

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The Impact of an Early Palliative Care Telehealth Intervention on Caregiver Burden and Quality of Life in Caregivers of Stroke Patients

Protocol summary

Study aim

Determining the effect of early palliative care telehealth intervention on the caregiver burden and quality of life in caregivers of stroke patients

Design

A randomized, parallel-group, controlled clinical trial with 35 caregivers in each group. Randomization process will be performed using the Block Randomization method.

Settings and conduct

Imam Hossein, Shohadaye Tajrish, and Logman-e Hakim hospitals in Tehran city

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Having a first-degree relative with the patient (father, mother, spouse, sister, brother, child) 2) Having responsibility for full-time care and follow-up of the patient's treatment (having the largest share of care) 3) Being literate 4) Having a smart phone Exclusion criteria: 1) Having a confirmed diagnosis of psychological disorders by a psychiatrist 2) People whose patient died during the study 3) People who do not attend two (or more) of the total number of training and follow-up sessions 4) People who have participated in training sessions related to other similar research 5) Incomplete completion of questionnaires

Intervention groups

The intervention group will receive early palliative care training across five virtual 30–40 minute sessions. The sessions cover: 1) palliative care principles for stroke patients; 2) problem-solving and the COPE (creativity, optimism, problem-solving, and specialized information) framework; 3) self-care practices including nutrition, exercise, smoking cessation, relaxation, and help-seeking; 4) management of physical and emotional symptoms, self-assessment, and symptom reporting to guide physician prioritization of palliative care and spiritual concerns; and 5) values elicitation, advance care planning, and decision-making support. The control group will receive standard nurse-delivered hospital training.

Main outcome variables

Caregiver burden; Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240609062065N6**

Registration date: **2026-08-11, 1405/05/20**

Registration timing: **prospective**

Last update: **2026-08-11, 1405/05/20**

Update count: **0**

Registration date

2026-08-11, 1405/05/20

Registrant information

Name

Amir mohamad Nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 916 095 7427

Email address

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-23, 1405/06/01

Expected recruitment end date

2026-11-22, 1405/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Impact of an Early Palliative Care Telehealth Intervention on Caregiver Burden and Quality of Life in Caregivers of Stroke Patients

Public title

The Impact of an Early Palliative Care Telehealth Intervention in Caregivers of Stroke Patients

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a first-degree relative with the patient (father, mother, spouse, sister, brother, child) Having responsibility for full-time care and follow-up of the patient's treatment (having the largest share of care) Being literate Having a smart phone

Exclusion criteria:

Having a confirmed diagnosis of psychological disorders by a psychiatrist People whose patient died during the study People who do not attend two (or more) of the total number of training and follow-up sessions People who have participated in training sessions related to other similar research Incomplete completion of questionnaires

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be selected via convenience sampling and randomly assigned to intervention or control groups using block randomization with a block size of four. The block lists were numbered from 1 to 6, and each patient received a unique identification code. Allocation concealment will be maintained through sealed, opaque, sequentially numbered envelopes.

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 Shahid Beheshti University of Medical Sciences

Street address

Arabi Ave, Daneshjoo Blvd

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2026-06-07, 1405/03/17

Ethics committee reference number

IR.SBMU.RETECH.REC.1405.166

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

Stroke

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

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

Caregiver burden

Timepoint

Before the intervention, immediately after the intervention, and 8 weeks later

Method of measurement

Zarit caregiver burden scale

2**Description**

Quality of life

Timepoint

Before the intervention, immediately after the intervention, and 8 weeks later

Method of measurement

SF-36 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group will receive early palliative care training across five virtual 30–40 minute sessions. The sessions cover: 1) palliative care principles for stroke patients; 2) problem-solving and the COPE (creativity, optimism, problem-solving, and specialized information) framework; 3) self-care practices including nutrition, exercise, smoking cessation, relaxation, and help-seeking; 4) management of physical and emotional symptoms, self-assessment, and symptom reporting to guide physician prioritization of palliative care and spiritual concerns; and 5) values elicitation, advance care planning, and decision-making support.

Category

Other

2

Description

Control group: This group will receive standard nurse-delivered hospital training.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Amir Mohamad Nazari

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Shahid Madani St

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1617763141

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2

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

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Recruitment center

Name of recruitment center

Loghman-e Hakim Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

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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

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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Master's Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Phone**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

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