

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

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Name of organization / entity

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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.

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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 be 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 be 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

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Full name of responsible person

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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

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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

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