Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of an AI-Augmented Home-Based Palliative Care Education Program on Functional Status and Quality of Life in Stroke Survivors and Their Family Caregivers

Protocol summary

Study aim
Determining the effect of AI augmented home based palliative care education on the quality of life and functional status of patients with ischemic stroke and the quality of life of their family caregivers.

Design
Randomized controlled clinical trial, three parallel groups, pretest and post-test design, no blinding, involving 90 patient and family caregiver and a 1:1:1 allocation ratio. Randomization is performed using fixed blocks of six and implemented using sealed envelopes.

Settings and conduct
Research setting: Participants will be recruited from hospitals affiliated with Tehran University of Medical Sciences. One intervention group will receive home-based palliative care education augmented by an AI chatbot, while the second intervention group will receive home-based palliative care education alone.

Participants/Inclusion and exclusion criteria
Patient inclusion criteria: Age 18 years or older; confirmed ischemic stroke; NIHSS of 5 to 20; discharge home; not ventilated; no coexisting disabling chronic conditions. Family caregiver inclusion criteria: Primary caregiver; first-time experience caring for a person with ischemic stroke; Persian literacy; smartphone and internet access; no self-reported history of mental illness; not a healthcare team member; no uncorrected visual or hearing difficulties. Exclusion criteria: Unwillingness to continue cooperation; patient's acute medical deterioration or hospital readmission; patient death or permanent transfer to a long-term care facility; change in the primary caregiver; receipt of additional home nursing or physiotherapy services.

Intervention groups
Control group: Usual care Test group 1: Home based palliative care education with an AI chatbot Test group 2: Home based palliative care education without an AI chatbot

Main outcome variables
Patients' quality of life; family caregivers' quality of life; patients' functional status

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20261024071545N1**
Registration date: **2026-10-28, 1405/08/06**
Registration timing: **prospective**

Last update: **2026-10-28, 1405/08/06**
Update count: **0**

Registration date
2026-10-28, 1405/08/06

Registrant information

Name
Mobina Momeni Daraby

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2026-12-21, 1405/09/30

Expected recruitment end date
2027-08-21, 1406/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of an AI-Augmented Home-Based Palliative Care Education Program on Functional Status and Quality of Life in Stroke Survivors and Their Family Caregivers

Public title

Effect of an AI-Augmented Home-Based Palliative Care Education Program on Functional Status and Quality of Life in Stroke Survivors and Their Family Caregivers

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria for patients: Age 18 years or older. Inclusion criteria for patients: Confirmed diagnosis of ischemic stroke by a neurologist based on clinical findings and imaging. Inclusion criteria for patients: No coexisting disabling chronic diseases that may affect functional status or quality of life, such as dementia, multiple sclerosis, or chronic kidney disease. Inclusion criteria for patients: Discharge from an acute-care hospital to home. Inclusion criteria for patients: National Institutes of Health Stroke Scale (NIHSS) score of 5–20. Inclusion criteria for patients: Not receiving invasive mechanical ventilation Inclusion criteria for family caregivers: An unpaid family member who is the patient's primary caregiver and provides most of their daily care. Inclusion criteria for family caregivers: First-time experience in caring for a patient with ischemic stroke. Inclusion criteria for family caregivers: Ability to read and write in Persian. Inclusion criteria for family caregivers: No self-reported history of mental illness. Inclusion criteria for family caregivers: Not being a member of the healthcare team. Inclusion criteria for family caregivers: No uncorrected visual or hearing impairments. Inclusion criteria for family caregivers: Access to the internet and ability to use a smartphone.

Exclusion criteria:

Unwillingness to continue cooperation Occurrence of an acute medical condition or hospital readmission. Death of the patient during the study, or permanent transfer of the patient to a care facility, resulting in the termination of the family caregiver's role. Change in the patient's primary caregiver during the study. Receipt of dedicated home nursing or physiotherapy services outside usual care during the study Failure to use the AI chatbot for one week in the AI intervention group Previous or concurrent participation in another similar educational program. Loss to follow-up due to inability to contact the participant. Incomplete questionnaires, defined as completion of fewer than 70% of the questionnaire items.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly allocated to three groups (two intervention groups and one control group) using block randomization with replacement. Blocks of six will be used, with the first intervention group designated as Group A, the second intervention group as Group B, and the control group as Group C. All possible allocation sequences will be written on separate cards, and each card will be assigned a number. The numbers will then be written on separate slips of paper and randomly drawn until the target sample size is reached. Allocation concealment will be ensured using sealed envelopes. Each envelope will contain the letter corresponding to the assigned group according to the predetermined allocation sequence. The envelopes will be sealed by a research team member and provided to the researcher.

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

Research Ethics Committee of School of Nursing and midwifery -Tehran University

Street address

6th floor. Central Headquarters of Tehran University of Medical Sciences, at the corner of Ghods Street, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2026-10-20, 1405/07/28

Ethics committee reference number

IR.TUMS.FNM.REC.1405.134

Health conditions studied

1

Description of health condition studied
Ischemic Stroke
ICD-10 code
I63
ICD-10 code description
Cerebral infarction

Primary outcomes

1

Description
patient quality of life
Timepoint
Before the intervention and after completion of the one-month intervention.
Method of measurement
Stroke-Specific Quality of Life Proxy (SS-QOL Proxy)

Secondary outcomes

1

Description
Functional status of patient
Timepoint
Before the intervention and after completion of the one-month intervention.
Method of measurement
Barthel Index

2

Description
Quality of life of family caregiver
Timepoint
Before the intervention and after completion of the one-month intervention.
Method of measurement
Adult Carer Quality of Life Questionnaire (AC-QoL)

Intervention groups

1

Description
Intervention group 1: The home-based palliative care education program will be delivered individually by the researcher to patients and their family caregivers through six face-to-face sessions over one month. In parallel, family caregivers will have smartphone access to an artificial intelligence-based educational chatbot developed using ChatGPT (OpenAI) and Custom GPT, powered by GPT-5.5 or the latest stable model available at the time of the study. The chatbot will serve as an educational assistant to reinforce face-to-face education and answer questions related to the study-approved educational content, including skin care, mobility exercises, and nutrition. It will not provide independent treatment recommendations or prescribe medications. Before the intervention, caregivers will receive training on how to use the chatbot and understand its limitations. The chatbot's responses will be assessed for accuracy before implementation, and a sample of conversations will be reviewed weekly throughout the study. Usage frequency, number of questions, and interaction duration will be recorded as indicators of adherence to the intervention. Caregivers will be instructed not to enter identifiable patient information into the chatbot. The educational materials will be developed based on scientific literature and clinical guidelines and reviewed by experts and family caregivers for content validity, clarity, and comprehensibility.
Category
Lifestyle

2

Description
Intervention group 2: Participants will receive the same home-based palliative care education program, with identical educational content and six face-to-face sessions delivered by the researcher over one month, without the use of any artificial intelligence tools.
Category
Lifestyle

3

Description
Control group: Participants will receive usual post-discharge care and education throughout the study period. After data collection is completed, the home-based palliative care educational materials will be provided to the control group as an educational package for ethical reasons.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Tehran 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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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
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
All data is potentially shareable after anonymizing individuals.

When the data will become available and for how long
The access period will begin 12 months after the publication of the results.

To whom data/document is available
The data will not only be available to researchers working at academic and scientific institutions, but individuals employed in industry can also apply to access them.

Under which criteria data/document could be used
No other specific condition is required.

From where data/document is obtainable
They should be in contact with the corresponding author at the email address

What processes are involved for a request to access data/document
After the process of eligibility researcher and verification, the request recipient's information will be shared with study collaborators, and the publishable data will be made available.

Comments