Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+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
Isfehan
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
Maryam Heydari
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Kilometer 5 of Ravand Road, Shahid Beheshti Hospital, Kashan
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Sponsors / Funding sources

1

Sponsor
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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
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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