# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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)

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**Email address**
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**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
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End of Etemadzadeh Street, West Fatemi Street, Tehran
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## 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
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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**

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

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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**
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