

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of family-centered empowerment pattern on quality of life in stroke patient

Protocol summary

Study aim

Determination of the effect of empowerment based on family-centered model on quality of life in patients with cerebral stroke

Design

A clinical trial, with a control group, with a parallel group, a unilateral blind, randomized using a random number table, and 100 participants.

Settings and conduct

The caregivers of the patients in the intervention group receive the necessary training during eight sessions in the hospital meeting room and then the patients' quality of life is evaluated at one-month and two-month intervals and compared with the control group.

Participants/Inclusion and exclusion criteria

The study population consists of all patients with stroke and their families in Kashan, whose diagnosis has been confirmed by a neurologist and have a file in Shahid Beheshti Hospital.

Intervention groups

Patient caregivers in the intervention group receive the necessary training on their patient care during 8 training sessions. Care givers of the control group patients are not received any training during the study. After completion of the study, they will receive all necessary training.

Main outcome variables

Managing the cost of caring for stroke patients and changing the quality of life of stroke patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190617043915N1**

Registration date: **2019-08-06, 1398/05/15**

Registration timing: **retrospective**

Last update: **2019-08-06, 1398/05/15**

Update count: **0**

Registration date

2019-08-06, 1398/05/15

Registrant information

Name

Alireza Amini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4234 9285

Email address

a_amini1990@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-20, 1398/02/30

Expected recruitment end date

2019-06-20, 1398/03/30

Actual recruitment start date

2019-05-20, 1398/02/30

Actual recruitment end date

2019-06-20, 1398/03/30

Trial completion date

2019-08-06, 1398/05/15

Scientific title

The effect of family-centered empowerment pattern on quality of life in stroke patient

Public title

The effect of family-centered empowerment pattern on quality of life in stroke patient

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

cerebral strokes Patients with definitive diagnosis of a physician. Who has been suffering from stroke, for the first time. It has at least one complication of stroke, such as motor disorder, speech impairment, swallowing disorder, visual impairment, and urinary and fecal dysfunction.

Exclusion criteria:

Dissatisfaction to association in study. Patients death. It has more than once stroke.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done by simple and individual method using random number table. The table numbers were used downward. Even numbers were considered for intervention group and odd numbers for control group. Hiding was done by using opaque sealed envelopes with a random sequence. Each of the random sequences is registered on a card, then the cards are inserted into the envelopes, the envelopes are sealed and packed in the boxes. At the time of registration, one of the envelopes is opened in accordance with the order of entry of eligible participants to the study and then the group assigned to that participant is shown.

Blinding (investigator's opinion)

Single blinded

Blinding description

At the beginning of the study, participants are given the necessary explanations on how to do the task, but are not given any explanation as to which group they are in. At the end of the study, all training are provided to the control group as well.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical

Sciences

Street address

Ravandi Blvd,

City

Kashan

Province

Isfahan

Postal code

8715988141

Approval date

2018-03-17, 1396/12/26

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1396.37

Health conditions studied

1

Description of health condition studied

Quality of life for patients with stroke

ICD-10 code

I64

ICD-10 code description

Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description

Quality of life scores in the quality of life questionnaire for patients with stroke

Timepoint

Before the intervention, one and two months after receiving the training

Method of measurement

Quality of Life Questionnaire for Patients with Stroke

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Caregivers of patients with stroke who are in the intervention group receive eight sessions of patient care training and their patients' quality of life is measured at baseline, one month and two months later.

Category

Lifestyle

2

Description

Control group: The control group will not receive any training during the time the intervention group is being trained and after completing the third questionnaire (2 months after the study starts) all the training provided to

the intervention group will be provided to the control group.
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Beheshti hospital
Full name of responsible person
Alireza amini
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8715981151
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Fax
+98 31 5554 8900
Email
beheshtihospital@kaums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hamid Reza Banafsheh
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Ravandi Blvd
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+98 31 5557 5057
Email
research@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Alireza amini
Position
Student
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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