Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of using spiritual care program on hope of patients with stroke

Protocol summary

Study aim
Determining the effect of using spiritual care program on hope of patients with stroke

Design
The present study is a randomized two-group clinical trial study that will be performed with the participation of 108 patients. The research units will be selected by available sampling method and will be randomly 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 108 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. 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
Patients' hope

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160110025929N36**
Registration date: **2021-09-27, 1400/07/05**
Registration timing: **prospective**

Last update: **2021-09-27, 1400/07/05**
Update count: **0**

Registration date
2021-09-27, 1400/07/05

Registrant information

Name
Mehdi Molavi Vardanjani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 81 3422 5056

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of using spiritual care program on hope of

patients with stroke

Public title
The effect of spiritual care program on hope
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: **108**
Randomization (investigator's opinion)
Randomized
Randomization description
In the present study, the patients were registered according to the sample size (108) 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 36 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
Ethics Committee of Hamadan University of Medical Sciences
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh St.
City
Hamadan
Province
Hamadan
Postal code
38698-65178
Approval date
2021-09-04, 1400/06/13
Ethics committee reference number
IR.UMSHA.REC.1400.450

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' hope
Timepoint
One month after the intervention
Method of measurement
Patients' hope questionnaire

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' Hope 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
Khodayar Oshvandi

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Shahid Beheshti Blvd., Besat hospital, Hamadan

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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
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
Khodayar Oshvandi

Position
Professor

Latest degree
Ph.D.

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