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
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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

1
Ethics committee
Name of ethics committee

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 center

1

Recruitment center
Name of recruitment center
Besat hospital
Full name of responsible person
Azim Azizi
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Sponsors / Funding sources

1

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Name of organization / entity
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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
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
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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