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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

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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

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