

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of using spiritual care program on sleep quality and Spiritual health of patients with stroke

Protocol summary

Study aim

Determining the effect of using spiritual care program on sleep quality and Spiritual health of patients with stroke

Design

The present study is a randomized two-group clinical trial study that will be performed with the participation of 112 patients. The research units will be selected by available sampling method and permuted block method divided into two groups of control and test.

Settings and conduct

The present study is a randomized two-group clinical trial with the participation of 112 patients with stroke in Hamadan. In the intervention group, group sessions of the spiritual care program will be held in 4 sessions, one session per week for 45 to 60 minutes by the researcher. The topics of the sessions will include assessing the spiritual needs of patients with stroke, religious care for stroke patients, spiritual care-support for stroke patients, and evaluation of spiritual care, respectively. The patients' hope questionnaire will be administered one month after the last care session. The control group will receive only routine medical care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of adult stroke according to the doctor; not having mental disorders; lack of vision and hearing diseases. Exclusion criteria: hospitalization of the patient due to recurrence of the disease; absence more than once in meetings; reluctance to continue participating in the study.

Intervention groups

Intervention group: the group sessions of the spiritual care program will be held by the researcher for the intervention group during 4 sessions, 1 session per week for 45 to 60 minutes. Assessment of patients' hope after spiritual care intervention will be done one month after the last care session. Control group: patients in the control group will receive only routine care.

Main outcome variables

sleep quality and Spiritual health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211227053551N1**

Registration date: **2022-01-03, 1400/10/13**

Registration timing: **prospective**

Last update: **2022-01-03, 1400/10/13**

Update count: **0**

Registration date

2022-01-03, 1400/10/13

Registrant information

Name

Vahid Yousofvand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3252 6339

Email address

v.yousofvand@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of using spiritual care program on sleep quality and Spiritual health of patients with stroke

Public title
The effect of spiritual care program on sleep quality and Spiritual health

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of stroke according to the doctor Not having mental disorders Lack of vision and hearing diseases
Exclusion criteria:
Hospitalization of the patient due to recurrence of the disease Absence more than once in meetings Reluctance to continue participating in the study

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **112**

Randomization (investigator's opinion)
Randomized

Randomization description
In the present study, the patients were registered according to the sample size (112) and according to the inclusion criteria, and using the blocking method (using a two-block method, two letters A and B with different permutations we place in blocks and randomly select 56 blocks and assign each block to 2 people) will be assigned to two groups.

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

کمیته اخلاق دانشگاه علوم پزشکی همدان

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh St.

City

Hamadan

Province

Hamadan
Postal code
38698-65178
Approval date
2021-12-11, 1400/09/20
Ethics committee reference number
IR.UMSHA.REC.1400.711

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

I67.81

ICD-10 code description

Acute cerebrovascular insufficiency

Primary outcomes

1

Description

Patients' sleep quality and Spiritual health

Timepoint

One month after the intervention

Method of measurement

Patients' Pittsburgh Sleep Quality and Paloutzian and Ellison Spiritual health questionnaires

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: group sessions of the spiritual care program will be held in 4 sessions, one session per week for 45 to 60 minutes by the researcher. The content of these sessions has been localized due to the identification of the spiritual needs of Iranian patients and its adaptation to the international clinical guide and texts related to spiritual care, through a group agreement of Iranian health system experts. The Patients' sleep quality and Spiritual health Questionnaire will be administered one month after the last care session.

Category

N/A

2

Description

Control group: the control group will receive only routine medical care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Azim Azizi

Street address

Shahid Beheshti Blvd., Besat hospital, Hamadan

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Phone

+98 918 107 0758

Email

azimazizi1360@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh St.

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Phone

+98 81 3838 0535

Email

s_bashirian@umsha.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Deputy of research and technology

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

Hamedan University of Medical Sciences

Full name of responsible person

Azim Azizi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh St.

City

Hamedan

Province

Hamadan

Postal code

38698-65178

Phone

+98 81 3838 0535

Email

azimazizi1360@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Azim Azizi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh St.

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Phone

+98 81 3838 0535

Email

azimazizi1360@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Vahid Yousofvand

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh St.

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Phone

+98 81 3838 0535

Email

v.yousofvand@gmail.com

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

Undecided - It is not yet known if there will be 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

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