

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The Effect of Home Care Training on Patient Caregivers on Depression and Quality of Life in Stroke Patients at Imam Khomeini Medical Center in Urmia in 2020

Protocol summary

Study aim

Determining the Effect of Home Care Training on Caregivers on Depression and Quality of Life in Stroke Patients at Imam Khomeini Medical Center in Urmia in 2020

Design

Samples will be selected by available sampling method from Imam Khomeini Medical Center of Urmia and then randomly assigned to two equal groups of intervention and control.

Settings and conduct

By referring to medical records of stroke patients, the researcher obtained the contact number and address of all patients who had had a stroke for more than four months and less than two years. In a briefing for caregivers on two consecutive days, the first day for intervention group caregivers and the second day for control group caregivers will explain the goals, stages, and duration of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Ages 18 to 75 years - The patient's willingness to participate in the study - Ischemic stroke based on the patient's document patients who had had a stroke for more than four months and less than two years - Has good cognitive ability (short Cognitive Test score greater than or equal to Exclusion criteria: - Being physically and mentally ill during an acute illness - Recurrence of stroke during the study - Patient death

Intervention groups

The intervention will include home-based care training for caregivers during four 60-minute sessions once a week by the researcher at the patients' home face-to-face, with discussion and discussion between the researcher and the patient's primary caregiver.

Main outcome variables

Depression Scores; Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200316046794N1**

Registration date: **2020-03-27, 1399/01/08**

Registration timing: **prospective**

Last update: **2020-03-27, 1399/01/08**

Update count: **0**

Registration date

2020-03-27, 1399/01/08

Registrant information

Name

sevda zangbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3223 4897

Email address

sevdazangbari2016@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Home Care Training on Patient Caregivers on Depression and Quality of Life in Stroke Patients at Imam Khomeini Medical Center in Urmia in 2020

Public title

The Effect of Home Care Training on Patient Caregivers on Depression and Quality of Life in Stroke Patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who have had a stroke for more than four months and less than two years. Patients who have had a stroke for more than a month and less than a year. Patients who have no affected of orthopedic, neurologic and rheumatologic chronic disease

Exclusion criteria:

Being patient in acute conditions in terms of physical and mental incidence of recurrent stroke during the study
Patient death

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Using simple randomization based on random number table. Patients will be divided into two groups by random number table.

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 Urmia University of Medical Sciences

Street address

Orjhans Street, Resalat Blvd

City

urmia

Province

West Azarbaijan

Postal code

571478334

Approval date

2020-02-29, 1398/12/10

Ethics committee reference number

IR.UMSU.REC.1398.496

Health conditions studied**1****Description of health condition studied**

Cerebral infarction

ICD-10 code

I63.9

ICD-10 code description

A disorder characterized by a sudden loss of sensory function due to an intracranial vascular event.

Primary outcomes**1****Description**

Depression scores in Beck Questionnaire in pre and post-stroke patients between experimental and control groups

Timepoint

Before and after intervention

Method of measurement

Beck Depression Questionnaire and Stroke Specific Quality of Life Questionnaire (SSQOL)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Includes home-based care training for caregivers during four 60-minute sessions once a week by the researcher at the home of patients face-to-face, with discussion and discussion between the researcher and the patient's primary caregiver.

Category

Lifestyle

2**Description**

Control group: No training will be given to prevent depression

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital of Urmia
Full name of responsible person
Nader Aghakhani
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Vice chancellor for research, Urmia University of Medical Sciences

Grant code / Reference number

11915-9999

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

Yes

Title of funding source

Oroumia University of Medical Sciences

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
Oroumia University of Medical Sciences
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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

Use data only for research purposes

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Everyone has access to published data

Under which criteria data/document could be used

Raw statistical data will not be released but statistical analysis will be available

From where data/document is obtainable

Responsible for clinical trial registration

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

It will be possible with the permission of the Ethics Committee and the Research Deputy of Urmia University of Medical Sciences

Comments