Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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

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38698-65178

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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, Ṡhahid Fahmideh St.

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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

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Person responsible for scientific inquiries

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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

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Full name of responsible person
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Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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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