

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of emotion regulation training on stress coping styles, problem solving, alexithymia, quality of life and pain intensity in patients with peptic ulcer

Protocol summary

Study aim

Determining the effectiveness of emotion regulation training on coping styles, problem solving, alexithymia, quality of life and pain intensity in patients with peptic ulcer

Design

Clinical trial with two groups of control and experimental

Settings and conduct

The present study will be a quasi-experimental type. The data of this study will be selected from patients aged 20 to 50 years with a diagnosis of peptic ulcer who have referred to Ayatollah Taleghani Hospital in Tehran and have endoscopic indications and have been approved by a gastroenterologist. Gpower was used to estimate the sample size; Considering the effect size of 0.8, alpha of 0.5 and power of 0.80, a total of 42 people were obtained for each group of 21 people. Patient samples will be selected using the available method. Participation in the study will be based on their satisfaction and optional, and before completing the research questionnaires, the purpose of the study will be explained to them. Inclusion criteria in the group of patients will be the diagnosis of peptic ulcer symptoms in them through endoscopic diagnostic test. Prior to data collection, the necessary permits will be obtained from the Vice Chancellor for Medical Sciences of Shahid Beheshti University and Taleghani Hospital.

Participants/Inclusion and exclusion criteria

Has not received any psychological intervention in the last 1 year, no personality disorders, no psychotic disorders, no substance abuse, no use of psychiatric drugs.

Intervention groups

Ulcer peptic patients

Main outcome variables

stress coping styles, problem solving, alexithymia, quality of life and pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201103049252N2**

Registration date: **2022-01-15, 1400/10/25**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-15, 1400/10/25**

Update count: **0**

Registration date

2022-01-15, 1400/10/25

Registrant information

Name

Abbas Masjediarani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-03, 1400/08/12

Expected recruitment end date

2022-02-01, 1400/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of emotion regulation training on stress coping styles, problem solving, alexithymia, quality of life and pain intensity in patients with peptic ulcer

Public title

The effectiveness of emotion regulation training on stress coping styles, problem solving, alexithymia, quality of life and pain intensity in patients with peptic ulcer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having ulcer peptic

Exclusion criteria:

Psychotic disorder

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Using another person for treatment

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of shahid beheshti University of Medical Sciences

Street address

Yaman blvd

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2021-10-26, 1400/08/04

Ethics committee reference number

IR.SBMU.MSP.REC.1400.519

Health conditions studied**1****Description of health condition studied**

Ulcer peptic

ICD-10 code

K27.2

ICD-10 code description

Acute peptic ulcer, site unspecified, with both hemorrhage and perforation

Primary outcomes**1****Description**

Psychotherapy

Timepoint

3 month

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group:Excitement regulation protocol This protocol is based on Brooks' 1980 treatment for duodenal ulcer.All patients will receive a manual designed to complete the treatment process. Patients in the treatment group will receive a handbook that (A) Explain the rationale of the treatment plan in terms of the relationship between anxiety, emotional inhibition, and gastric ulcer.B) Graphically shows the constant cycle of worry and anxiety. (C) Identifies several main irrational beliefs that lead to unnecessary anxiety. (D) provide examples of negative self-talk, positive self-talk, and general self-confrontation. E) Explained the concept of decisiveness. (F) provide examples of indecisive, aggressive, and assertive behaviors. (G) Provide space for recording important experiences with newly learned behaviors. And (h) provide charts for recording daily wound pain during the follow-up period.The handbook for control patients will include only (a) a general description of the relationship between anxiety, emotional control,

and gastric ulcer, and (b) diagrams for recording daily ulcer pain during the follow-up period. The emotional skills training program consisted of eight 60-90 minute treatment sessions that will be conducted separately with the patients in the treatment group. All treatments will be performed by the first author. Patients will receive four sessions of treatment focusing on anxiety management training and four sessions of rigorous training. Anxiety Management Training: The anxiety management section of the program will follow the proposal of Richardson (1976) and typically, the first four of the eight treatment sessions will be devoted to training. During an initial training phase, the patient, with the help of the therapist (a), examined their irrational, erroneous, and anxious beliefs (Ellis, 1973; Richardson), and negative self-talk about a variety of everyday stressful situations. Will identify and (b) develop and write examples of meaningful, alternative, more realistic, and relaxing personal beliefs and conversations with oneself. Training for courage and assertiveness of emotions: The second 4 sessions will be dedicated to this training. The component of teaching courage and emphatic expression of emotions The emotional skills training program will follow the broad format proposed by Lazarus (1971). The two main stages of this component were (a) cognitive reconstruction focusing on correcting misconceptions about assertiveness and the consequences of non-judgment (with particular reference to wound problems) and (b) practicing the behavior of relevant situations in patients' daily homes and workplaces. For example, most wound patients will report irreversible behaviors in interpersonal situations as a way to "control" emotions and avoid emotional distress (as directed by the therapist). Much of the courage training time will be spent pointing to the need to learn self-awareness, and chronic resentment will be severely emphasized by periodic outbursts of anger and subsequent stressful guilt.

Category

Treatment - Other

2

Description

Control group: Treatment as Usual will be performed in the control group. In this group, once a week for 15 minutes for 6 weeks, the therapist will be in contact with patients, but there will be no major psychological interventions. In this group of patients, attention placebo treatment will be performed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Asieeftekhari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Asie eftekhari

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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

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
Asie Eftekhari

Position
PHD student

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Full name of responsible person
Abbas masjedi arani

Position
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is accessible to defined individuals

When the data will become available and for how long

Start of access period of the year 2022

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Review of documents for publishing research articles

From where data/document is obtainable

Researchers present in the research

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

Documents for publishing an article in a journal

Comments