Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of "Partnership Care Model" on quality of life and activity daily living in Patients' Cerebrovascular accident

Protocol summary

Study aim
To determine the effect of the partnership care model on the quality of life and the activity of daily living among stroke patients

Design
This study is a clinical trial with two intervention and control groups. Patients are randomly (lottery technique) allocated into two groups and the study is single blind.

Settings and conduct
This study is carried out at the Rafideh Rehabilitation Comprehensive Hospital, affiliated to the University of Welfare Sciences in Tehran.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Stroke patients under rehabilitation at Rofaydeh Rehabilitation Hospital; Age over 60 years; Passed two weeks from the acute treatment period; Desire and ability to communicate and decide Exclusion Criteria: Heart Failure class III and IV; Malignancies requiring chemotherapy.

Intervention groups
Intervention group 1: Partnership educational visits: these visits are done weekly, with the participation of 4 to 6 homogeneous patients and the presence of nurses and physicians, in order to motivate and prepare patients to participate in the care and treatment process. Intervention group 2: Follow-up partnership visits: these visits are done monthly, at least for 6 months, in order to do follow up the adherence and continuing the participation. Control group: during at least two weeks of hospitalization, these patients are visited by physicians every day and in the case of occurrence and diagnosis of a problem, rehabilitation interventions are done.

Main outcome variables
Patients' Quality of life; Activity of daily living

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180930041185N1**
Registration date: **2018-11-03, 1397/08/12**
Registration timing: **prospective**

Last update: **2018-11-03, 1397/08/12**
Update count: **0**

Registration date
2018-11-03, 1397/08/12

Registrant information

Name
Eesa Mohammadi

Name of organization / entity
Faculty of Medical Sciences Tarbiat Modares University

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-06, 1397/08/15

Expected recruitment end date
2019-06-05, 1398/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of "Partnership Care Model" on quality of life and activity daily living in Patients' Cerebrovascular

accident

Public title
Effect of the Partnership Care Model in Patients with cerebrovascular accident
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Having at least 2 weeks history of treatment for Stroke Being at the age of 60 years old and more Willing to take part in the study Ability of communication and decision making
Exclusion criteria:
Heart failure (class III , IV) Having malignancies requiring chemotherapy
Age
From **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
The allocation of subjects is done by the randomization technique lottery. As 80 cards are numbered for 80 patients and placed in a basket. Then two blank envelopes are determined, one as intervention and one as control. Then, by drawing cards from the basket, some numbers are selected alternately for the two envelopes. Then the patients admitted the hospital receive a number based on their reception order (based on the cards in the pockets).
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants are unaware of the study groups they are allocated to.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
University/Regional Research Ethics Committee
Street address
No. 21, First Besat Ave., West Fathemi Ave.
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۶۹۳۱۱۱
Approval date
2018-07-01, 1397/04/10
Ethics committee reference number
IR.NIMAD.REC.1397.236

Health conditions studied

1

Description of health condition studied
Stroke / Cerebrovascular Accident
ICD-10 code
I64
ICD-10 code description
Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description
Patients' Quality of Life Score based on SF-36 questionnaire
Timepoint
Measurements are done before the intervention, one month after completing the first phase of intervention, and then for up to 6 months, monthly in each follow-up visit.
Method of measurement
Short Form- 36 (SF-36) Questionnaires related to quality of life

2

Description
Activity of Daily Living Score based on The Lawton Criteria
Timepoint
Measurements are done before the intervention, one month after completing the first phase of intervention, and then for up to 6 months, monthly in each follow-up visit.
Method of measurement
The Lawton Questionnaire to measure the Elderly's Activity of Daily Living

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients will receive stroke care and treatment based on partnership care model (PCM). After assessment and recording basic information (demographic variables, care requirements and problems highlighted in the first step of PCM), the care program will prepared and implemented for the intervention group in accordance with the PCM. The program has two phases: (i) an educational partnership meeting; and (ii) a follow-up partnership meeting. In the first phase, at least three educational partnership will be held at the rehabilitation centers weekly; the partnership comprised of 4–6 patients, a nurse and a physician. The nurse will be the leader of the team and the chair of the meetings. The physician will support the patients in decision making. The purpose of these meetings will be motivating and making the patients ready. In the first meeting, the nature, causes and complications of CVA will be introduced to the patients. The second meeting will address non-drug therapy (nutrition and activity regimens). In this meeting, nutrition and activity regimens will be arranged, evaluated and justified for each participant in response to his/her questions, level of distress, condition and status. In the third meeting drug therapy for underlying diseases such as high blood pressure and diabetes will be discussed. Prescription drugs, their effects, their usage and dosage, their importance and side effects will be discussed in addition to address patient's anxiety and answer any questions about the drugs. In the second phase, follow-up partnership meetings will be held monthly in the rehabilitation center for 6 months. These meetings will be held by the partnership of 4–6 patients, the nurse and the physician. The goal of the meetings will be to encourage, support and evaluate the patient compliance and participation during care. At each meeting, in the first 40–45 minutes, blood pressure will be taken and problems with the disease will be considered and addressed, new prescriptions or nutrition regimens will be offered, and previous medical care intervention will be evaluated. The SF-36 & ADL questionnaires are also completed by patients in each session.

Category

Rehabilitation

2

Description

Control group: Patients in the control group include stroke patients who receive routine care at the rehabilitation center. These patients are screened and hospitalized at least one month after the attack by the physician.After determining the needs and problems of rehabilitation, physiotherapist or speech therapist referral and rehabilitation is performed, then they are discharged at most after three weeks.They will visited by a researcher at the center. These patients, like the patients in the intervention group, have been visited by a research associate to complete the questionnaires' the quality of life and the Activity of Daily Living at specified intervals.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Rofaydeh Rehabilitation Hospital

Full name of responsible person
Dr. Feridon Layeghi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
National Institute for Medical Research Development

Full name of responsible person
Dr. Reza Malekzadeh

Street address
No. 21, First Besat Ave. West Fathemi Ave.

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NIMAD@RESEARCH.AC.IR

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Grant name
Elite Grant

Grant code / Reference number

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

Title of funding source
National Institute for Medical Research Development

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

Faculty of Medical Sciences, Tarbiat Modares University

Full name of responsible person

Eesa Mohammadi

Position

Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Eesa Mohammadi

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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

I must provide all information for the sponsoring institution.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

No application

When the data will become available and for how long

No application

To whom data/document is available

No application

Under which criteria data/document could be used

No application

From where data/document is obtainable

No application

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

No application

Comments