

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of virtual training on the quality of life and caregiver burden of stroke patients after discharge

Protocol summary

Study aim

Determining the effect of virtual training on the quality of life and caregiving burden of stroke patients after discharge from Shahid Beheshti Hospital, Kashan.

Design

Clinical trial with control group, randomized, on 60 patients with quadruple block method

Settings and conduct

For the intervention group, a group will be formed in ETA and all caregivers will be added to this group simultaneously. For 3 weeks and on even days of the week, the content of the educational care program, which has been approved by the competent professors, will be shared within the group, and each participant will be encouraged to use the materials at the same time through telephone follow-up. The method of sending different files in the group will be the same on all days and at specific times, and the topics of the files sent each day will be appropriate for the discussion of that day. Each person will be reminded of the need to use the program files and follow up on the programs throughout the day through telephone calls and, if people are online, through messages in ETA.

Participants/Inclusion and exclusion criteria

Failure to respond to calls or messages sent at least twice by caregivers will result in exclusion from the study.

Intervention groups

In this study, educational messages about caring for stroke patients will be sent to caregivers of the intervention group in the form of pictures and educational videos through the social network Ita. The control group only received routine hospital care.

Main outcome variables

Total Caregiver Burden Score for Stroke Patients, Total Quality of Life Score for Stroke Patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181224042096N2**

Registration date: **2024-12-07, 1403/09/17**

Registration timing: **registered_while_recruiting**

Last update: **2024-12-07, 1403/09/17**

Update count: **0**

Registration date

2024-12-07, 1403/09/17

Registrant information

Name

Maryam Heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5520 5997

Email address

maryamheydari779@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-30, 1403/09/10

Expected recruitment end date

2025-03-20, 1403/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of virtual training on the quality of life and caregiver burden of stroke patients after discharge

Public title

The effect of virtual training on the quality of life and caregiving burden of stroke patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Definitive diagnosis of stroke by doctor Being discharged from the hospital Family or informal caregiver Age over 18 years Having at least the ability to read, write and speak Persian No hearing or vision impairment Not taking neurotic drugs Willingness to participate in research Having written informed consent to participate in the research Having a smartphone Having skills in using social networks No history of participating in an educational or research program similar to this study

Exclusion criteria:

Caregiver's unwillingness to continue participating in the research Patient death during research Failure to respond to calls or messages sent at least 2 times Other serious disability concurrent with stroke in patients

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The study subjects will be randomly assigned to two intervention and control groups using a four-way block method. The randomization method will be as follows: first, the intervention group will be coded with the letter A and the control group with the letter B, and then, using the website www.sealedenvelope.com/simple-randomiser/v1/lists, a randomization list will be prepared by selecting a sample size of 60 (two groups of 30) and using a balanced four-way block method. Then, through the obtained randomization list, the subjects entering the study will be assigned to one of the two groups A or B. For example, suppose that in the first four-way block, the permutation method is ABBA, so the first and fourth samples will be assigned to group A and the second and third samples to group B, and so on until the last sample (the 60th person).

Blinding (investigator's opinion)

Single blinded

Blinding description

At the beginning of the study, caregivers were given the necessary explanations regarding how to perform the task, but no explanation was given about which group they would be placed in. At the end of the study,

educational materials were provided to the control group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences

City

Kashan

Province

Isfahan

Postal code

8713783976

Approval date

2024-10-19, 1403/07/28

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1403.146

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

Caregivers of stroke patients

ICD-10 code

I63.9

ICD-10 code description

Cerebral infarction

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

Zarit care burden score and World Health Organization short form quality of life score

Timepoint

Before, after and immediately 6 weeks after the intervention

Method of measurement

Zarit questionnaire is used to check caregiver burden. To check the quality of life questionnaire, the shortened form of the World Health Organization (WHOQOL-Brief) questionnaire is used due to the small number of questions and as a result of convenience.

Secondary outcomes

1

Description

Quality of life score

Timepoint

Before, after and 6 weeks after the intervention

Method of measurement

World Health Organization Quality of Life Short Form Questionnaire

Intervention groups

1

Description

Intervention group: For the intervention group, a group will be formed in ETA and all caregivers will be added to this group at the same time, and for 3 weeks and on even days of the week, the content of the educational care program, which has been approved by the relevant professors, will be shared within the group and from Through telephone follow-up, each participant will be encouraged to use the materials at the same time.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Kashan

Full name of responsible person

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Kilometer 5 of Ravand Road, Shahid Beheshti Hospital, Kashan

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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

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Maryam Heydari

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

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

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

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Person responsible for updating data**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Maryam Heydari

Position

Nurse

Latest degree

Master