

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effect of expressive writing on anxiety sensitivity and severity of symptoms in patients with irritable bowel syndrome

Protocol summary

sensitivity and Severity of gastrointestinal symptoms
(before intervention, 1 month after intervention)

Study aim

To determine the effect of written expression of emotions on anxiety sensitivity and severity of gastrointestinal symptoms in patients with irritable bowel syndrome

Design

It is a controlled clinical trial with parallel groups on 72 patients that are blinded and randomized. For randomization, the double-blinding method was used using the envelope in the package.

Settings and conduct

After obtaining the necessary approval, the patients with irritable bowel syndrome who met the inclusion criteria, referred to the gastrointestinal clinics of Firoozgar and Rasoul Akram hospitals, were selected by the researcher. Subsequently, participants entered the study after giving them thorough explanations and obtaining informed consent. Study questionnaires were completed before and one month after the intervention. The experimental group received a white booklet to write their expression. The control group received only routine care. Telephone follow-ups were performed weekly for both groups.

Participants/Inclusion and exclusion criteria

criteria into the study: Having irritable bowel syndrome based on a doctor's diagnosis, willingness of patients to participate in the study, Be literate enough. Exclusion criteria: Patients who do not participate in pre-test or post-test evaluations, Not writing in the booklet more than 2 times or a total of 4 sessions.

Intervention groups

The experimental group received a white booklet describing their feelings and concerns about irritable bowel syndrome. Patients write their feelings at home by expressing their emotions in the booklet once a week for 15 to 30 minutes once a week for a month. The control group provided only routine care by clinic staff. they received.

Main outcome variables

The effect of written emotional expression on Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200831048567N1**

Registration date: **2020-10-28, 1399/08/07**

Registration timing: **retrospective**

Last update: **2020-10-28, 1399/08/07**

Update count: **0**

Registration date

2020-10-28, 1399/08/07

Registrant information

Name

Marzieh Borjian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6691 6095

Email address

borjian.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-07, 1398/07/15

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

2019-10-07, 1398/07/15

Actual recruitment end date

2020-03-05, 1398/12/15

Trial completion date

2020-03-05, 1398/12/15

Scientific title

The effect of expressive writing on anxiety sensitivity and severity of symptoms in patients with irritable bowel syndrome

Public title

The effect of expressive writing on anxiety sensitivity and severity of symptoms in patients with irritable bowel syndrome

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having IBS based on a doctor's diagnosis Satisfaction and willingness of patients to participate in the study Having symptoms classified based on the irritable bowel syndrome Severity Index (SI-IBS); in the mild, moderate, or severe scale The diagnosis was made at least 3 months ago Be literate enough to write and complete questionnaires The patient is physically and mentally fit to write Does not suffer from acute mental disorders based on the doctor's diagnosis and registration Does not take anti-anxiety medications for the past 3 months based on the patient's record At the same time, participants do not have other functional or structural gastrointestinal disorders based on the patient's record

Exclusion criteria:

Diagnosis of any disease during the study by the treating physician Patient's dissatisfaction or unwillingness to cooperation or to continue with the study Patients who do not participate in pre-test or post-test evaluations Not writing in the booklet more than 2 times or a total of 4 sessions Hospitalization of the patient due to exacerbation of gastrointestinal symptoms during the study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **72**

Actual sample size reached: **89**

Randomization (investigator's opinion)

Randomized

Randomization description

Continuous method was used for selection and double blind method was used to allocate the participants to the study and control groups. In this way, the researcher writes different states of the two groups (4 modes: 1. control-intervention; 2. Intervention - control; 3. Intervention - intervention; 4. Control - control) on 4 note cards and puts each in an envelope. These envelopes were placed in a box and the researcher did not know in which group the participant would be placed until the

card was chosen. Before assigning, encountering the research units, the researcher removed one of the envelopes from the box to determine which group of patients were included in the study, respectively. This process continued until all 4 cards were taken out of the box, then the cards were returned to the box and the random selection of cards was repeated. The sampling process continued until the desired sample volume was completed and then stopped.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study was single blinded; individuals were not aware of the study hypotheses or that there were writing condition. Participants were aware that they were consenting to take part in a writing intervention that could reduce their symptoms.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

Street address

No 1, Sholevar Ave., South Kargar Street., Enghlab Square

City

Tehran

Province

Tehran

Postal code

1313935196

Approval date

2019-06-30, 1398/04/09

Ethics committee reference number

IR.IUMS.REC.1398.326

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

Rate of anxiety sensitivity

Timepoint

Before the intervention and 1 month after the intervention (written emotional expression)

Method of measurement

Based on the score of (0-144) Revised Anxiety Sensitivity Index (ASI-R)

2

Description

Severity of gastrointestinal symptoms

Timepoint

Before the intervention and 1 month after the intervention (written emotional expression)

Method of measurement

Obtaining a score between 75-500 Based on Irritable Bowel Syndrome Severity Index (IBS-SI) Questionnaire.

Secondary outcomes

1

Description

Anxiety Sensitivity Score in the Revised Anxiety Sensitivity Index (ASI-R) Questionnaire

Timepoint

Before the intervention and 1 month after the intervention

Method of measurement

Revised Anxiety Sensitivity Index (ASI-R) Questionnaire

2

Description

Gastrointestinal symptom severity score in Irritable Bowel Syndrome Severity Index (IBS-SI)

Timepoint

Before the intervention and 1 month after the intervention

Method of measurement

Irritable Bowel Syndrome Severity Index (IBS-SI) Questionnaire

Intervention groups

1

Description

Intervention group: Patients with irritable bowel syndrome who Receive expressive writing from a researcher.

Category

Other

2

Description

Control group: Patients with irritable bowel syndrome who receive routine pre-discharge training from ward staff.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Ms. Razm Ahang

Street address

Firoozgar hospital, Beh Afarin Street, Karim Khan Street, Valiasr Square

City

Tehran

Province

Tehran

Postal code

1593747811

Phone

+98 21 8214 1000

Email

h_firoozgar@yahoo.com

Web page address

<https://firoozgar.iums.ac.ir/>

2

Recruitment center

Name of recruitment center

Rasoul Akram hospital

Full name of responsible person

Ms. Abbasi

Street address

Rasoul Akram hospital, Niyayesh Street, Sattar-Khan Avenue

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 1000

Email

ayhealth.co@gmail.com

Web page address

<https://hrmc.iums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Abbas Motavlian

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2030

Fax

+98 21 8862 2692

Email

motevalian.a@iums.ac.ir

Web page address<https://iums.ac.ir/>**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****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Marzieh Borjian

Position

Master student of med _Surgery

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No 1, Sholevar Ave., South Kargar Street., Enghlab Square

City

Tehran

Province

Tehran

Postal code

1313935196

Phone

+98 21 8879 4302

Fax**Email**

M.Borjian@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr. Alice Khachian

Position

Associate Professor, Department of med _Surgery

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

School of Nursing & Midwifery Rashid Yasemi St. Vali Asr St.Tehran- Iran

City

Tehran

Province

Tehran

Postal code

199613883

Phone

+98 21 8879 4302

Fax**Email**

khachian.a@iums.ac.ir

Web page address<https://fnm.iums.ac.ir>**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Marzieh Borjian

Position

Master student of med _Surgery

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No 1, Sholevar Ave., South Kargar Street., Enghlab Square

City

Tehran

Province

Tehran

Postal code

1313935196

Phone

+98 21 8879 4302

Email

M.Borjian@yahoo.com

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

Research findings and results file (only part of the data such as information about the main outcome or the like can be shared).

When the data will become available and for how long

Start of access period after the publication of the article (late 1399)

To whom data/document is available

Researchers working in academic and scientific

institutions

Under which criteria data/document could be used

In this study, no studies and/or judgments were made about patients' writings as well as their content analysis. only the information related to the participants' unidentifiable questionnaire file was statistically analyzed (using SPSS software version 16 with a level of significance of 0.05) in two sections of descriptive and inferential statistics. The findings and results of the present study will be allowed to be used in other related research at a broader level and reference in other studies.

From where data/document is obtainable

1. Dr. Alice Khachian / E-mail address khachian.a@iums.ac.ir
2. Marzieh Borjian (Master student of Internal Surgery Nursing, Iran University of Medical Sciences) / E-mail address: M.Borjian@yahoo.com
Address of the Faculty of Nursing and Midwifery: Tehran, Vali Asr St., above Vanak Sq., Rashid Yasemi St. Faculty Contact Number: 021-43651000 / Postal Code: 1996713883 / Fax: 882011978

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

To receive the documentation file of the present study, applicants can send their request to use and determine how the findings of this research are used in their study, to the above-mentioned e-mail addresses. Will be provided to them.

Comments