Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of comprehensive tele-empowerment program on self-care behaviours, uncertainty and readmission in patients with heart failure

Protocol summary

Study aim
Determining the effect of comprehensive tele-empowerment program on self-care behaviors, uncertainty and readmission of heart failure patients

Design
Randomized clinical trial; with control group, parallel groups, without blindness

Settings and conduct
Selecting 96 patients with heart failure referred to Imam Khomeini Hospital in Tehran and dividing them into two groups of control and intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of class II or III heart failure according to the New York Heart Association classification; Diagnosis of heart failure for at least 3 months; Ability to read and write; Access and ability to use smartphones and the Internet; Willingness to participate and complete intervention. Exclusion criteria: Mental and cognitive disorders; Having vision, hearing or speaking deficits; Participation in similar programs; Heart failure exacerbation; Experience of severe psychological distress.

Intervention groups
The control group receives usual care. the intervention group will receive 10 weeks of intervention including 6 weeks of comprehensive tele-empowerment program and 4 weeks of follow-up. Empowerment program will be implemented weekly through the Internet (online and offline) with the following topics: Familiarity with heart failure, clinical manifestations monitoring, diet modification, physical activity improvement, drug management, stress management, spiritual self-awareness and offering religious coping strategies. Simultaneously, patients will join virtual groups on the electronic messaging app and 5 stages of the empowerment program, including 1) needs assessment 2) goal setting 3) structured education 4) self-care plan development 5) evaluation will be repeated each week. Finally, patients will be followed up by telephone and their questions will be answered.

Main outcome variables
Self-care behaviors and uncertainty

General information

Reason for update
The sampling time was updated. Because of more cooperation, the recruitment center was changed to Imam Khomeini Hospital in Tehran.

Acronym

IRCT registration information
IRCT registration number: **IRCT20100725004443N30**
Registration date: **2022-02-25, 1400/12/06**
Registration timing: **prospective**

Last update: **2023-07-13, 1402/04/22**
Update count: **3**

Registration date
2022-02-25, 1400/12/06

Registrant information

Name
Masoumeh Zakerimoghadam

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 2286 2160

Email address
zakerimo@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-19, 1401/11/30

Expected recruitment end date

2023-07-30, 1402/05/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of comprehensive tele-empowerment program on self-care behaviours, uncertainty and readmission in patients with heart failure

Public title

The effect of comprehensive tele-empowerment program on self-care, uncertainty and readmission in patients with heart failure

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Medical diagnosis of class II or III heart failure (according to the New York Heart Association [NYHA] classification) based on the patient's medical record Medical diagnosis of heart failure for at least 3 months Ability to read and write Persian language Access and ability to use smart phones and the Internet Willingness to participate and complete intervention sessions, social media group interactions, and data collection measures

Exclusion criteria:

Diagnosed mental and cognitive disorders documented in the medical record Having vision, hearing, or speaking deficits Participation in or experience of joining similar empowerment programs Heart failure exacerbation reporting experience of severe psychological distress during the study period.

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: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be selected by continuous sampling and the patients will be placed in two groups of control and case by Block Balanced Randomization (BBR). By using the free website http://www.randomization.com/, the assignment sequence will take place. In such a way that the number of subjects in each block will be set to 4, for the control group letter A and for the case group, the letter B will be considered, and finally, by approving the Randomization Sequence in the system for 24 blocks, The assignment sequence will be created for the 96 samples by combining the letters A and B. Finally, the cards containing the blocks will be placed inside the standard envelope, and as a result, allocation concealment will be considered and observed. Based on qualified samples, a Shuffling Envelope will be taken by the researcher accidentally. Finally, the random allocation method will be determined by the research samples.

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 the School of Nursing and Midwifery, Tehran University of Medical Scien

Street address

Room 604, Sixth Floor, Office building of Tehran University of medical Sciences, Intersection of Ghods St., Keshavarz Blvd., Tehran.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2022-02-09, 1400/11/20

Ethics committee reference number

IR.TUMS.FNM.REC.1400.194

Health conditions studied

1

Description of health condition studied

Patients with heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes

1

Description

Self-care behaviors

Timepoint

Before the intervention, immediately after ending the intervention

Method of measurement

Nine-Item European Heart Failure Self-Care Behavior Scale (EHFScBS-9)

2

Description
uncertainty
Timepoint
Before the intervention, immediately after ending the intervention
Method of measurement
Mishel Uncertainty in Illness Scale - Community form (MUIS-C)

Secondary outcomes

1

Description
Number and duration of emergency hospital readmission of patients
Timepoint
Immediately after ending the intervention
Method of measurement
Self-Report of Patients

Intervention groups

1

Description
Control group: These patients do not receive any intervention from the researcher, and after the initial visit by the physician, patients will be provided with routine care in heart failure.
Category
Behavior

2

Description
Intervention group: Patients in the intervention group will receive 10 weeks of intervention, including 6 weeks of comprehensive tele-empowerment program and 4 weeks of follow-up. Initially, patients will join virtual groups of 10 to 15 people, and the empowerment program will be done comprehensively and according to the physical, psychological and spiritual needs of patients; through the Internet and on the electronic massaging platform. Each week, a specific topic will be addressed to promote patients' self-care. Topics will include familiarity with heart failure and clinical manifestations monitoring, diet modification, physical activity improvement, drug management, stress management and relaxation techniques, spiritual self-awareness and religious coping strategies. The content of each session will be available to all patients equally for 6 weeks as a combination of online and offline sessions (3 online sessions and 3 offline sessions).In offline sessions, an e-booklet and/or an instructional video will be sent to virtual groups, and in online sessions, a Skyroom link will be placed in the virtual group to hold online group sessions. Online group meetings with members of groups of 10 to 15 people formed on the social network will be held for 45 to 60 minutes via the Skyroom platform. This empowerment program will include 5 steps entitled 1) Needs Assessment 2) Goal Setting 3) Structured Education 4) Self-Care Plan Development 5) Evaluation which all steps will be repeated by the researcher and through the electronic messaging program for all the mentioned sessions for each week. Finally, over the next four weeks, patients will be followed up by a 10-minute phone call and their questions will be answered.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
Masoumeh Zakerimoghadam
Street address
Imam Khomeini Hospital Complex, Tohid Square, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Email
Imamhospital@tums.ac.ir
Web page address
https://ikhc.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fotouhi
Street address
Keshavarz Blvd., Ghods St., Central Organization of the University, 6th floor of Research and Technology Department
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Tehran
Postal code
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Phone
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Fax
Email

vcr@sina.tums.ac.ir

Web page address

http://vcr.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

Ali Khanipour-Kencha

Position

Master Student of Medical-Surgical Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Nursing and Midwifery School of Tehran University, Easte Nosrat St., Tohid Square, Tehran, Iran

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Province

Tehran

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Phone

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Email

ali.khanipour76@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Masoumeh Zakerimoghadam

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Ali Khanipour-Kencha

Position

Master Student of Medical-Surgical Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The collected deidentified IPD including demographic information, medical history, study outcomes, and other

relevant variables

When the data will become available and for how long

Data will be available 6 months after publication of the study results up to a period of 5 years after the end of the study.

To whom data/document is available

The deidentified IPD and supporting information will be made available to qualified researchers upon reasonable request.

Under which criteria data/document could be used

Access to the data will be granted to qualified researchers and for research purposes only. Researchers must be affiliated with an academic or research institution and provide the approved proposal and evidence of their qualifications, such as a curriculum vitae or publication record. Requests will be reviewed by the corresponding author to ensure that they are consistent with the study's original aims and objectives.

From where data/document is obtainable

To obtain the deidentified IPD, interested researchers should submit a request to the corresponding author by email.

What processes are involved for a request to access data/document

To request access to the deidentified IPD, interested researchers should submit a request to the corresponding author including a detailed research plan that outlines the research question(s) being addressed, the specific data being requested, and the analytic methods to be used. Researchers should also provide the approved proposal and also evidence of their qualifications and data protection plans. Requests will be reviewed by the corresponding author to ensure that they are consistent with the study's original aims and objectives. Upon receipt of a request, the corresponding author will review the request and respond within 10 business days.

Comments