

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of spiritual care on the quality of life of patients with stroke

Protocol summary

Study aim

The effect of spiritual care on the quality of life of patients with stroke

Design

After obtaining permission, the researcher goes to the relevant center to select samples. The sampling method is random and based on coin toss

Settings and conduct

In this study, spiritual care will be performed individually and twice a week in the morning or afternoon shifts at the patient's personal home. A landline and mobile phone number will be taken from the patient or the patient's companion to follow up and ask any questions about the disease. The control group is not given any training. One month after the completion of the educational intervention, the Stroke Quality of Life Scale questionnaire will be completed by both intervention and control groups.

Participants/Inclusion and exclusion criteria

Patients between the ages of 18-60. Patients who are conscious and oriented. Be able to speak Persian. Do not have severe hearing and vision impairment. Willing to participate in the study. The patient has no history of mental illness. The patient has no history of hospitalization due to stroke. The patient has the ability to self-care and more than 48 hours have passed since the onset of cerebral haemorrhage (acute stage).
Exclusion criteria: The patient's unwillingness to continue participating in the study for any reason. Perform any procedure outside the routine program. Illness for any reason Death of the patient

Intervention groups

In the intervention group, the spiritual care model is trained for 90 minutes in the patient's personal home for seven sessions in each session. Then, two weeks and one month after the end of the training, a quality of life questionnaire will be provided to patients.

Main outcome variables

Improving and improving the quality of life of patients with stroke

General information

Reason for update

Acronym

SQP

IRCT registration information

IRCT registration number: **IRCT20161116030926N9**

Registration date: **2022-01-19, 1400/10/29**

Registration timing: **prospective**

Last update: **2022-01-19, 1400/10/29**

Update count: **0**

Registration date

2022-01-19, 1400/10/29

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3275 4961

Email address

alilu@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

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 spiritual care on the quality of life of

patients with stroke

Public title
The effect of spiritual care on the quality of life of patients with stroke

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are between the age group of 18-60.
Patients who are alert and oriented. Have the ability to speak Persian. Do not have severe hearing and vision impairment. Have a desire to participate in the study.
The patient has no history of mental illness. The patient does not have a history of hospitalization due to stroke.
Exclusion criteria:
The patient's unwillingness to continue participating in the study for any reason. Perform any procedure outside the routine program. Illness for any reason Death of the patient

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of randomization is by using coin toss, so that the line intervention group and the valve control group are considered and the coin will be tossed according to the desired sample size.

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

Urmia University of Medical Sciences

Street address

South Khayyam Street

City

Urmia

Province

West Azarbaijan
Postal code
5951973896
Approval date
2022-01-01, 1400/10/11
Ethics committee reference number
IR.UMSU.REC.1400.388

Health conditions studied

1

Description of health condition studied

stroke

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

In this study, the SS-QoL (Stroke-Specific Quality of Life scale) quality scale will be used to determine the quality of life of a patient rescued from a stroke. This questionnaire consists of 12 items, each of which represents a major dimension of the 12 dimensions of SS-QOL. The answer is 2 methods, for the first group (physical) the answer is 1 - I can not do at all 2- I do very hard 3- I do a little hard 4- I do hard 5- I do without effort. For group 2, which is the psycho-social dimension, answering as 1- I totally agree 2- I slightly agree 3- I have no opinion 4- I slightly disagree 5- I strongly disagree The minimum score will be 12 and the maximum score will be 60 And a higher score will indicate a better quality of life

Timepoint

Two weeks and one month after the intervention

Method of measurement

By quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group consists of 50 people who are randomly selected by tossing a coin. Patients will enter the study phase after discharge. Also in this study, spiritual care will be performed individually and twice a week in the morning or evening shifts, in the patient's private home for seven sessions and for 90 minutes. Also, in order to have a greater impact and improve the quality of education, the guidance and advice of Dr. Heiman Mohammad Fakheh (PhD in Psychology) will be used. A landline or mobile phone number will be taken from the patient or the patient's companion to follow up and ask any questions about the

disease.
Category
Lifestyle

2

Description

Control group: They do not receive any training.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital in Urmia

Full name of responsible person

Leila Alilo

Street address

Urmia - Resalat Boulevard - Emergency Alley - Urmia
University of Medical Sciences

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+98 44 3223 4897

Fax

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Email

aliluleyla@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Leila Alilo

Street address

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia University of Medical Sciences

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

Oroumia University of Medical Sciences

Full name of responsible person

Leila Alilo

Position

phd

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

ارومیه - بلوار رسالت - کوی اورژانس - دانشگاه علوم پزشکی
ارومیه

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5714783734

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Email

aliluleyla@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Leila Alilo

Position

ph.d

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Leila Alilo
Position
ph.d
Latest degree
Ph.D.
Other areas of specialty/work
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Email
aliluleyla@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

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

Title and more details about the data/document

It is available to everyone as an educational pamphlet

When the data will become available and for how long

One year after printing

To whom data/document is available

All stroke patients

Under which criteria data/document could be used

Charter to improve the quality of life and stroke patients

From where data/document is obtainable

Author

What processes are involved for a request to access data/document

One year after printing

Comments