

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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)

Phone

+98 31 5255 4395

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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

AgeFrom **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

City

Esfahan

Province

Isfahan

Postal code

8174673461

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
Street address
Ayatollah Kashani Hospital, Ayatollah Kashani Main

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Hagh Jooi Javanmard
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Vice Chancellor for Research and Technology,
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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

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Email

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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 irtc site using the search terms related to the study

Comments