

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Determining the effectiveness of, mindfulness-based cognitive therapy and expressive writing on the reduction of trauma-induced experiences

Protocol summary

Study aim

Determining the effectiveness of mindfulness-based cognitive therapy and expressive writing on the reduction of post traumatic stress symptoms and experiential avoidance.

Design

Clinical trials with control group, Parallel Group, non random groups

Settings and conduct

Participants will first complete the informed consent forms for participation. Then, they will be examined based on the inclusion criteria. Then, participants will be assigned into 3 groups (7 in each group). Before and after the interventions the study variables will be assessed using the questionnaires. The follow-up will be one month after the end of the interventions. The interventions will be provided in neighborhood houses and health centers. The control participants will also receive the interventions after the follow-up.

Participants/Inclusion and exclusion criteria

The study sample will be people who show mild to moderate symptoms of post traumatic stress disorder. Inclusion Criteria: 1- 18 years of age and above, 2- having experienced at least one traumatic event, 3- experiencing mild to severe signs and symptoms (indicated by clinical interview and the PTSD Checklist for DSM-5 (PCL-5)), 3- not diagnosed with post-traumatic stress disorder (PTSD), major depressive disorder (MDD), or psychotic symptoms, 4- not receiving pharmacological treatment for psychological disorders. Exclusion Criteria: 1- Suffering from conditions preventing them from participation, 2- receiving pharmacological treatment at the time of the study, 3- diagnosed with major depressive disorder (MDD) (with a score above 28 on the Beck Depression Inventory (BDI)), 4- not interested in continuing participation in the study.

Intervention groups

1- Mindfulness-Based Cognitive Therapy group 2- expressive writing group 3- Control group

Main outcome variables

Post Traumatic Stress Symptoms, Mindfulness, Experiential Avoidance, Depression, General health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181004041228N1**

Registration date: **2018-10-19, 1397/07/27**

Registration timing: **prospective**

Last update: **2018-10-19, 1397/07/27**

Update count: **0**

Registration date

2018-10-19, 1397/07/27

Registrant information

Name

Soofi Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6636 6629

Email address

s.moradi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-28, 1397/08/06

Expected recruitment end date

2018-11-23, 1397/09/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Determining the effectiveness of, mindfulness-based cognitive therapy and expressive writing on the reduction of trauma-induced experiences

Public title
Mindfulness-based cognitive therapy and expressive writing on the reduction of trauma-induced experiences

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
18 years of age and above. Having experienced at least one traumatic event. Experiencing mild to moderate signs and symptoms (indicated by clinical interview and the PTSD Checklist for DSM-5 (PCL-5)). Not diagnosed with post-traumatic stress disorder (PTSD), major depressive disorder (MDD), or psychotic symptoms. Not receiving pharmacological treatment for psychological disorders.
Exclusion criteria:
Suffering from conditions preventing them from participation. Receiving pharmacological treatment at the time of the study. Diagnosed with major depressive disorder (MDD) (with a score above 28 on the Beck Depression Inventory (BDI-II)). Not interested in continuing participation in the study.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not randomized

Randomization description

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 Beheshti University of Medical Sciences

Street address

No.17, Sadat Alley, South Khosh Ave, Hashemi Ave, Tehran Town.

City

Tehran

Province

Tehran

Postal code

1346635159

Approval date

2017-03-06, 1395/12/16

Ethics committee reference number

IR.SBMU.MSP.REC.1395.604

Health conditions studied

1

Description of health condition studied

Post Traumatic Stress Symptoms

ICD-10 code

F43.9

ICD-10 code description

Reaction to severe stress, unspecified

Primary outcomes

1

Description

Score in the post-traumatic stress disorder checklist for Diagnostic and Statistical Manual of Mental Disorders, 5th Edition

Timepoint

Before the intervention, after the intervention, one month after the end of the intervention

Method of measurement

Post-traumatic stress disorder checklist for Diagnostic and Statistical Manual of Mental Disorders, 5th Edition

2

Description

Score in the Multidimensional Experiential Avoidance Questionnaire

Timepoint

Before the intervention, after the intervention, one month after the end of the intervention

Method of measurement

Multidimensional Experiential Avoidance Questionnaire

3

Description

Score in the Five Facet Mindfulness Questionnaire

Timepoint

Before the intervention, after the intervention, one month after the end of the intervention

Method of measurement

Secondary outcomes

1

Description

Score in the Beck Depression Inventory-II

Timepoint

Before the intervention, after the intervention, one month after the end of the intervention

Method of measurement

Beck Depression Inventory-II

2

Description

Score in the General Health Questionnaire-28

Timepoint

Before the intervention, after the intervention, one month after the end of the intervention

Method of measurement

General Health Questionnaire-28

Intervention groups

1

Description

Intervention group 1: Mindfulness-Based Cognitive Therapy (MBCT) group (8 sessions of group MBCT; groups with 7 members)

Category

Treatment - Other

2

Description

Intervention group 2: expressive writing (EW) group (4 sessions of group therapy; groups with 7 members)

Category

Treatment - Other

3

Description

Control group: Control group

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Health Department of Tehran

Full name of responsible person
Zeinab Nasiri

Street address

Kurdistan Highway, Shahid Gornam Highway, North Arshad Ave., Building of social and cultural deputy.

City

Tehran

Province

Tehran

Postal code

1985717434

Phone

+98 21 8210 6000

Email

info@farhangi.tehran.ir

2

Recruitment center

Name of recruitment center

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ali Ziai

Street address

No.2, Arabi Ave, Velenjak, , Tehran,Tehran Province

City

Tehran

Province

Tehran

Postal code

1985717434

Phone

+98 21 2243 9951

Email

msp@sbm.ac.ir

3

Recruitment center

Name of recruitment center

Deputy of Health System Research of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shahnam Arshi

Street address

5th floor, The former building of the Ministry of Health, Hafez str., Jomhori Ave., Tehran.

City

Tehran

Province

Tehran

Postal code

1134845764

Phone

+98 21 6673 6810

Email

HSR.health@sbm.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor in Research Affairs

Full name of responsible person

Afshin Zarghi

Street address

No.2, Arabi Ave, Velenjak, , Tehran,Tehran Province

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 21 2243 9770

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

Vice Chancellor in Research Affairs

Proportion provided by this source

70

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

Soofi Moradi

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

No.2, Arabi Ave, Velenjak, , Tehran,Tehran Province

City

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1985717434

Phone

+98 21 2243 9951

Email

s.moradi@sbmu.ac.ir

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soofi Moradi

Position

PhD Student

Latest degree

Master

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soofi Moradi

Position

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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