# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Jun 2026

## Investigating the Effect of Spiritual-Religious Practice on Public Health and Life Satisfaction of War Survivors Hospitalized Due to Covid-19

## Protocol summary


**Study aim**

Determining the Impact of Spiritual-Religious Care Program on Public Health and Life Satisfaction of Hospitalized Veterans with Covid-19 Diagnosis.

**Design**

A clinical trial with two intervention and comparison groups, a blind, randomized, block-assisted strain will be performed on 70 patients with Covid.

**Settings and conduct**

This clinical trial will be performed at Sasan Hospital in Tehran. This study is a one-way blind and the data analyzer in this study is blind. Participants include veterans with Covid-19.

**Participants/Inclusion and exclusion criteria**

Entry requirements: Be a veteran (reviewed by the Medical Commission of the Martyr and Veterans Affairs Foundation and received the percentage of veterans). Veterans who have a corona test reported positive by PCR and clinical diagnosis by imaging and diagnosed by a Quid-19 physician. Be admitted to the ward. Be vigilant and have GCS = 15/15. The patient should be hospitalized on the first day. Not having any clinical condition, such as diagnosed neurological problems, that affects a person's ability to participate in a spiritual-religious care program. No entry: Any clinical condition such as drowsiness or level of consciousness below 15 that may occur after enrollment and restrict the patient during caregiving exercises. The patient becomes ill at the beginning of the study or within the first 48 hours and is transferred to the ICU. The patient dies within the first 48 hours of the study.

**Intervention groups**

In this study, participants are divided into two groups of intervention and comparison. In the intervention group, patients will be taught spiritual-religious care, in the comparison group, patients will receive only their usual treatments.

**Main outcome variables**

Blood oxygen level; fever; heart beat; blood pressure; General Health Questionnaire SF12; Life Satisfaction Questionnaire; Spiritual care.


## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20210227050517N1**
Registration date: **2021-06-26, 1400/04/05**
Registration timing: **prospective**

Last update: **2021-06-26, 1400/04/05**
Update count: **0**

**Registration date**

2021-06-26, 1400/04/05

**Registrant information**


**Name**

Raheleh Mahdavitaree

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 3355 4128

**Email address**

mahdavi.raheleh@gmail.com


**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2021-07-06, 1400/04/15

**Expected recruitment end date**

2021-08-23, 1400/06/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the Effect of Spiritual-Religious Practice on Public Health and Life Satisfaction of War Survivors Hospitalized Due to Covid-19

**Public title**

Investigating the Effect of Spiritual-Religious Practice on Covid-19

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Be a veteran (reviewed by the Medical Commission of the Martyr and Veterans Affairs Foundation and received the percentage of veterans). PCR is positive. Be in the ward. Be vigilant. The patient should be hospitalized on the first day. Lack of any clinical condition such as diagnosed neurological problems that affect a person's ability to participate in a spiritual-religious care program.

**Exclusion criteria:**

Any clinical condition such as drowsiness or level of consciousness below 15 that may occur after enrollment and restrict the patient during caregiving exercises. The patient becomes ill at the beginning of the study or within the first 48 hours and is transferred to the ICU. The patient dies within the first 48 hours of the study.

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, patients were first divided into two groups: less than 60 years and 60 years and more. Then, in order to assign the patient to the intervention or control group in this study, the method of randomization blocks with a volume of 4 was used. These blocks were prepared in R software using the blockrand package. If there is an admission order in the file of each patient, the patient who accepts the conditions for admission to the study, if the patient is 60 years and older, enters the study using randomly defined blocks of volume 4 for people 60 years and older And if he is less than 60 years old, he enters the study using other randomly defined blocks for people under 60 years old. The patient is assigned to the intervention or comparison group in the same way according to the random table, and the next individuals are included in the study in the same way according to the random table. There is no concealment in this study.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this study, the patient and the researcher are in the intervention and comparison group, while the other members, including the clinical caregiver, outcome assessor, and data analyzer, do not know which patients are in which study group.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

**Street address**

No. 11, Pish Namaz Alley, Mahallati Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1175875513

**Approval date**

2021-04-27, 1400/02/07

**Ethics committee reference number**

IR.SBMU.PHARMACY.REC.1400.006

## Health conditions studied

### 1

**Description of health condition studied**

Covid-19

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19, virus identified

## Primary outcomes

### 1

**Description**

According to the General Health Questionnaire, the general health score will be measured in veterans with Covid-19 before and after the intervention. At the beginning of the study, a general health questionnaire will be completed for all participants. Then the

intervention will be done. After the intervention, the general health questionnaire will be completed for the patients on the 30th day.

**Timepoint**

General health will be measured at the beginning of the study before the intervention and on the 30th day.

**Method of measurement**

Questionnaire 12-Item Short Form Survey

**2**

**Description**

Life satisfaction score according to life satisfaction questionnaire will be measured in veterans with Covid-19 before and after the intervention. At the beginning of the study, a life satisfaction questionnaire will be completed for all participants. Then the intervention will be done. After the intervention, the resuscitation satisfaction questionnaire for patients will be completed on the seventh day.

**Timepoint**

Life satisfaction will be measured at the beginning of the study before the intervention and on the seventh day.

**Method of measurement**

Satisfaction With Life Scale Questionnaire

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

In this study, participants are divided into two groups of intervention and control. The intervention group, in addition to the usual treatments prescribed by doctors in the hospital, receives a spiritual-religious care package that includes a seven-day period and three times a day reciting dhikr or Allah and Surah Hamad. Thus, the patient who has entered the intervention group for seven days should recite Surah Al-Hamd 3 times and Zikr Ya Allah 66 times every morning, noon and night. In order to remind, a table has been prepared that the patient enters in the table every time he recites the dhikr. Saying dhikrs is controlled and reminded daily by the researcher who is present in the hospital. The intervention is non-invasive and does not interfere with other treatment processes.

**Category**

Rehabilitation

**2**

**Description**

Control group: Control group: Patients in the control group receive only the usual treatments prescribed by doctors in the hospital.

**Category**

N/A

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Sasan hospital

**Full name of responsible person**

Roghaye Esmaeeli

**Street address**

No.43, after the crossroads of Palestine, Keshavarz Boulevard,Valiasr Square, Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1415983391

**Phone**

+98 21 8896 5170

**Email**

info@sasanhospital.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Ali Ziyaee

**Street address**

Shahid Chamran Highway - Yemen St. - Shahid Abbas Arabi St. (Parvaneh) - Next to Taleghani Hospital - Shahid Beheshti University of Medical Sciences and Health Services - Headquarters Building 2- Floor 5- Deputy of Research and Technology

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 2243 9781

**Email**

Mpajouhesh@sbmu.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Raheleh Mahdavitaree

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No. 11, Pish Namaz Alley, 17 Shahrivar St., Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1175875513

**Phone**

+98 21 3355 4128

**Email**

mahdavi.raheleh@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Raheleh Mahdavitaree

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No. 11, Pish Namaz Alley, 17 Shahrivar St., Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1175875513

**Phone**

+98 21 3355 4128

**Email**

mahdavi.raheleh@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Raheleh Mahdavitaree

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No. 11, Pish Namaz Alley, 17 Shahrivar St., Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1175875513

**Phone**

+98 21 3355 4128

**Email**

mahdavi.raheleh@gmail.com

## 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**

There is no more information.

**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**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not 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 final report of this study will be published as an article after the end of the study and data analysis.

**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**

No access restrictions.

**Under which criteria data/document could be used**

The final report of this study will be published as an article and will be made available to the public.

**From where data/document is obtainable**

mahdavi.raheleh@gmail.com

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

The final report will be available as an article in the Journal of Veteran Medicine.

**Comments**