Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of online mindfulness training based on stress reduction (MBSR) on mental health and quality of work life of nurses fighting on the frontlines against COVID-19

Protocol summary

Study aim
The effectiveness of stress-based online mindfulness training on the mind health & the quality of work lifeof nurses working on the front lines of the fight against Covid-19

Design
A phase-blind, randomized, single-sided (data analyzers) clinical trial will be performed on 36 nurses working on the Covid-19 frontline. A table of random numbers will be used.

Settings and conduct
This project will be carried out in Taleghani Educational and Medical Center affiliated to Urmia University of Medical Sciences and the intervention group will be trained online at home for 8 weeks.

Participants/Inclusion and exclusion criteria
Full time employee. At least 2 years of service. At least 3 months of work experience in the "ICU" department (due to adaptation to the work environment). Absence of acute psychiatric illnesses such as psychosis. If medical drugs are used, the dose of the drug is stable during exercise and if the dose is changed, inform the researchers. Not addicted to drugs and alcohol. Lack of previous experiences of mindfulness.Do not receive any psychological interventions and counseling during exercise from other sources. Absence of acute physical illness with pain that prevents exercise. Exclusion criteria also include the absence of more than 10% of the training time, leave and cause with a major stressful event (including coronary heart disease, imminent death, divorce, etc.) in the existence of research has it.

Intervention groups
Intervention group: including nurses working on the front line of the fight against Covid-19 who will participate in a stress-based mindfulness training program for 8 sessions. Control group: including nurses working on the front line of the fight against Covid-19 who will participate in a stress-based mindfulness training program after completing the research.

Main outcome variables
Mental health Quality of working life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181203041832N1**
Registration date: **2020-10-05, 1399/07/14**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-05, 1399/07/14**
Update count: **0**

Registration date
2020-10-05, 1399/07/14

Registrant information

Name
Haedeh Feizipour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 44 3193 7286

Email address
feizipour.h@umsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01

Expected recruitment end date
2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of online mindfulness training based on stress reduction (MBSR) on mental health and quality of work life of nurses fighting on the frontlines against COVID-19

Public title

The effectiveness of online mindfulness training on mental health and quality of work life of nurses fighting on the frontlines against COVID-19

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Full time employee At least 2 years of service At least 3 months of work experience in the "ICU" (due to adaptation to the work environment) Ability to use an online application through an Internet-connected device (e.g. smartphone, computer or laptop) Access the online Skyroom app Non-interference of the training program with nurses' shifts Provided that the medication is taken, inform the researchers if the dose of the medication is stable during the exercise, or if the dose changes Commitment to daily mindfulness exercises and active participation in the training course.

Exclusion criteria:

Acute psychiatric illnesses such as psychosis Psychiatric medication for the past 6 months Acute physical illness with pain that prevents exercise Addiction to drugs and alcohol Previous experiences of mindfulness Psychological interventions or counseling during exercise from other sources Facing a severe traumatic event in the last 6 months

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Due to the fact that patients with COVID-19 are admitted to Taleghani Hospital in Urmia, so first to achieve the objectives of the study and according to the conditions of admission, 36 people will be selected based on purposive sampling. Then this number will be divided into two groups of intervention (n = 18) and control (n = 18) completely randomly. It should be noted that the selected samples will be coded from number one to 36 and then will be placed in one of the intervention or control groups based on the table of random numbers.

Blinding (investigator's opinion)

Single blinded

Blinding description

It should be noted that first the subjects will be explained about the objectives of the study and after their agreement to participate in the present study will be selected as the study sample, in the present study only responsible for data analysis about the objectives of the study , Will be kept blind.

Placebo

Not used

Assignment

Parallel

Other design features

In this study, the intervention group will be trained for 8 weeks, but the control group will not receive any training and after completing the research, will participate in this course if desired.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Urmia University of Medical Sciences

Street address

Jahad Square, Resalat Blvd., Emergency Alley,

City

Urmia

Province

West Azarbaijan

Postal code

5715974147

Approval date

2020-06-02, 1399/03/13

Ethics committee reference number

IR.UMSU.REC.1399.105

Health conditions studied

1

Description of health condition studied

There is not disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Depression Score in Symptom Checklist 90-Revised (SCL-90-R)

Timepoint

Before intervention - Immediately after intervention - One month after intervention

Method of measurement

Symptom Checklist 90-Revised (SCL-90-R)

2

Description

Stress score in the Symptom Checklist 90-Revised (SCL-90-R)

Timepoint

Before - after - one month after the intervention

Method of measurement

Symptom Checklist 90-Revised (SCL-90-R)

3

Description

Pathological fear score in the Symptom Checklist / SCL 90

Timepoint

Before - after - one month after the intervention

Method of measurement

Symptom Checklist 90-Revised (SCL-90-R)

4

Description

Psychosomatic disorders score in the Symptom Checklist 90-Revised (SCL-90-R)

Timepoint

Before - after - one month after the intervention

Method of measurement

Symptom Checklist 90-Revised (SCL-90-R)

5

Description

Aggression score in the mental disorders Symptom Checklist 90-Revised (SCL-90-R)

Timepoint

Before - after - one month after the intervention

Method of measurement

Symptom Checklist 90-Revised (SCL-90-R)

6

Description

Obsessive-compulsive disorder score in the symptom checklist scl90

Timepoint

Before - after - one month after the intervention

Method of measurement

Symptom Checklist 90-Revised (SCL-90-R)

7

Description

Interpersonal Sensitivity Score in Symptom Checklist 90-Revised (SCL-90-R)

Timepoint

Before - after - one month after the intervention

Method of measurement

Symptom Checklist 90-Revised (SCL-90-R)

8

Description

Quality of work life score in the Work-Related Quality of Life scale for healthcare workers

Timepoint

Before - after - one month after the intervention

Method of measurement

The Work-Related Quality of Life scale for healthcare workers

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The Nurses working on frontline of fighting against COVID-19 disease. The intervention that is to be done in this scientific study is: Mindfulness-Based Stress Reduction (MBSR). Mindfulness-based stress reduction is a group program that was developed by Jon Kabat-Zinn in the 1970s to treat patients struggling with life’s difficulties and physical and/or mental illness (Kabat-Zinn, 2013). This training course is held in 8 online sessions (one session of 1.5 hours per week) for the nurses of the intervention group. Formal exercises include: 1. Body Scan 2. The Breath (exercise that facilitates mindfulness by focusing on the breath). 3. Mindful Eating 4. Sitting exercise 5.Walking Meditation 6.Mindful Stretching 7. Simply Watching

Category

Treatment - Other

2

Description

Control group: Will not receive any intervention until the research project is completed

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

The Taleghani Educational and Medical Center

Full name of responsible person

Haedeh Feizipour

Street address

Resalat Boulevard. University of Medical Sciences

City

Urmia

Province

West Azarbaijan

Postal code
57147-83734
Phone
+98 44 3193 7286
Email
h.feizipour@gmail.com
Web page address
https://fa.irct.ir/user/trial/50750/update/recruitment_center

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Iraj Mohebbi
Street address
Resalat Boulevard. University of Medical Sciences
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3193 7224
Fax
+98 44 3224 0642
Email
mohebbi_iraj@yahoo.co.uk
Web page address
https://fa.irct.ir/user/trial/50750/update/sponsor
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Naser Gharebaghi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Medical Education
Street address
Resalat Boulevard. University of Medical Sciences
City
Urmia
Province
West Azarbaijan
Postal code
57147-83734
Phone
+98 44 3193 7286
Email
gharabaghi.n@umsu.ac.ir
Web page address
http://faculty.umsu.ac.ir/Site/CV.aspx?STID=247&Ln=fa

Person responsible for scientific inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Haedeh Feizipour
Position
Head of Counseling and Mental Health Department of Urmia University of Medical Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Resalat Boulevard. University of Medical Sciences
City
Urmia
Province
West Azarbaijan
Postal code
57147-83734
Phone
+98 44 3193 7286
Email
h.feizipour@gmail.com
Web page address
https://nm.umsu.ac.ir/index.aspx?fkeyid=&siteid=67&pageid=23613

Person responsible for updating data

Contact
Name of organization / entity
Urmia University
Full name of responsible person
Firouzeh Sepehrianazar
Position
Professor
Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

بلوار والفجر دانشکده ادبیات

City

Urmia

Province

West Azarbaijan

Postal code

5756151818

Phone

+98 44 3346 2733

Email

f.sepehrianazar@urmia.ac.ir

Web page address

http://facultystaff.urmia.ac.ir/Site/CV.aspx?STID=32&Ln=fa

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

Due to the confidentiality and confidentiality of personal data

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Only part of the data, such as the original outcome information, can be shared.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Only for researchers working in academic institutions

Under which criteria data/document could be used

The required training and guidance will be provided for similar studies and scientific researches.

From where data/document is obtainable

by Email: h.feizipour@gmail.com

What processes are involved for a request to access data/document

1. Full introduction of the applicant that must be one of the researchers of academic institutions 2. Sending her/his research resume to the mentioned email address 3. Sending a response to the researcher's request via email within 3 weeks

Comments