Clinical Trial Protocol
Iranian Registry of Clinical Trials
08 Nov 2022

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

Inclusion/Exclusion criteria

Inclusion criteria: Having ulcer peptic
Exclusion criteria: Psychotic disordr

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

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
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 az 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
Asieeftekhiari

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Yaman
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Tehran
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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 eftekhiari
Street address
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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
Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Abbas Masjedi Arani
Position
Professor
Latest degree
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Other areas of specialty/work
Psychology
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Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences

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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Abbas Masjedi Arani
Position
Professor
Latest degree
Ph.D.
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