

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### 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**

Last update:

Update count: **0**

##### Registration date

2017-04-21, 1396/02/01

##### Registrant information

###### Name

Azim Azizi

###### Name of organization / entity

Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3838 0150

###### Email address

a.azizi@umsha.ac.ir

##### 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

## 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)

### 2

#### Description

satisfaction of information

#### Timepoint

8 days before and after the intervention

#### Method of measurement

satisfaction of information questionnaire

## 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

**City**

Hamadan

**Grant name****Grant code / Reference number****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****Type of organization providing the funding**

*empty*

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

Hamadan University of Medical Sciences

**Full name of responsible person**

Azim Azizi

**Position**

PhD in Nursing

**Other areas of specialty/work****Street address**

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**Web page address**

## **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*