Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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

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vghassemi71@gmail.com

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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9138813944

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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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Person responsible for scientific inquiries

Contact

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Position
Resident

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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