Clinical Trial Protocol
Iranian Registry of Clinical Trials
12 Nov 2020

The effect of informational support on anxiety and satisfaction of family caregivers of patients with hemiplegic stroke

Protocol summary

Summary
Objective: This study will be done to evaluate the effect of informational support on the satisfaction and anxiety of family caregivers of patients with hemiplegic stroke.

Design: This study is a quasi-experimental clinical trial with two groups (intervention and control) and pre-test - post-test design. Setting and conduct: This study will be done by participating 84 family caregivers of stroke hemiplegic patients admitted to hospital neurology Farshchian (Sina) in Hamadan. Each group consists of 42 patient’s people. Participants, including major eligibility criteria: The family member is responsible for the patient care; minimum age of 18 years; ability to read and write; lack of neurological disease, mental illness and anxiety; lack of drugs and psychotropic substance abuse; lack of communication problems; Be able to speak and understand the language of Farsi; unemployment in health centers. Exclusion criteria: Don't have willingness family caregivers to continue to study at any moment; death of the patient; family member cannot participate in all educational sessions; creating unwanted problems for the patient, such as re-bleeding and severe hemodynamic disorders that affect on the family.

Intervention: In experimental group, family caregivers will receive some informational support that is consist of introductory neurology ward tour, training sessions and educational booklet and pamphlet about matters related to stroke. No intervention will be done in control group.

In both groups will be measure level of anxiety by Spielberger questionnaire and family caregiver’s satisfaction by satisfaction of information questionnaire before and after the intervention. Main outcome measure: The main outcome is the anxiety and satisfaction of information on family caregivers.

General information

Acronym
IRCT registration information

IRCT registration number: IRCT2017022032129N2
Registration date: 2017-04-21, 1396/02/01
Registration timing: registered_while_recruiting

Registration date
2017-04-21, 1396/02/01

Registrant information

Name
Azim Azizi

Name of organization / entity
Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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+98 81 3838 0150

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Recruitment status
Recruitment complete

Funding source
Vice Chancellor for Research and Technology of Hamadan University of Medical Sciences

Expected recruitment start date
2017-04-09, 1396/01/20

Expected recruitment end date
2017-09-11, 1396/06/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of informational support on anxiety and satisfaction of family caregivers of patients with...
hemiplegic stroke

Public title
The effect of informational support on anxiety and satisfaction of family caregivers

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: The family member is responsible for the patient care; minimum age of 18 years; ability to read and write; lack of neurological disease, mental illness and anxiety; lack of drugs and psychotropic substance abuse; lack of communication problems; Be able to speak and understand the language of Farsi; unemployment in health centers. Exclusion criteria: Don’t have willingness family caregivers to continue to study at any moment; death of the patient; family member cannot participate in all educational sessions; creating unwanted problems for the patient, such as re-bleeding and severe hemodynamic disorders that affect on the family.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 84

Randomization (investigator's opinion)
Not randomized

Randomization description
Not blinded

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
Ethics Committee of Hamedan University of Medical Sciences

Street address
Hamadan University of Medical Sciences, Shahid Fahmide boulevard, Hamadan

City
Hamadan

Postal code
009881338380717

Approval date
2017-01-20, 1395/11/01

Ethics committee reference number
IR.UMSHA.REC.1395.529

Health conditions studied

1
Description of health condition studied
stroke

ICD-10 code
G46.4

ICD-10 code description
Cerebellar stroke syndrome

Primary outcomes

1
Description
The anxiety in caregivers of patients with stroke

Timepoint
8 days before and after the intervention.

Method of measurement
Anxiety Inventory (STAI)

Secondary outcomes

1
Description
The satisfaction of caregivers of patients with stroke

Timepoint
8 days before and after the intervention.

Method of measurement
Family caregivers satisfaction

Intervention groups

1
Description
The intervention study was conducted in two phases the first phase information support family caregivers for individual training, oral and face-to-face patient care to the patients and their relatives were tailored to the needs. The second stage consists of two one-hour group training session focused on the overall needs of patients with stroke and their carers group discussion about the problems and concerns as every other day will be held.

The manual includes general information about stroke,
its cause, explanation about the different aspects of treatment, including surgery, adverse events, patient’s diet, the symptoms and how to prevent it, how to deal with disabilities

**Category**

Prevention

**Recruitment centers**

1

**Recruitment center**

Name of recruitment center
Farshchian Educational and Medical Center

Full name of responsible person
Zhaleh Mollaei

Street address
Mirzadeheshghi St. Farshchian Educational and Medical Center

City
Hamadan

**Sponsors / Funding sources**

1

**Sponsor**

Name of organization / entity
Hamadan University of Medical Sciences, Vice chancellor for Research

Full name of responsible person
Saeid Bashirian

Street address
Hamadan University of Medical Sciences, Shahid Fahmide boulevard, Hamadan

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Hamadan

Grant name

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

Title of funding source
Hamadan University of Medical Sciences, Vice chancellor for Research

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
empty

Type of organization providing the funding
empty

**Person responsible for scientific inquiries**

Contact

Name of organization / entity
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Full name of responsible person
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Position
PhD in Nursing

Other areas of specialty/work

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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