Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Comparative study of the effectiveness of mindfulness-based cognitive therapy with emotion-oriented group therapy on experiential avoidance, cognitive emotion regulation and anxiety sensitivity in patients with gastric ulcer

Protocol summary

Study aim

the effectiveness of group mindfulness-based cognitive therapy with emotion-oriented therapy on experiential avoidance, cognitive emotion regulation, and anxiety sensitivity in patients with gastric ulcers.

Design

A controlled, parallel-group, randomized, first-phase, clinical trial on 45 patients

Settings and conduct

In this study, the number of 45 patients from among patients with a gastric ulcer who visited internal medicine clinics in Mashhad during the research period (first quarter of 2023) selected as available, and with the help of randomization software in three groups of cognitive therapy based on mindfulness is replaced by emotion-oriented and control. They complete the demographic information questionnaire, cognitive avoidance, emotional regulation, and anxiety sensitivity. The number of intervention sessions for the first group is eight and the second group is ten sessions at Dr. Alami's counseling center. In this period of time, the control group does not receive any intervention. This study was not blinded to the researcher and participants

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Minimum diploma education; age between 18 and 50 years old; Absence of chronic disease except for gastric ulcer Exclusion criteria: no will to cooperate; Absence in more than two sessions

Intervention groups

Group mindfulness-based cognitive therapy: Participants in this study will receive eight sessions, once a week, each session lasting 90 minutes along with routine medical treatment. Group emotional therapy: participants will receive 90 minutes of routine medical treatment for ten sessions, twice a week. Control group: Participants in this group do not receive any intervention during the study and receive only routine medical treatment

Main outcome variables

Experiential avoidance, cognitive emotion regulation, anxiety sensitivity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221108056439N1**
Registration date: **2023-01-21, 1401/11/01**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-21, 1401/11/01**
Update count: **0**

Registration date

2023-01-21, 1401/11/01

Registrant information

Name

Fatemeh Amanloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3870 3119

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-05, 1401/10/15

Expected recruitment end date
2023-03-06, 1401/12/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the effectiveness of mindfulness-based cognitive therapy with emotion-oriented group therapy on experiential avoidance, cognitive emotion regulation and anxiety sensitivity in patients with gastric ulcer

Public title
The effectiveness of psychological treatments on patients with gastric ulcers
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
age 18-50 no mental condition Not suffering from chronic physical illness other than gastric ulcer education diploma and higher
Exclusion criteria:
drug abuse no willing to participation in study
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Permuted Block Randomization method with a block size of 6 was used to randomly assign people to three equal groups. A block randomization design was generated using the free website Randomization.com (http://randomization.com). Randomization is individual and the central concealment method is used. People are registered in a central list in the order of their entry into the study and get a code. During the study, contact is made with the person outside the team and each person is assigned to the desired group
Blinding (investigator's opinion)
Single blinded
Blinding description
Data will be collected by someone who is not aware of the research objectives. The collected data will be entered into the software and analyzed by a person who is not aware of the research objectives
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethic committee of Mashhad University of Medical Sciences
Street address
Paris colony, Azadi Sq, Mashahd
City
mashahd
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2022-09-10, 1401/06/19
Ethics committee reference number
IR.MUMS.REC.1401.202

Health conditions studied

1

Description of health condition studied
gastric ulcer
ICD-10 code
K25
ICD-10 code description
Gastric ulcer

Primary outcomes

1

Description
cognitive emotion regulation
Timepoint
before intervention and after the intervention and one month after intervention
Method of measurement
emotional regulation questionnaire of Garnevsky and Kraij

2

Description
anxiety sensitivity
Timepoint
before intervention and after the intervention and one month after intervention
Method of measurement
anxiety sensitivity questionnaire of Taylor and Cox

3

Description
experimental avoidance
Timepoint
before intervention and after the intervention and one month after intervention
Method of measurement
Experiential Avoidance Questionnaire Bund et al(2007)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Mindfulness based on cognitive therapy: The intervention will take place for eight weeks and the sessions will be held weekly. Each session lasts 90 minutes. The content of the sessions was designed based on the study of Tizdell and Segal (2000).
Category
Behavior

2

Description
Intervention group: emotion oriented: this intervention is designed for ten sessions. The design of the meetings was based on the studies of Greenberg (2016) and Johnson (2005). The sessions will be twice a week and each session will be 90 minutes.
Category
Behavior

3

Description
Control group: will receive only routine medical treatments during the intervention period
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Seyedi Clinic
Full name of responsible person
Javad Jahani-mehr
Street address
Aslani
City
Mashahd
Province
Razavi Khorasan
Postal code
9163765416
Phone
+98 912 033 1640
Email
jahanimehrij1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
fatemeh amanlu
Street address
Bolvar Razavi
City
Mashahd
Province
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Postal code
9178194346
Phone
+98 51 3870 3119
Email
amanloo.fatemeh5@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Private
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
Islamic Azad University
Full name of responsible person
Fatemeh Amanloo
Position
PHD.Student
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
No.20,Golestan,91/1 Hashemiye Blvd,Vakilabad Blvd
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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
In this study, none of the patients' personal information will be shared. And only data related to the main outcome of the intervention is shared.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers in academic institution psychologist, physicians
Under which criteria data/document could be used
Applicants are only allowed to use the information that is available to them only in clinical work and should not publish this information.
From where data/document is obtainable
amanloo.fatemeh5@gmail.com Fatemeh Amanlu
What processes are involved for a request to access data/document
Applicants' emails will be answered within a maximum of one week
Comments