Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

The effect of spiritual practice along routine medical care on the recovery of patients hospitalized with Covid-19: a randomized clinical trial

Protocol summary

Study aim
The effect of spiritual practice along routine medical care on the recovery of patients hospitalized with Covid-19: a randomized clinical trial

Design
A clinical trial with two intervention and comparison groups, a blind, randomized, block-assisted strain will be performed on 70 patients with Covid-19.

Settings and conduct
Imam Hussein Hospital The patient will be asked to provide spiritual care for 7 days. The intervention lasts one week, three times a day for 10 minutes each time, a total of 21 sessions. According to previous clinical trials, Surah Hamd and Zikr "Ya Allah" (from the divine names) which has been used in previous studies for the recovery of patients were selected.

Participants/Inclusion and exclusion criteria
Inclusion criteria: positive PCR hospitalized Exclusion criteria: Any clinical condition that affects a person's ability to participate in a spiritual self-care program ICU admission Teenagers and children Pregnancy

Intervention groups
The intervention group will recite Surah Al-Hamd three times and 'Ya Allah' 66 times in spiritual practice(comparison group: without spiritual practice).

Main outcome variables
Vital signs HADS Questionnaire Duration of hospitalization Transfer to ICU and death

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201101049219N1**
Registration date: **2021-06-10, 1400/03/20**
Registration timing: **retrospective**
Last update: **2021-06-10, 1400/03/20**
Update count: **0**

Registration date
2021-06-10, 1400/03/20

Registrant information

Name
Batool Mousavi

Name of organization / entity
Janbazan Medical and Engineering Research Center (JMERC), Tehran, Iran

Country
Iran (Islamic Republic of)

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+98 21 2241 6699

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-22, 1399/05/01

Expected recruitment end date
2020-12-05, 1399/09/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of spiritual practice along routine medical care on the recovery of patients hospitalized with Covid-19: a randomized clinical trial

Public title
Effects of spiritual practice on recovery of Covid-19

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with positive Covid-19 test report. Patients hospitalized due to Covid-19.

Exclusion criteria:

Any clinical condition that affects a person's ability to participate in a spiritual self-care program, such as diagnosed psychological problems. Any clinical condition that may limit the patient spiritual practice such as drowsiness or decrease level of consciousness. ICU addmision Teenagers and children Pregnancy

Age

From **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

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

Research ethics committee veterans and martyrs affair foundation (VMAF)

Street address

No. 17, Farokh St., Moghadas Ardebili St.,Yaman St., Chamran Highway, Tehran, Iran

City

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Province

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Postal code

1985946563

Approval date

2020-05-12, 1399/02/23

Ethics committee reference number

IR.ISAAR.REC.1399.001

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07. 1

ICD-10 code description

U07.1:Confirmed cases of COVID-19 with positive or presumptive-positive test results

Primary outcomes

1

Description

According to the hospital stress and anxiety questionnaire, the score of hospital anxiety will be measured in patients with Covid-19 before and after the intervention. At the beginning of the study, a hospital anxiety questionnaire will be completed for all participants. Then the intervention will be done. After the intervention on the seventh day, the hospital anxiety questionnaire will be completed for the patients.

Timepoint

Hospital anxiety will be measured at the beginning of the study before the intervention and on the seventh day.

Method of measurement

Hospital Anxiety and Depression Scale

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: 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
Imam Hussein hospital

Full name of responsible person
Batool Mousavi

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No. 17, Farokh St., Moghadas Ardebili St.,Yaman St., Chamran Highway, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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?
No

Title of funding source
مرکز تحقیقات مهندسی و علوم پزشکی جانبازان

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Janbazan Medical and Engineering Center

Full name of responsible person
Batool Mousavi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Others

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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
The principle investigator
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