Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

The effect of spiritual self-care educational program in the form of compact disc (CD) along with telephone follow-up on the quality of life of stroke patients and their caregivers after discharge from hospitals.

Protocol summary

Study aim
Determining the effect of presenting a spiritual program along with telephone follow-up on the quality of life of stroke patients and their caregivers after discharge from hospitals.

Design
The clinical trial has a control group, for this purpose 70 patients and their primary caregivers were easily selected and randomly assigned to two control or intervention groups by asking samples take out a card from a bag containing 70 cards, number one to 70. Then put the even people in one group and the single people in the other group. In the intervention group, a CD will be given to them and follow-up will be done by phone.

Settings and conduct
By referring to the neurology department of Kashani Hospital in Isfahan and collecting samples, the pre-test questionnaires are completed and after randomizing the content of the program, the intervention group will be given a CD and will be followed up by phone.

Participants/Inclusion and exclusion criteria
An adult patient with a definite diagnosis of stroke that has a Barthel index score less than 90. Patients have a hospital record and are being discharged from the hospital. Patients have no global or Wernicke aphasia . Patients have no congestive heart failure, dialysis and mental retardation. The patient was independent in performing his tasks before the stroke occurred. The patient and his/her caregiver are physically and mentally ready to answer questions. Do not have serious mental disorders and have at least literacy and the ability to speak Persian. Do not have hearing or vision impairment.

Intervention groups
A spiritual self-care training program will be provided to the intervention group in the form of a CD, and this group will be followed up by telephone during the study, and the control group will not receive the program for comparison.

Main outcome variables
the quality of life of patients and their caregivers

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210302050552N1**
Registration date: **2022-04-27, 1401/02/07**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-27, 1401/02/07**
Update count: **0**

Registration date
2022-04-27, 1401/02/07

Registrant information

Name
Maryam Rezaei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-04, 1401/01/15

Expected recruitment end date
2022-08-06, 1401/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of spiritual self-care educational program in the form of compact disc (CD) along with telephone follow-up on the quality of life of stroke patients and their caregivers after discharge from hospitals.

Public title
The effect of spiritual self-care educational program in the form of CD along with telephone follow-up on the quality of life of stroke patients and their caregivers after discharge from hospitals.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Adult patients with definitive diagnosis of stroke for the first time The patient's Bartel index score is equal or less than 90 The patient has a hospital record in Isfahan Ayatollah Kashani Hospital The patient is being discharged from the hospital Before the stroke, the patient was independent in performing his/her tasks, The patient and caregiver are willing to participate in the study and have given informed written consent. Physical and mental readiness of the patient to answer questions Patient or caregiver is literate The patient and caregiver should be able to speak Persian The caregivers were older than 18 The caregiver delivers care to the patient in 24 hours. The caregiver should not receive any remuneration for the care Caregiver and patient have a computer or cell phone with android system
Exclusion criteria:
Patient has global or Wernicke aphasia The patient does not have congestive heart failure (CHF) , mental retardation and renal failure with dialysis The patient or caregiver have a serious physical or mental disorder The patient with an acute condition Receiving specific stroke rehabilitation as a complementary treatment program by the patient patient with low consciousness caregivers have a history of participating in a training program or research related to this study Patient or caregiver with visual or auditory impairment
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples will be divided into intervention and control groups using simple random assignment. In order to place the patient in the control or intervention group, we ask the patient or his companion to take a card out of the bag at random and depending on whether the selected card number is randomly paired or odd, the patient assigned in the intervention or control group. This drawing consists of a bag containing 70 cards with numbers from 1 to 70 written on them) Each card that is selected is discarded from the bag. By contract, the card selectors with even number will be in the intervention group and the card selectors with odd numbers will be in the control group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the School of Nursing, Management and Rehabilitation, Isfahan University of Medi
Street address
Hezar Jarib St., Isfahan University of Medical Sciences, School of Nursing and Midwifery, Ethics Committee
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Approval date
2021-05-08, 1400/02/18
Ethics committee reference number
IR.MUI.NUREMA.REC.1400.020

Health conditions studied

1

Description of health condition studied
Quality of Life
ICD-10 code
I67.9
ICD-10 code description
Cerebrovascular disease, unspecified

Primary outcomes

1

Description

Mean score of quality of life of stroke patients in William's stroke quality of life questionnaire for patients

Timepoint

Measuring the quality of life of patients at the beginning of the study (before the intervention) and immediately and 6 weeks after the start of their use of the content of the spiritual self-care program

Method of measurement

William Stroke Quality of Life Questionnaire for Patients

2

Description

Mean quality of life score of caregivers of stroke patients with general quality of life questionnaire for caregivers

Timepoint

Measuring the quality of life of caregivers at the beginning of the study (before the intervention) and immediately and 6 weeks after the start of their use of the content of the spiritual self-care program

Method of measurement

General Quality of Life Questionnaire for Caregivers

Secondary outcomes

empty

Intervention groups

1

Description

The content of the spiritual self-care program through a CD contains various items such as audio, video and PowerPoint files of experts in this field for spiritual promotion that are provided to patients with stroke and their caregivers. During the intervention, patients and their caregivers are followed by phone and Whats App about their questions, and feedback, and how to do the exercises.

Category

Rehabilitation

2

Description

In order to compare the results of the intervention in the intervention group, this group will not receive content.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Kashani Hospital

Full name of responsible person

Taghi Hashemi

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Ayatollah Kashani Hospital, Ayatollah Kashani Main Street, Isfahan

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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?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Hojatollah Yousefi
Position
Professor, Faculty Member
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All participants' personal data can be shared after identifying individuals
When the data will become available and for how long
Access period starts from 1401
To whom data/document is available
Only researchers working in academic and scientific institutions will be allowed to access the data of this study
Under which criteria data/document could be used
The use of the results of this study and personal data is allowed after identifying individuals
From where data/document is obtainable
Hojatollah Yousefi, School of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezar Jarib St, 81746 -73461 Email: yousefi@nm.mui.ac.ir, Mobile: 09133022900, Tel:+98 31 37927543, Fax:+98 31 36699398
What processes are involved for a request to access data/document
After confirming the study and printing the results, the information will be available through the irct site using the search terms related to the study
Comments