Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the Effectiveness of Interactive Intelligent Chatbots and Virtual Education in Early Palliative Care for Heart Failure Patients on Expected Outcomes

Protocol summary

Study aim
Comparing the Effectiveness of Interactive Intelligent Chatbots and Virtual Education in Early Palliative Care for Heart Failure Patients on Expected Outcomes

Design
The clinical trial includes a control group, with two parallel intervention groups, randomized, with a sample size of 90 participants, 30 per group. For randomization, the block randomization method is used.

Settings and conduct
The present study After obtaining the necessary approvals, eligible patients will be selected through convenience sampling at the Mahdi Clinic Heart Failure Clinic. Following the provision of explanations and obtaining informed consent, a sample size of 90 participants will be randomly allocated into three groups (two intervention groups and one control group).not blinding

Participants/Inclusion and exclusion criteria
Inclusion Criteria for Patients Informed Consent: Providing informed consent to participate in the study.Age: Individuals aged 18 to 65 years.Heart Failure Stage: Stage B or C heart failure, based on the American College of Cardiology/American Heart Association classification system, confirmed by a heart failure specialist physician. Literacy: Ability to read and write in Persian.Technology Access: Access to the internet and ability to use a mobile phone. Inclusion Criteria for Family Caregivers informed Consent: Providing informed consent to participate in the study.Age: Individuals over 18 years of age.Literacy: Ability to read and write in Persian. -Technology Access: Access to the internet and ability to use a mobile phone.

Intervention groups
Recipient of early palliative care education based on ENABLE through an online platform Recipient of early palliative care education based on ENABLE through an interactive ai chatbot

Main outcome variables
Patient Quality of Life- Mortality- Hospitalization Frequency-Patients' Health Status- Caregiver Outcomes-Technology Acceptance Readiness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250908067182N1**
Registration date: **2025-09-25, 1404/07/03**
Registration timing: **prospective**

Last update: **2025-09-25, 1404/07/03**
Update count: **0**

Registration date
2025-09-25, 1404/07/03

Registrant information

Name
seyed mahdi sharifi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3222 7550

Email address
seyedmahdisharifi80@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-11-01, 1404/08/10

Expected recruitment end date
2027-03-01, 1405/12/10

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the Effectiveness of Interactive Intelligent Chatbots and Virtual Education in Early Palliative Care for Heart Failure Patients on Expected Outcomes

Public title
Comparing the Effectiveness of Interactive Intelligent Chat bots and Virtual Education in Early Palliative Care for Heart Failure Patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
inclusion criteria for patients are as follows:Informed Consent: Providing informed consent to participate in the study.Age: Individuals aged 18 to 65 years.Heart Failure Stage: Stage B or C heart failure, based on the American College of Cardiology/American Heart Association classification system, confirmed by a heart failure specialist physician.Literacy: Ability to read and write in Persian.Technology Access: Access to the internet and ability to use a mobile phone. inclusion criteria for family caregivers are as follows:Informed Consent: Providing informed consent to participate in the study.Age: Individuals over 18 years of age.Literacy: Ability to read and write in Persian.Technology Access: Access to the internet and ability to use a mobile phone.
Exclusion criteria:
Age
From **18 years** old to **65 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
This randomize clinical trial will be divided into three groups (two intervention groups and one control group) using randomized block allocation with replacement. To this end, blocks of six are selected. The first intervention group is designated with the letter A, the second intervention group with the letter B, and the control group with the letter C. All possible combinations are written on separate cards, and each card is assigned a number. These numbers are then written on paper and randomly drawn until the required sample size is achieved. Allocation concealment will be performed using sealed envelopes. Specifically, one of the letters (A, B, or C) is placed inside each envelope according to the predetermined sequence, and then the envelope is sealed by a research collaborator and provided to the investigator.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
Secondary trial Id
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of School of Nursing and midwifery And Rehabilitation- 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
2025-09-08, 1404/06/17
Ethics committee reference number
IR.TUMS.FNM.REC.1404.111

Health conditions studied

1

Description of health condition studied
heart failure
ICD-10 code
I50
ICD-10 code description
Heart failure

Primary outcomes

1

Description
patient quality of life
Timepoint

before and after intervention

Method of measurement

Kansas city Questionnaire

2

Description

Caregiving Outcomes

Timepoint

before and after intervention

Method of measurement

bcos Questionnaire

3

Description

Functional Assessment of Chronic Illness Therapy

Timepoint

before and after intervention

Method of measurement

FACIT PAL-14 Questionnaire

4

Description

Patient Readiness to Engage in Health Information Technology

Timepoint

Before and after intervention

Method of measurement

PRE-HIT Questioner

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The participants will receive online education, and the intervention will be implemented based on the ENABLE model in an online format. Initially, an in-person session will be held with patients and their family caregivers, during which necessary information will be provided regarding their disease, palliative care, and the structure of the intervention program. Afterwards, a six-week early palliative care program will be delivered through weekly webinars via Google Meet or Skyroom. Each session will last between 45 minutes and one hour.

Category

Lifestyle

2

Description

Intervention group: Participants will receive the educational content via a chatbot. The intervention, based on the ENABLE model, will be delivered through an intelligent interactive chatbot. First, an in-person training session will be held for the patient and their family caregiver on how to use the chatbot (installation, login, and interaction). In addition, initial training will be provided on how to use the system, how to ask questions, how to recognize emergency conditions, and an introduction to the applications of the chatbot. A written user guide will also be accessible within the system. The educational content, developed according to the ENABLE model, will be prepared in the form of short text files, simple audio files, infographics, and short videos, and then uploaded to the chatbot's internal platform. The duration of the intervention will be six weeks, similar to the first group. To assess adherence to chatbot use, engaging with the chatbot less than twice per week for two consecutive weeks will be considered a significant reduction in adherence. In such cases, in addition to reminder messages sent by the chatbot to the patient and their family, the researcher will also contact them to inquire about the reason. Furthermore, if interaction is discontinued for more than seven days, it will be regarded as sustained non-engagement, and the participant will be excluded from the study.

Category

Lifestyle

3

Description

Control group: Participants will continue to receive routine care, including all required medical and supportive services, as before, through healthcare centers. After completion of the study, in order to observe ethical considerations, the educational content developed based on the ENABLE model will be provided to them.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

The Imam Khomeini Hospital Complex, mahdi clinic

Full name of responsible person

seyedmahdisharifi

Street address

Imam Khomeini Hospital Complex, Keshvarz Boulevard, Tehran, Iran.

City

tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Phone

+98 21 6693 9009

Email

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Deputy for Research and Technology
Street address
Central Organization of Tehran University of Medical Sciences, 6th floor, Keshvarz Boulevard, corner of Ghods Street.
City
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Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3619
Email
rmo@tums.ac.ir
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
Tehran University of Medical Sciences
Full name of responsible person
seyedmahdi sharifi
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Boys' Dormitory of Medical Sciences, Farshchi Moghaddam, North Kargar Street, Tehran, Iran
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
parvaneh asgari
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
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1419733171
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Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
seyedmahdisharifi
Position
Master’s student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Boys' Dormitory of Medical Sciences, Farshchi Moghaddam, North Kargar Street, Tehran, Iran
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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
Yes - There is a plan to make this available

When the data will become available and for how long
The access period is 12 months after the publication of the article

To whom data/document is available
Researchers employed at reputable institutions with a motivation for improvement.

Under which criteria data/document could be used
Provided that their aim is the treatment and improvement of the condition of patients with heart failure.

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