Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 months 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

Five Facet Mindfulness Questionnaire

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 Gomnam 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@sbmu.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@sbmu.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
Tehran
Province
Tehran
Postal code
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
Other areas of specialty/work
Psychology
Street address
No.2, Arabi Ave, Velenjak، , Tehran,Tehran Province
City
Tehran
Province
Tehran
Postal code
1985717434
Phone
+98 21 6636 6629
Email
s.moradi@sbmu.ac.ir

Person responsible for updating data

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
Tehran
Province
Tehran
Postal code
1985717434
Phone
+98 21 6636 6629
Email
s.moradi@sbmu.ac.ir

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