

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The effect of positive psychological interventions on self-companion and resilience of Psychosomatic patients

Protocol summary

Study aim

Determining the effect of positive educational interventions on self-compassion and resilience in psychosomatic patients

Design

A randomized clinical trial with a control group on a sample size of 60 psychosomatic patients. Random permutation block method is used for randomization

Settings and conduct

The control group will be performed in patients referred to Imam Reza and Ibn Sina Hospital clinics and private practices. The diagnosis is based on DSM-5 diagnostic criteria for Somatic symptoms and related disorders and the absence of other psychiatric disorders. Then the patients will be randomly divided into intervention and control groups. Patients in the intervention group will undergo treatment sessions for 6 weeks and each session will last 90 minutes. And in the control group, no psychological treatment will be done for the patients. And for this group, the movie will be played, and only after the end of the intervention, the control group will have treatment sessions.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: age between 20-60 years, diagnosis of psychosomatic disorders, having a smartphone. The criteria for not entering the study include: No psychological treatment in the last 6 months, no addiction, no diagnosis of severe psychological diseases, no stressful factor in the person's life in the last 6 months, and no severe psychiatric symptoms.

Intervention groups

Patients in the intervention group will undergo treatment sessions for 6 weeks (for 90 minutes). And in the control group, no psychological treatment will be done for the patients. and after the treatment of the control group, they will receive training on positive interventions.

Main outcome variables

Resilience; Self-Compassion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230729058963N1**

Registration date: **2023-12-12, 1402/09/21**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-12, 1402/09/21**

Update count: **0**

Registration date

2023-12-12, 1402/09/21

Registrant information

Name

vahideh ghassemi gonabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 2570

Email address

vghassemi71@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of positive psychological interventions on self-companion and resilience of Psychosomatic patients

Public title

The effect of positive psychological interventions in psychosomatic patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of psychosomatic disorders Having a smartphone Age between 20-60 years

Exclusion criteria:

Not undergoing psychotherapy in the last 6 months Do not have an addiction Do not have a severe psychiatric illness such as psychotic illnesses In the last 6 months, there is no severe stressor Do not have severe psychiatric symptoms

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random permutation block method is used for randomization. In this method, blocks of size 2 and 4 are randomly selected in order to avoid predictability of future treatment type. According to the sample size of 60 people, 10 blocks of size 4 are selected from the blocks AABB, ABAB, ABBA, BABA, BBAA, BAAB and 10 blocks of size 2 are selected from the blocks AB, BA using a random number table. Concealment of random allocation is done with the help of sealed envelopes.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Koh Sangi, 40 Beheshti Dr, No. 125, Unit 10

City

Mashhad

Province

Razavi Khorasan

Postal code

9176758684

Approval date

2023-04-11, 1402/01/22

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1402.083

Health conditions studied

1

Description of health condition studied

Psychosomatic disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Resilience

Timepoint

At the beginning of the study (before the start of the intervention) and after the end of the intervention

Method of measurement

Connor and Davidson Resilience Scale

2

Description

Self-compassion

Timepoint

At the beginning of the study (before the start of the intervention) and after the end of the intervention

Method of measurement

Self-compassion scale (Neff)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the intervention will undergo therapy sessions (positive psychology interventions) for 6 weeks and each session will last 90 minutes. First step: introducing people to each other, general explanation about the program, as well as discussion about the lack of positive resources. The second step: determining the capabilities of the secretary in order to create and strengthen unity. The third step: familiarizing people with the nature of forgiveness and forgiveness. Step 4: Emphasize good memories and gratitude as a lasting

form of gratitude. Fifth step: Acceleration in enjoying pleasure as a possible threat to gradual pleasure. Step 6: Teaching people around how to actively react constructively to the good news they receive from others.

Category

Other

2**Description**

Control group: no psychological treatment will be done for the patients. And for this group, the movie will be played, and only after the end of the intervention, the control group will have treatment sessions.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital

Full name of responsible person

Vahideh Ghasemi Gonabadi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Mohebati

Street address

University St., next to Hoize Cinema, Qurashi Building, Research and Technology Vice-Chancellor

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vcresraech@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Vahideh Ghassemi Gonabadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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No.125, Beheshti Ave Kohsangi Blvd

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

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City

Mashhad

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available