Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of telehealth and in-person discharge education program on adherence of stroke patient and perceived stress of caregivers

Protocol summary

Study aim
Comparing the effect of telehealth and in person education on t adherence in stroke patients and caregivers' perceived stress

Design
The present study is a two-group, parallel, single-blind clinical trial that will be conducted on 70 stroke patients and their family members. Sampling is by block randomization method, where blocks of four are obtained by R software, and after completing all blocks, blocks are randomly selected.

Settings and conduct
The locations are the neurology ward of Loghman and Imam Hussein hospitals. The samples assigned to two groups, receive discharge education face-to-face in a group and remotely and on a platform. The training is provided individually and in groups with family members. Only the analyst is unaware of the assignment of the two groups.

Participants/Inclusion and exclusion criteria
Patient inclusion criteria: Age 18 to 70 years, willingness to participate Aware and trainable No history of receiving thrombolytic drugs Family caregiver inclusion criteria: Primary caregiver (at least twice a week) Literate and able to communicate First experience caring for a stroke patient Patient exclusion criteria: Physical/mental illness affecting quality of life Participation in another educational program Hearing/vision/touch disorders or inability to speak Persian Caregiver exclusion criteria: Previous participation in a similar program Caring for another person Reported mental/neurological disorders Employment in the medical/therapeutic profession

Intervention groups
Intervention group 1: Stroke patients and their families who receive telehealth education during discharge Intervention group 2: Stroke patients and their families who receive face-to-face education during discharge

Main outcome variables
adherence of stroke patient perceived stress of caregivers

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251027067779N1**
Registration date: **2026-06-27, 1405/04/06**
Registration timing: **prospective**

Last update: **2026-06-27, 1405/04/06**
Update count: **0**

Registration date
2026-06-27, 1405/04/06

Registrant information

Name
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Name of organization / entity

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-08-23, 1405/06/01

Expected recruitment end date
2027-01-20, 1405/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of telehealth and in-person discharge education program on adherence of stroke patient and perceived stress of caregivers

Public title
Education program on adherence of stroke patient and perceived stress of caregivers

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Be literate in reading and writing. Be able to communicate Be responsible for the first experience of caring for a stroke patient. Family members as spouses or other adults who are responsible for the patient's care, or who are more involved in the patient's care issues and problems than other family members, or who provide care to the patient at least twice a week and are willing to participate in the study. The age range of people is between 18 and 70 years. Willingness to participate in research Hospitalization in the neurology department of hospitals affiliated with Shahid Beheshti University of Medical Sciences Patient is alert, aware of time, place, and person, and trainable. The patient has not received thrombolytic medication and is hospitalized due to complications from the stroke.

Exclusion criteria:
Having known physical or mental illnesses that affect quality of life, such as dialysis, or other known mental problems, such as depression and schizophrenia, that require medication or a specific diet (according to patient self-report). People who participated in another training program during the research. The caregiver is caring for a patient other than the stroke patient. The caregiver has a known mental or neurological disorder (according to self-report). Take care of members of the medical and healthcare staff.

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Random block sampling will be carried out in two groups: telehealth and face-to-face learning. The random assignment sequence and block list will be obtained by the statistical consultant using R software. The number of people assigned to each group is 35. In this method, the desired blocks of four are formed. Initially, 20 blocks of four are identified and A (face-to-face learning) and B (telehealth group) are determined.The samples are then randomly assigned to groups at consecutive intervals according to blocks selected from 20 prepared blocks. For example, after randomly selecting a block such as the ABAB block, patients are randomly assigned to the face-to-face, telehealth, face-to-face, and telehealth groups. After creating the random sequence, sampling must be done by concealing the created sequence. In such a way that the assigned group for the samples is not known before the individual is assigned. This is done by placing the random sequence inside an envelope and selecting an opaque envelope. At the time of participant registration, based on the order in which the eligible samples enter the study, one of the envelopes is opened in order and the assigned group of that participant is revealed. The code of each patient will also be assigned to his or her family member. Individuals are randomly assigned to the desired group through the randomized blocks in the order in which they enter the study.

Blinding (investigator's opinion)
Single blinded

Blinding description
This research is single-blind due to the nature of the intervention, which is education and is presented in two ways. Both the researcher and the samples know which group they are placed in, and only the data analyst is unaware of the group assignment.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Beheshti Medical Sciences School of Nursing and Midwifery

Street address
Tehran, Vali Asr Street, Ayatollah Hashemi Rafsanjani Highway Intersection, in front of Shahid Rajaee Heart Hospital, Faculty of Nursing and Midwifery

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Approval date
2026-02-17, 1404/11/28

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1404.256

Health conditions studied

1

Description of health condition studied

سکته مغزی ایسکمیک

ICD-10 code

Z55.8

ICD-10 code description

Other problems related to education and literacy

Primary outcomes

1

Description

Treatment adherence of stroke patients

Timepoint

Post-discharge education will be provided in the form of 2-3 30-minute training sessions, in person and online, and data will be collected according to the treatment plan before and eight weeks after the completion of the intervention, and the results will be compared.

Method of measurement

In the study, a comparison of distance and face-to-face education during discharge on treatment adherence of stroke patients will be conducted, and to examine this variable, the Medanlou Treatment Adherence Questionnaire will be used, which includes 40 questions and 7 subscales. The scope of attention in treatment includes 9 questions, willingness to participate in treatment includes 7 questions, ability to adapt treatment to life includes 7 questions, integration of treatment with life includes 5 questions, insistence on treatment includes 4 questions, commitment to treatment includes 5 questions, and measures in implementing treatment includes 3 questions. The measurement scale in this questionnaire is a 6-part Likert scale, which is designed from completely with a score of 5 to not at all with a score of zero, and the minimum score is zero and the maximum is 200.

2

Description

Caregivers' Perceived Stress Questionnaire

Timepoint

Post-discharge education will be provided in the form of 2-3 30-minute training sessions, both in person and online, and data on perceived stress will be collected before and eight weeks after the completion of the intervention, and the results will be compared.

Method of measurement

To assess caregivers' perceived stress, the Perceived Stress Questionnaire was developed by Cohen et al., 1983. This scale has 14 items with a five-point Likert scale, from never to very much, and each item has a value between 0 and 4, with questions such as: During the past month, to what extent have you been upset because of a problem that you did not expect? During the past month, to what extent have you felt that your problems have piled up so much that you cannot cope with them? It measures perceived stress and is a single-component scale. The minimum possible score is 0 and the maximum is 56. A score between 0 and 18: the level of perceived stress is low, a score between 18 and 36: medium, and a score above 36: high.

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: Face-to-face education during discharge for stroke patients and their caregivers. The education program will include three 30- to 40-minute sessions (one individual session and two group sessions including groups of 3 to 5 people) about the definition of stroke, the importance of continuing treatment, the level of adherence to the medication adherence program, and the importance of medications, the problems of stroke patients (special diet plan for patients with swallowing disorders, motor rehabilitation and speech therapy program), principles of preventing recurrence and team structure for treatment (the importance of family presence with the patient and interaction in the educational program, the importance of playing the role of the patient and family in various sessions and the patient's treatment and care plan), and daily care of stroke patients and preventing recurrence, including education on recommendations to prevent recurrence of stroke (anger control, control of stressful stimuli, proper nutrition, medication and care adherence) and education on the causes of recurrence (non-compliance with the medication and care plan, lack of cooperation of the family in the patient's treatment and care process, lack of cooperation of the patient with the treatment staff, and non-compliance with the treatment and medication plans).

Category

Behavior

2

Description

Intervention group: The second intervention group:telehealth education during discharge for stroke patients and their families. Virtual education will be provided through the provision of virtual educational content (offline) in a channel created in one of the internal messaging platforms agreed upon by the patients. The content of the education program will be sent by sending three educational videos or audio files along with PDFs (each video 30 minutes) within a week, at the beginning of the week, three days later, and at the end of the week. In case of any questions or uncertainties, the patient and their companions will be given a phone number to call.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Loghman Hakim Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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Grant name
Research Committee of Shahid Beheshti University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahid Beheshti 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
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Neda Sanaie
Position
Associate professor
Latest degree
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Other areas of specialty/work
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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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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
Participants data file

When the data will become available and for how long
One year after the publication of the article

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Data will be made available upon request for secondary studies.

From where data/document is obtainable
Responsible author of the article nedasanaie@ymail.com

What processes are involved for a request to access data/document
After sending an email to the responsible person and evaluating the type and reason, the requested documents are sent.

Comments