

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of Mindfulness-Based Stress Reduction (MBSR) on pain intensity, anxiety, depression and quality of life of patients with chronic pain: Randomized Clinical Trials

Protocol summary

Study aim

This research was conducted with the purpose of effectiveness of Mindfulness-Based Stress Reduction (MBSR) on pain intensity, anxiety, depression and quality of life of patients with chronic pain: Randomized Clinical Trials.

Design

This study was a quasi-experimental study with a pretest, posttest and control group as a randomized clinical trial.

Settings and conduct

The statistical population of this study consisted of all patients with chronic pain referred to Imam Reza Army Hospital of Army of the Islamic Republic of Iran. Among these patients, 50 people who met the inclusion criteria and were willing to participate in the study were selected by convenience sampling and randomly assigned to the experimental and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria the study were: the presence of at least one symptom of pain without any specific medical reason for at least 6 months, age between 18 and 60 years, the education level of at least middle school (8th grades). Exclusion criteria were: substance abuse and severe psychiatric problems such as psychosis.

Intervention groups

The experimental group received mindfulness-based stress reduction therapy (8 sessions for 8 week) and the control group did not receive any intervention.

Main outcome variables

pain intensity anxiety depression quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171031037145N2**

Registration date: **2020-11-21, 1399/09/01**

Registration timing: **retrospective**

Last update: **2020-11-21, 1399/09/01**

Update count: **0**

Registration date

2020-11-21, 1399/09/01

Registrant information

Name

Farshad Sheybani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2721

Email address

farshad.sheybani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

2019-04-21, 1398/02/01

Actual recruitment end date

2019-05-22, 1398/03/01

Trial completion date

2019-09-23, 1398/07/01

Scientific title

Effectiveness of Mindfulness-Based Stress Reduction (MBSR) on pain intensity, anxiety, depression and quality

of life of patients with chronic pain: Randomized Clinical Trials	
Public title	effect of stress reduction on chronic pain
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	presence of at least one symptom of pain without any specific medical reason for at least 6 months age between 18 and 60 years the education level of at least middle school (8th grades)
Exclusion criteria:	substance abuse severe psychiatric problems such as psychosis
Age	From 18 years old to 60 years old
Gender	Both
Phase	N/A
Groups that have been masked	• Data analyser
Sample size	Target sample size: 50 Actual sample size reached: 47
Randomization (investigator's opinion)	Randomized
Randomization description	Based on the announcement and invitation that was installed in Imam Reza hospital to participate in this research, the applicants called and expressed their desire to participate in the research. After the initial screening, patients were informed about the study and the form of informed consent were given to them. If the form is approved and signed, the therapist will conduct a structured clinical interview for DSM5 (SCID-5) and if they complied with the inclusion and exclusion criteria, the patient would enter the study as a research sample. Based on this, 50 patients were selected. After selecting patients and randomly assigning them to experimental and control groups. Patients were randomly assigned to two groups of 25 using 4 and 6 blocks with a ratio of 1: 1. Random allocation sequences of patients in both groups were performed using Randomizer software. Consecutive opaque numbered envelopes were used to conceal the allocation.
Blinding (investigator's opinion)	Single blinded
Blinding description	The data analyzer did not know the names of the study groups, and the groups were numbered.
Placebo	Not used
Assignment	Parallel
Other design features	

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of AJA University of Medical Sciences

Street address

End of Etemadzadeh Street, West Fatemi Street , Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2018-12-09, 1397/09/18

Ethics committee reference number

IR.AJAUMS.REC.1397.052

Health conditions studied

1

Description of health condition studied

Chronic Pain

ICD-10 code

R52.1

ICD-10 code description

Chronic intractable pain

Primary outcomes

1

Description

Anxiety: In this study, the severity of anxiety was measured using the Beck Anxiety Inventory

Timepoint

Before and after the intervention

Method of measurement

Beck Anxiety Inventory

2

Description

Quality of life: Quality of life is a person's perception of the state of life in the field of culture and value system in which she lives, and this concept is related to goals, expectations, criteria and important matters.

Timepoint

Before and after the intervention

Method of measurement

World Health Organization Quality of Life-BREF (WHOQOL-BREF)

3

Description

Pain intensity: An unpleasant sensory and psychological experience associated with possible or actual tissue damage.

Timepoint

Before and after the intervention

Method of measurement

numeric pain rating scale

4

Description

Depression: Depression is a transient decrease or persistence of neuropsychological stress that manifests itself as a physical component (such as headache, fatigue, insomnia, constipation, hypotension) and a psychological component (such as feelings of hopelessness, sadness, inferiority).

Timepoint

Before and after the intervention

Method of measurement

Beck Depression Inventory-II (BDI-II)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The MBSR-based group intervention was based on the 8-session John Kabat-Zin approach, with a duration of 1.5 hours per session. The content of the MBSR 8 sessions was as follows: Session 1: Communication skills and conceptualization, the need to use mindfulness training, providing explanations about the auto-guidance system. Session 2: Review of last week's homework, body scan, meditation exercises, mindfulness-based breath training (MBRT). Session 3: Review of last week's homework, sitting meditation, practice review, three-minute breathing space training. Session 4: Review of last week's homework, a five-minute practice of "seeing or hearing," mindfulness-based breath training and body scan. Session 5: Review of last week's homework, breathing exercises, sitting meditation (awareness of breathing, body, sounds, and thoughts), explanations about stress and its relationship to pain, awareness of the effect of pleasant and unpleasant events on feelings, thoughts and body feelings. Session 6: Review of last week's homework, vigilant yoga, discussion of different views of thoughts or substitute thoughts, sitting meditation (Mindfulness of sounds and thoughts). Session 7: Review of last week's homework, sleep hygiene, repeating the homework of the previous sessions, and providing a list of fun activities. Session 8: Review of last week's homework, body scan, summing up the sessions, Check out and discuss about the programs and continuing the exercises for management of pain.

Category

Behavior

2

Description

Control group: The control group did not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Farshad Sheybani

Street address

End of Etemadzadeh Street, West Fatemi Street, Tehran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 4382 2449

Email

sheybani.f@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Dr Alireza Dadashi

Street address

End of Etemadzadeh Street, West Fatemi Street, Tehran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 4382 2449

Email

sheybani.f@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Artesh 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
Iran University of Medical Sciences
Full name of responsible person
Farshad Sheybani
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
School of Behavioral Sciences and Mental Health
Shahid Mansouri Street, Niyayesh Street, Satarkhan
Avenue
City
Tehran
Province
Tehran
Postal code
1445613111
Phone
+98 21 6655 1655
Email
sheybani.f@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Farshad Sheybani
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
School of Behavioral Sciences and Mental Health
Shahid Mansouri Street, Niyayesh Street, Satarkhan

Avenue
City
Tehran
Province
Tehran
Postal code
1445613111
Phone
+98 21 6655 1655
Email
sheybani.f@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Farshad Sheybani
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
School of Behavioral Sciences and Mental Health
Shahid Mansouri Street, Niyayesh Street, Satarkhan
Avenue
City
Tehra
Province
Tehran
Postal code
1445613111
Phone
+98 21 6655 1655
Email
sheybani.f@iums.ac.ir

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

Disagreement of the supervisor of this research

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable