

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The Effectiveness of Psychotherapy Method Based on Spiritual Care on Reducing Anxiety and Symptoms of Respiratory Distress in Patients with COVID-19

Protocol summary

Study aim

Determining the effectiveness of cognitive-behavioral psychotherapy based on spiritual care on reducing anxiety in patients with Covid 19

Design

This study is a clinical trial that has a control and intervention group and will be performed without blinding. The sampling method is non-random simple that the target population is patients hospitalized with Covid 19 in Imam Reza (AS) Hospital in Mashhad. The number of samples is estimated at 30% with a drop of 5%. Therefore, the statistical sample size will be 30 people.

Settings and conduct

The study site is Imam Reza AS Hospital in Mashhad and its target population is patients with Covid 19 in Imam Reza (AS) Hospital in Mashhad. In the present study, after the formation of intervention groups, psychotherapy based on spiritual care based Bussing protocol will be performed. Data collection will be done through the Hospital Anxiety and Depression Scale (HADS) questionnaire. And data analysis is done using SPSS version 21.

Participants/Inclusion and exclusion criteria

Have a minimum of trainability, Have a minimum level of awareness 10, The total duration of hospitalization is at least 14 days to evaluate the effect of the intervention, Have a minimum age of 15 and a maximum of 65 years Being a Muslim, Absence of psychiatric illness.

Intervention groups

After selecting the sample in a purposeful way (through the hads questionnaire and patients whose medical interpretation of respiratory distress has no medical justification and is included in the file), a pre-test will be performed. Richards and Bergin will perform the intervention in five sessions to identify the spiritual

challenges of individuals that reinforce the anxiety created by the trained research team. The control group will not receive any other intervention in addition to conventional drug therapies.

Main outcome variables

Anxiety and respiratory distress caused by anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210513051282N2**

Registration date: **2021-11-23, 1400/09/02**

Registration timing: **retrospective**

Last update: **2021-11-23, 1400/09/02**

Update count: **0**

Registration date

2021-11-23, 1400/09/02

Registrant information

Name

seyed mahmoud tabatabaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 5777

Email address

tabanet@um.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-10-07, 1400/07/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effectiveness of Psychotherapy Method Based on Spiritual Care on Reducing Anxiety and Symptoms of Respiratory Distress in Patients with COVID-19

Public title
Evaluation of the effectiveness of psychotherapy method based on spiritual care on reducing anxiety and respiratory distress syndrome

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Willingness to participate in the study Have a minimum level of awareness 10 Be at least 15 and at most 65 years old The patient is physically fit Being a Muslim
Exclusion criteria:
 History of receiving psychological interventions during the last 6 months History of receiving psychiatric medication during the last 6 months with severe psychiatric illness (psychosis, bipolar disorder and mental retardation) Death of the patient

Age
From **15 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Sample people will be selected randomly without substitution (lottery). In the lottery method, a number or code is prepared for each member of the community. Then the numbers are written on pieces of paper. The pieces of paper are placed in a container. It is given and mixed well, then a sample with a certain volume is selected.

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

Organizational Ethics Committee of Mashhad University of Medical Sciences

Street address

Department of Medical Ethics Committee, School of Medicine, Campus, Azadi University, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9194568899

Approval date

2021-08-28, 1400/06/06

Ethics committee reference number

IR.MUMS.REC.1400.161

Health conditions studied

1

Description of health condition studied

- Patients with Covid admitted to Imam Reza Hospital in Mashhad

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

- Anxiety

Timepoint

Before intervention, one week after intervention

Method of measurement

The Hospital Anxiety and Depression Scale (HADS) questionnaire will be administered.

Secondary outcomes

1

Description

Reduce respiratory distress from increased anxiety

Timepoint

Before intervention, one week after intervention

Method of measurement

The patient's respiratory symptoms are examined by a physician

Intervention groups

1

Description

Experimental group: Spiritual-religious care sessions based on the model (Bergin and Richards) focusing on the religion of Islam and the opinion of the religious expert of the research team in 5 sessions twice a week for 45 to 60 minutes.

Category

Behavior

2

Description

Control group: Control group: There is no spiritual care for the control group and they receive only normal and routine care in the hospital. If the results of the study were significant, in order to observe ethics, after studying, the necessary information will be provided to them by CD and pamphlet

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Fatemeh Rezaei

Street address

Ibn Sina St., Imam Reza Hospital Square, Imam Reza Hospital

City

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9178787665

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Rezaeif@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Mahmoud Tabatabaei

Street address

University Street in front of the University 18 Central Building of Mashhad University of Medical Sciences Office of the Leadership Institution

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917786655

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tabanet@um.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Rezaei

Position

therapist and psychologist resercher

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Mahmoud Tabatabaei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Ethics

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Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Rezaei

Position

Therapist and psychologist resercher

Latest degree

Master

Other areas of specialty/work

Psychology

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Fax**Email**

rezaei@mums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Yes - There is 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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the main consequences of the data, including anxiety and respiratory distress, will be shared.

When the data will become available and for how long

The data will be available after the end of the study from September 1401.

To whom data/document is available

Data is available for researchers working in universities and scientific institutes Will be accessible.

Under which criteria data/document could be used

The data will be provided with the permission of the University of Medical Sciences and only the use of its results for further research.

From where data/document is obtainable

- Email: Dr. Tabatabai tabanet@um.ac.ir

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

The applicant must send a written request to the author of the article by e-mail and after contacting the author by phone, the author will provide information to the applicant by email for a maximum of 20 days after obtaining permission from Mashhad University of Medical Sciences. The data will be provided with the permission of Mashhad University of Medical Sciences and only the use of its results for further research.

Comments

None