# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Evaluation effectiveness of compassion-focused therapy on shame and self-criticism in patients with a psychotic disorder

## Protocol summary

**Study aim**
Evaluation effectiveness of compassion-focused therapy on shame and self-criticism in patients with a psychotic disorder

**Design**
A clinical trial with a control group, with parallel, randomized, phase 2 groups will be performed on 60 patients. The random block method is used.

**Settings and conduct**
A clinical trial with a control group, with parallel, randomized, phase 2 groups will be performed on 60 patients. The random block method is used. Intervention is a method for people with the psychotic disorder to receive 10 sessions of psychotherapy. This study will be performed on patients admitted to Golestan Hospital in Ahvaz. Blinding is not applicable to this study.

**Participants/Inclusion and exclusion criteria**
Inclusion condition: Patients with a psychotic disorder
Exclusion criteria: History of any mental disorder

**Intervention groups**
Intervention group: After the patients are selected, based on the treatment group, the patients are placed in the intervention group and receive treatment focused on compassion, and after treatment, their shame and self-criticism will be assessed by a questionnaire. Control group: After the patients are selected, based on the treatment group, the patients are placed in the control group and receive normal treatment, and then their shame and self-criticism will be assessed by a questionnaire.

**Main outcome variables**
self-criticism shame

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20161228031626N5**
Registration date: **2021-12-31, 1400/10/10**
Registration timing: **retrospective**

Last update: **2021-12-31, 1400/10/10**
Update count: **0**

**Registration date**
2021-12-31, 1400/10/10

**Registrant information**

**Name**
Hatam Boostani

**Name of organization / entity**
Ahvaz Jundishapur University of Medical Sciences

**Country**
Iran (Islamic Republic of)

**Phone**
+98 61 3374 3038

**Email address**
tabibi.y@ajums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-03-30, 1400/01/10

**Expected recruitment end date**
2021-04-01, 1400/01/12

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Evaluation effectiveness of compassion-focused therapy on shame and self-criticism in patients with a psychotic disorder

**Public title**

Evaluation effectiveness of compassion-focused therapy on shame and self-criticism in patients with psychotic disorder

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with psychotic disorder

**Exclusion criteria:**

History of other mental illness disorders

**Age**

No age limit

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In order to divide patients into two groups, the randomized block method is used. In this method, group A is related to the intervention and group B is considered as the control and is classified into 4 blocks including AABB, ABAB, ABBA, BBAA, BABA, BAAB, according to the selected permutations. The patient is classified into one of the intervention or control groups. Random allocation software was used for randomization

**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**

Ethics committee of Ahvaz Jundishapur University of of Medical Sciences

**Street address**

Ahvaz Golestan Hospital ,Golestan Blvd, Ahvaz

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

157945-6135

**Approval date**

2021-06-22, 1400/04/01

**Ethics committee reference number**

IR.AJUMS.HGOLESTAN.REC.1400.062

## Health conditions studied

### 1

**Description of health condition studied**

psychotic disorder

**ICD-10 code**

F23

**ICD-10 code description**

Brief psychotic disorder

## Primary outcomes

### 1

**Description**

shame

**Timepoint**

Before and after intervention

**Method of measurement**

Self-Compassion Scale (SCS questioner)

### 2

**Description**

self-criticism

**Timepoint**

Before and after intervention

**Method of measurement**

Self-Compassion Scale (SCS questioner)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: After the patients are selected, based on the treatment group, the patients are treated with compassion-focused treatment and after the treatment, the information is re-evaluated. The compassion-focused treatment protocol will be implemented in accordance with the content of the treatment in 10 sessions. The basic principles of compassion-focused therapy point out that external soothing thoughts, factors, images, and behaviors must be internalized, and in this case, the human mind, as it responds to external factors, in the face of this Relax inside. Sessions 1 and 2: Evaluation based on compassion-focused treatment approach, Session 3: Understanding compassion, Session 4: Preparing clients to improve compassionate attention and concentration, Session 5: Illustration of daily compassion, Session 6: Examining the role of self-criticism and shame using the metaphor of two teachers, introducing compassionate self, Session 7: Introducing multiple selves references,

exercising multiple selves, Session 8: Compassionate thinking and argument and compassionate behavior, Session 9: Balancing thinking and mind in a compassionate way, Session 10: Writing a letter of compassion

**Category**

Treatment - Other

**2**

**Description**

Control group: After the patients are selected, the patients are treated normally based on the group therapy and the information is re-evaluated after the treatment.

**Category**

Treatment - Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Ahvaz Golestan Hospital

**Full name of responsible person**

Hatam Boostani

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

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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**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Hatam Boostani

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Psychiatrics

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## Person responsible for scientific inquiries

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**Position**

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**Other areas of specialty/work**

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## Person responsible for updating data

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Maryam Khalafi
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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 more 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**
No - There is not 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