# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Comparing the effectiveness of online group compassion-based therapy and acceptance and commitment therapy on the psychological symptoms of patients with peptic ulcer

## Protocol summary

**Study aim**

Comparing the effectiveness of online group compassion-based therapy and acceptance and commitment therapy on the psychological symptoms of patients with peptic ulcer

**Design**

A clinical trial with a control group, with parallel groups including two intervention groups and one group without treatment, without blinding, randomized, on 45 patients, random number generator software was used for randomization.

**Settings and conduct**

The recent clinical trial was conducted at an open-label university medical center using the available sampling method. The study objectives were explained to the participants, who will be screened for inclusion criteria. Those meeting the criteria will be randomly assigned to one of three groups, each comprising 15 people. The first group will receive 6 sessions of acceptance and commitment psychotherapy, the second group will receive 6 sessions of psychotherapy based on self compassion, and the third group will not receive any treatment. Scales will be completed before and after the treatment.

**Participants/Inclusion and exclusion criteria**

Having peptic ulcer diagnosed by a gastroenterologist, Age between 18 and 60 years, At least having a diploma degree, Ability to use smartphones, Not having neurological disorders.

**Intervention groups**

Psychotherapy based on compassion and commitment in 6 sessions of 90 minutes in groups and online. Psychotherapy based on self-compassion in 6 sessions of 90 minutes in a group and online. The control group did not receive the intervention.

**Main outcome variables**

Severity of depressive symptoms, Severity of anxiety symptoms, The amount of quality of life, The amount of stress

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20220316054306N3**
Registration date: **2024-08-25, 1403/06/04**
Registration timing: **registered_while_recruiting**

Last update: **2024-08-25, 1403/06/04**
Update count: **0**

**Registration date**

2024-08-25, 1403/06/04

**Registrant information**

**Name**

Shahab Lotfinia

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 23871

**Email address**

lotfiniashahab@sbmu.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2024-06-18, 1403/03/29

**Expected recruitment end date**

2024-09-19, 1403/06/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparing the effectiveness of online group compassion-based therapy and acceptance and commitment therapy on the psychological symptoms of patients with peptic ulcer

**Public title**

Effectiveness of compassion-based therapy and acceptance and commitment therapy on the psychological symptoms of peptic ulcer patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Having peptic ulcer diagnosed by a gastroenterologist Age between 18 and 60 years At least having diploma degree Ability to use smartphones

**Exclusion criteria:**

having neurological disorders

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **45**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

All the people who entered the study were given a code, then these codes were entered into the Randomly assign online software (https://www.graphpad.com/quickcalcs/randomize1.cfm) and the software randomly assigned each code to a group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethic committee of Shahid Beheshti University of Medical Science

**Street address**

Bldg No.2 Shahid Beheshti University of Medical science, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1983963113

**Approval date**

2024-06-18, 1403/03/29

**Ethics committee reference number**

IR.SBMU.MSP.REC.1403.159

## Health conditions studied

### 1

**Description of health condition studied**

Peptic ulcer

**ICD-10 code**

K27

**ICD-10 code description**

Peptic ulcer, site unspecified

## Primary outcomes

### 1

**Description**

Severity of depressive symptoms

**Timepoint**

Before and after intervention

**Method of measurement**

Based on the score obtained in Depression Anxiety Stress Scales

### 2

**Description**

Severity of anxiety symptoms

**Timepoint**

Before and after intervention

**Method of measurement**

Depression Anxiety Stress Scales

### 3

**Description**

Severity of stress

**Timepoint**

Before and after intervention

**Method of measurement**

Depression Anxiety Stress Scales

### 4

**Description**

The amount of quality of life

**Timepoint**

Before and after intervention

**Method of measurement**

Based on the score obtained in the World Health Organization Quality of Life Scale

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: Psychotherapy sessions based on acceptance and commitment: The sessions will be conducted online and consist of 6 sessions, each lasting 90 minutes. First session: Establishing communication and introducing participants to the intervention topic. Second session: Discussing the temporary and ineffectiveness of methods using metaphors. Third session: Identifying ineffective strategies and accepting painful personal events. Fourth session: Explaining the avoidance of painful experiences and raising awareness about their consequences. Fifth session: Examining the interconnected relationship between behavior, emotions, and cognition. Sixth session: Explaining the concepts of role and context, introducing the concept of values, and creating motivation for change and commitment to action.

**Category**

Treatment - Other

### 2

**Description**

Intervention group: Self-compassion-based psychotherapy group meetings will be conducted online in six 90-minute sessions. The first session will focus on introducing the concept of compassion and its importance in life. In the second session, participants will be taught ways to enhance positive experiences, increase awareness of positive experiences, create positive experiences through mental visualization, and learn about compassionate behaviors. The third session will involve training in identifying negative self-evaluations and their impact on compassion. During the fourth session, participants will receive training on recognizing how and to what extent they practice compassion. The fifth session will focus on cultivating self-compassion through conscious attention. In the final session, participants will receive training on transforming negative self-compassion by engaging in behaviors that counteract those negative feelings.

**Category**

Treatment - Other

### 3

**Description**

Control group: Control group: Waiting list. Patients in this group do not receive any therapy.

**Category**

Other

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Ayatollah Taleghani Hospital

**Full name of responsible person**

Shahab lotfinia

**Street address**

Ayatollah Taleghani Hospital, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

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**Email**

taleghanihospital@sbmu.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr Afshin Zarghi

**Street address**

No.2 Shahid Beheshti University of Medical science, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

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**Email**

Intl_office@sbmu.ac.ir

**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**

Amir Sam Kianimoghadam

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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## Person responsible for scientific inquiries

**Contact**

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Shahid Beheshti University of Medical Sciences

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Shahab

**Position**

PhD student

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

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## Person responsible for updating data

**Contact**

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**Full name of responsible person**

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**Position**

PhD student

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available