

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effect of family-based care program on adherence of treatment regimen in patients with stroke

Protocol summary

Summary

The purpose of this research is recognizing Influence of family centered care program on adherence of therapeutic regime on stroke patient. Inclusion criteria included patients with ischemic stroke were 4 and 5 degrees Rankine scale and primary caregivers in the patient's family should have more than 4 days per week of patient care. Exclusion criteria included Change in primary care patients during the study period and placing the patient in the end stage of the disease. Research on patients with stroke and their primary care experience in both groups (30 patients) and comparison (n = 30) were performed. Comparison group, the received the rotin hospital program and experimental group received family-centered care programs including needs assessment, training, telephone follow up and refer. Study period for each sample was 2 months. Variable for assessment include Demographic data and adherence of therapeutic regimen in three areas of the rehabilitation, Food and Drug regimen.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202128978N1**
Registration date: **2012-03-18, 1390/12/28**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-18, 1390/12/28

Registrant information

Name

Nahid Dehghan Nayeri

Name of organization / entity

Tehran University of Medical Sciences

Country

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Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-04-17, 1390/01/28

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of family-based care program on adherence of treatment regimen in patients with stroke

Public title

The effect of using family-based care program on adherence to treatment regimen in stroke patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patient with first stroke; Rankin Scale score of 4-5, Patients discharged to home after hospitalization; Patients stay at least 5 days in hospital; there is primary carer of patients in the hospital for implementing of family centered care the program; Primary care patients at least 4 days a week to take care of the patient, Home carer patients are literate; we can contact with primary carer of patients. Exclusion criteria:

changes in individual patient care; Putting the patient at the end stage of disease according to the doctor.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

School of nursing and midwifery , Tohid Sq. Tehran

City

Tehran

Postal code

1419733171

Approval date

2011-04-17, 1390/01/28

Ethics committee reference number

13169

Health conditions studied

1

Description of health condition studied

Brain stroke

ICD-10 code

I64

ICD-10 code description

Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description

adherence to treatment regimen

Timepoint

2 months after discharge

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Family-centered care plan has four parts : Assessment, family education based on patient care need , Telephone follow-up care after discharge, Coordination and referrals between family and health care providers in related to caring of patient. 48 hours after patient admission, the questionnaire of demographic data for primary caregivers and patient filled by the researcher. in needs assessment stage, check list in three areas of assessment, rehabilitation, diet and medication regimen was completed. Educational content according to the need assessment, was prepared in three parts. family education developed and implemented based on andragogy theory. family education were conducted on 3 consecutive days in the hospital. Reassessment was done in training. Illustrated educational booklet was given to the patient's primary caregiver. In the telephone follow-up after discharge, Each week, call the family carer for educationa need and resolve care problems. in the referral stage, medical teams of each patient was identified and communication way with the treatment team, was foun and if necessary, appropriate reference was introduced to family for solve the care problem. After two months after the intervention, the questionnaire of adherence of therapeutic regimen was assessed via telephone.

Category

Other

2

Description

Comparing groups within two months of research applications received routine hospital program. After two months , the questionnaire of adherence of therapeutic regimen was filled via telephone.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shriati Hospital

Full name of responsible person

Sepideh mohamadi

Street address

Shriati Hospital, Tehran

City

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2**Recruitment center****Name of recruitment center**

Imam Khomai Hospital

Full name of responsible person

Mozhde ghabaee

Street address

Imam Khomai Hospital, Tehran

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran university of Medical Sciences

Full name of responsible person

Mrs arimi - expert of proposal

Street addressThe sixth floor, structure of TUMS, the Qods St.
Keshavarz Boulevard, Tehran , Iran**City**

Tehran

Grant name

پایان نامه

Grant code / Reference number

13169

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

Yes

Title of funding source

Tehran university of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Position

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Web page address**Person responsible for updating data****Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty