Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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

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

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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
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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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

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Marzieh Borjian
Position
Master student of med _Surgery
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Person responsible for updating data

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Email
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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
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