

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The efficacy of mindfulness based stress reduction program on mental well-being and quality of life in patients with COVID-19 after discharge: A Randomized Control Trial

Protocol summary

Study aim

the effectiveness of mindfulness-based stress reduction program on mental well-being, and quality of life of patients diagnosed with Covid-19 after discharge

Design

a randomized clinical trial with a control group A simple random sampling method and a quadruple block will be used for random assignment to the experimental and control groups. The test group will receive the intervention and the control group will receive routine care after discharge from the hospital. The intervention will be performed for 8 weeks. 50 people in each group

Settings and conduct

Hamyaran Salamat Arash Clinic for future calls.

Participants/Inclusion and exclusion criteria

Age 18-60 years Literacy and ability to communicate verbally Willingness and ability to participate in the sessions Ability to use cyberspace and messengers The ability to performing individual daily activities

Intervention groups

Control group: they don't receive the intervention. they receive routines. Intervention group: Intervention group: The intervention includes a mindfulness-based stress reduction program that will be 90 minutes of mindfulness-based treatment in 8 individual sessions over two months (one 90-minute session per week). The written exercises and audio files of each session will be delivered to the participants at the end of that session. The researcher (clinical psychologist) will review the homework of each participant and will review and resolve the problems related to it. The house will be finished. The intervention will take 2 months.

Main outcome variables

psychological well being- quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170218032635N3**

Registration date: **2020-12-27, 1399/10/07**

Registration timing: **prospective**

Last update: **2020-12-27, 1399/10/07**

Update count: **0**

Registration date

2020-12-27, 1399/10/07

Registrant information

Name

Afsaneh Sadooghiasl

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 4875

Email address

asadooghi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of mindfulness based stress reduction program on mental well-being and quality of life in patients with COVID-19 after discharge: A Randomized Control Trial

Public title

The efficacy of mindfulness based stress reduction program on mental well-being and quality of life in patients with COVID-19 after discharge

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18-60 Literacy and the ability to communicate verbally Willingness and ability to participate in mindfulness-based stress reduction virtual sessions Ability to use virtual space and messengers The ability of performing individual daily activities

Exclusion criteria:

Changing the patient's health status that prevents his continued participation in the study. Failure to attend meetings and follow up the intervention Changing the patient's condition and re-hospitalization The event of an unintended accident for a person (occurrence of a new physical problem, mental and psychological problem, death of a loved one) that affects the quality of life and well-being of the person.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

A quadruple block will be used to randomly assign samples to the test and control groups. Using the website, we will have a randomization list of 25 blocks of four in the form of AABB and other modes, and we will group one letter for the intervention group and one letter for the test group - according to the list.

<https://www.sealedenvelope.com/simple-randomiser/v1/lists>

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 Tarbiat Modares University

Street address

chamran highway-jalal al ahmed

City

Tehran

Province

Tehran

Postal code

14115-331

Approval date

2020-10-27, 1399/08/06

Ethics committee reference number

IR.MODARES.REC.1399.099

Health conditions studied

1

Description of health condition studied

stress

ICD-10 code

F43.0

ICD-10 code description

Acute stress reaction

2

Description of health condition studied

covid-19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

psychological well being

Timepoint

before intervention and 8 weeks after finishing intervention

Method of measurement

Ryff's psychological well being scale

2

Description

quality of life

Timepoint

before intervention and 8 weeks after finishing

intervention

Method of measurement

World Health Organization Quality Of Life- BREF

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention in this study is a mindfulness-based stress reduction program that will be a 90-minute mindfulness-based treatment in 8 individual sessions over two months (one 90-minute session per week). The written exercises and audio files of each session will be delivered to the participants at the end of that session. If necessary, group meetings will be conducted virtually via internal messengers. The researcher (clinical psychologist) will review the homework of each participant and will review and fix the problems related to it. After the training, the researcher will review the exercises of all the participants case by case and They will correct possible shortcomings. Each session will conclude with a review of what went on in the session, as well as a summary of the content of the session and the assignment of homework. The intervention will take 2 months. Two months after the end of the intervention, the tools will be completed again by both groups.

Category

Lifestyle

2

Description

Control group: They will receive routine care after discharge from the hospital.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamyaran Salamat Arash Clinic

Full name of responsible person

Mahdiyeh Hussein-zadeh Jolgeh

Street address

ghalanbar-zahedan

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Zahedan

Province

Sistan-va-Balouchestan

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rashkihossein11@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Dr. Mohammad Javan

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Web page address

<https://www.modares.ac.ir/med>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tarbiat Modares University

Proportion provided by this source

1

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

Tarbiat Modares University

Full name of responsible person

Afsaneh Sadooghiasl

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Title and more details about the data/document

The data will be released in groups without an identification code.

When the data will become available and for how long

After the journal's decision to accept and publish the results in paper form is finalized

To whom data/document is available

Editors of scientific journals

Under which criteria data/document could be used

No new analysis of the data is permitted and can only be used to inform or verify the quality and scientific accuracy of the study

From where data/document is obtainable

Afsaneh Sadooghiasl

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

After receiving a request from the editor in chief, a meeting will decide which piece of information they can publish and will be e-mailed or faxed after deleting any identifying code

Comments