for inclusion of study (having ROME III diagnostic criteria confirmed by digestion specialist for differentiation IBS from other functional gastrointestinal disorders). Treatment was started with stepwise method with one week interval so that first patient initially enters to the therapy schema. In second treatment session of first patient, second patient enters to the treatment schema and in third therapy session of first patient and second session of second patient, third patient and as the same way to fifth patient enter to treatment schema. Emotional schema therapy was implemented according to the Leahy therapeutic protocol through 12 sessions.

General information

Acronym

EST

IRCT registration information

IRCT registration number: **IRCT2016022826807N1**

Registration date: **2017-08-05, 1396/05/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-05, 1396/05/14

Registrant information

Name

Arefeh Erfan

Name of organization / entity

TUMS

Country

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Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-08-22, 1394/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of emotional schema therapy on the modification of emotional schemas and difficulties of emotional regulation in women with irritable bowel syndrome: single-subject design

Public title

The effectiveness of emotional schema therapy on the modification of emotional schemas and difficulties of emotional regulation with irritable bowel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria (having ROME III diagnostic criteria confirmed by digestion specialist for differentiation IBS from other functional gastrointestinal disorders, no consumption of psychiatry drugs during three months ago, no participation in psychology interventions session during six months ago, having high school education or higher, dominance on Persian language, have satisfaction for participation) and Exclusion criteria (having symptoms such as gastrointestinal bleeding, existence of blood in excretion, fever, losing weight, anemia during six months ago, nocturnal diarrhea, bellyache that awakes patients from sleep, palpable mass in physical examination, older than 50 and younger than 20, having a family history of colon cancer, having severe psychiatry disease)

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

The method of research is of single-subject design type. It was used A-B schema with stepwise method. Generally, the first position (A) is the basic line, in second position (B) is performed a therapeutic intervention and then, dependent variable is evaluated. In the study, independent variable is emotional schema therapy and dependent variables are therapeutic variations due use of the treatment method on the modification of emotional schemas and emotion regulation difficulty

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University Ethics Committee

Street address

enghelab tehran university of medical sciences

City

tehran

Postal code

iran

Approval date

2017-06-24, 1396/04/03

Ethics committee reference number

13962719

Health conditions studied

1

Description of health condition studied

Irritable bowel syndrome

ICD-10 code

k58.0

ICD-10 code description

Irritable bowel syndrome with diarrhoea

2

Description of health condition studied

Irritable bowel syndrome

ICD-10 code

k58.0

ICD-10 code description

Irritable bowel syndrome with diarrhoea

Primary outcomes

1

Description

emotional schemas

Timepoint

baseline stage tests in baseline as well as third, sixth, ninth and twelfth sessions. Also, at last session each patient was asked to refer once a month for three months

Method of measurement

baseline stage tests in baseline as well as third, sixth, ninth and twelfth sessions. Also, at last session each patient was asked to refer once a month for three months

2

Description

Emotion regulation difficulty

Timepoint

baseline stage tests in baseline as well as third, sixth, ninth and twelfth sessions. Also, at last session each patient was asked to refer once a month for three months

Method of measurement

Emotion regulation difficulty questionnaire (DERS)

3

Description

Psychological symptom

Timepoint

baseline stage tests in baseline as well as third, sixth, ninth and twelfth sessions. Also, at last session each patient was asked to refer once a month for three months

Method of measurement

DASS

4

Description

severity and frequency of physical symptoms

Timepoint

baseline stage tests in baseline as well as third, sixth, ninth and twelfth sessions. Also, at last session each patient was asked to refer once a month for three months

Method of measurement

BSS-FS

5

Description

quality of life

Timepoint

baseline stage tests in baseline as well as third, sixth, ninth and twelfth sessions. Also, at last session each patient was asked to refer once a month for three months

Method of measurement

quality of life quation for IBS

Secondary outcomes

empty

Intervention groups

1

Description

. It has been presented a summary of content of sessions of emotional schema therapy in Table 1. Table 1: a summary of content of sessions of emotional schema therapy Sessions Content of sessions First session Formation of therapeutic relation, planning of case formulation, presentation of treatment logic and treatment aims, presentation of etiologic model and treatment from emotional schema therapy approach Second session Normal and problematic emotions, consideration of painful emotions of patients and normalization of them, emotion self-awareness, instruction and introduction of emotion, identification and labeling of emotion, differentiation between different emotions, identification of emotion in physical and psychological state Third session Self-evaluation with the aim to recognize own emotion experiences, self-evaluation with the aim to identification of the amount of individuals emotion vulnerability, self-evaluation with the aim to identification of the strategies for emotion regulation, cognitive issues of emotion responses, physiologic issues of emotion responses, behavior outcomes of emotion responses and relation among them, introduction of rage emotion and the ways for

dominance on rage Forth session Proceeding identified emotional schemas in patient, verbal challenges and Socratic dialogue Fifth session Proceeding other identified emotional schemas in patient and verbal challenges and Socratic dialogue, instruction of the technique of writing of negative memorabilia with the aim to facility of emotion processing Sixth session prevention of social seclusion and avoidance, instruction of strategy of problem solving, training of interpersonal skills (talking, self-expression and conflict resolution), preliminary introduction of the conception of acceptance and emotion validation Seventh session Helping people for acceptance of own emotion, proceeding intervening emotional schemas in acceptance and experience of painful emotion, presentation of detached mindfulness technique Eighth session Introduction of kinds of negative beliefs about emotions and challenge to them, identification of false evaluation and their effects on the emotion states Ninth session Identification of the amount and the way of using of inhibition strategy and investigation of its emotion outcomes, instruction of emotion expression, encounter, training of abreaction, relaxation Tenth session Discussion about severity of schemas before and after of confrontation, proceeding reminder avoidance of patient Eleventh session Review of sessions and practice of learned skills Twelfth session Work on therapy program (prevention of recurrence), schematization for support sessions, homework, commitment to continuous usage of treatment practices According to the observed therapeutic sessions' content, therapist used a skill for patients and clarified it with examples of themselves.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Office Dr Peyman Adibi Gastroenterologist

Full name of responsible person

Street address

City

Isfahan,Facing Shariati Hospital,Shariati Building

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran university of medical Sciences

Full name of responsible person

Tehran university of medical Sciences

Street address

Tehran university of medical Sciences

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tehran university of medical Sciences

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**

Tehran university of Medical Sciences

Full name of responsible person

Arefeh Erfan

Position

MSc

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Tehran university Of Medical Sciences

Full name of responsible person

Arefeh Erfan

Position

MSc

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

tehran university Of Medical sciences

Full name of responsible person

arefeh erfan

Position

MSc Clinical Psychology

Other areas of specialty/work**Street address**

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City

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Web page address**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