# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## The effect of intervention of mindfulness based on stress reduction (MBSR) on the workplace well-being and nurse-patient interpersonal among nurses working at the psychiatric wards

## Protocol summary


**Study aim**
Investigating the impact of mindfulness-based stress reduction on nurses' workplace well-being and nurse-patient interpersonal reactions in psychiatric wards.

**Design**
In this single-center clinical trial with a control group without blinding, 66 nurses will be selected. Then the participants are placed in one of two intervention or control groups using simple randomization in a computer algorithm with an equal allocation ratio (1:1).

**Settings and conduct**
This study will be conducted at Ibn Sinai Psychiatric Hospital in Mashhad City. The intervention will be implemented for 8 weeks as a 2-hour session every week for the intervention group. The control group will not receive any intervention. Then, immediately after the intervention and three months after the onset of the intervention, the study tools will be completed by the nurses participating in the research.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Consent to participate in the research Having a bachelor's degree in nursing or higher Exclusion criteria: Participation in stress control courses during the last year Having a history of psychiatric disorders or disorders in the cognitive status, according to the participant's own report

**Intervention groups**
In this eight-week intervention, a body scan is performed in the first and second weeks. During the third and fourth weeks, the body scanning exercise begins with yoga. In the fifth and sixth weeks, the practice of body scanning stops, and sitting and focusing on breathing begins so that breathing will be used as an act to control attention. In the seventh week, in this week people generally use sitting techniques, yoga, and body scanning. In the eighth week, in this week, the subjects are asked to choose one of the taught techniques that fit their situation.

**Main outcome variables**
Workplace well-being Nurse-patient interpersonal activity


## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20230316057739N1**
Registration date: **2023-05-16, 1402/02/26**
Registration timing: **prospective**

Last update: **2023-05-16, 1402/02/26**
Update count: **0**

**Registration date**
2023-05-16, 1402/02/26

**Registrant information**


**Name**
JAVAD FATEMI

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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

**Funding source**

**Expected recruitment start date**
2023-06-10, 1402/03/20

**Expected recruitment end date**
2023-07-11, 1402/04/20

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The effect of intervention of mindfulness based on stress reduction (MBSR) on the workplace well-being and nurse-patient interpersonal among nurses working at the psychiatric wards

**Public title**
The effect of intervention of mindfulness based on stress reduction (MBSR) on the workplace well-being and nurse-patient interpersonal among nurses
**Purpose**
Education/Guidance
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Consent to participate in the research Having a bachelor's degree or above in nursing
**Exclusion criteria:**
Having a history of participation in stress control courses in the past year Having psychiatric disorders or impaired cognitive status according to the participants' self-report
**Age**
No age limit
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **33**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The limited randomization method applying the law of random allocation will be used. At first, 33 sealed cards related to the intervention group and 33 sealed cards related to the control group will be prepared. These cards will be placed in the lottery container. Then the cards are randomly removed from the container without replacement and the created sequence is recorded. Each of the created random sequences is recorded on a card and each card is placed inside opaque envelopes. In order to maintain the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the envelopes is glued and placed in a box in order. For each of the participants, one of the letter envelopes is opened in order and the assigned group of that participant is revealed.
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Other
**Other design features**
In this study, two groups i.e. intervention and control group, will participate. For the intervention group, the mindfulness program based on stress reduction will be implemented for 8 weeks. At this time, the control group will receive routine services.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of birjand University of Medical Sciences
**Street address**
Birjand-Ghaffari Street
**City**
Birjand
**Province**
South Khorasan
**Postal code**
9717853076
**Approval date**
2023-03-12, 1401/12/21
**Ethics committee reference number**
IR.BUMS.REC.1401.447

## Health conditions studied

### 1

**Description of health condition studied**
Workplace well-being
**ICD-10 code**
**ICD-10 code description**

### 2

**Description of health condition studied**
Nurse-patient interpersonal interaction
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Workplace well-being
**Timepoint**
Before the intervention, immediately after the intervention and three months after the start of the intervention
**Method of measurement**
The idiomaniac workplace well-being scale will be used to evaluate workplace well-being. The clinical interpersonal reaction index will be used to evaluate the nurse-patient interpersonal reaction.

**2**

**Description**
Nurse-patient interpersonal interaction
**Timepoint**
Outcomes will be measured before the intervention, immediately after the intervention, and 3 months after the start of the intervention.
**Method of measurement**
The idiomaniac workplace well-being scale will be used to evaluate workplace well-being. This scale has two intrapersonal and interpersonal dimensions. Each dimension contains 4 items. The clinical interpersonal reaction index with 18 items will be used to evaluate the nurse-patient impersonal reaction. This is a two-dimensional tool of perspective-taking and unconditional positive regard.

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
For the intervention group, an eight-week intervention will be conducted in the form of two-hour sessions that will be held every week. In the first and second weeks, the body is scanned. During the third and fourth weeks, the body scanning exercise begins with yoga and the participants continue to practice thinking with breathing in a sitting position for 15 to 20 minutes. In the fifth and sixth weeks, the practice of body scanning stops, and sitting and focusing on breathing begins so that breathing will be used as an act to control attention. In the seventh week, in this week people generally use sitting techniques, yoga, and body scanning. In the eighth week, in this week, the subjects are asked to choose one of the taught techniques that fit their situation.
**Category**
Lifestyle

**2**

**Description**
Control group: no intervention will be done for the control group. In other words, the nurses of this group will receive routine services.
**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Ibn sina hospital
**Full name of responsible person**
Javad Fatemi
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Mashhad-Hor e ameli blv
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Birjand University of Medical Sciences
**Full name of responsible person**
Seyyed Abolfazl Vagharseyyedin
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waghars@bums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Birjand 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**
Birjand University of Medical Sciences
**Full name of responsible person**
Javad Fatemi
**Position**

Employee

**Latest degree**
Bachelor

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Nursery

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## Person responsible for updating data

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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**
No - There is not 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