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
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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**
Hamadan University of Medical Sciences, Shahid Fahmideh St.

**Category**
N/A

**Ethics committee**

2

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

**Category**
N/A

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**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
Recruitment centers

1

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

1

Sponsor
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
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Latest degree
  Bachelor

Other areas of specialty/work
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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