Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of e-health education based on the therapeutic engagement model on the health and behavioral outcomes of patients with heart failure

Protocol summary

Study aim
Determining the effectiveness of e-health education based on the therapeutic engagement model on the health and behavioral outcomes of patients with heart failure

Design
A parallel-group, single-blind, blocked randomization controlled clinical trial on 88 patients

Settings and conduct
This study will be conducted as a randomized clinical trial on 88 heart failure patients over the age of 18 who have completed the informed consent form in Farshchian Cardiovascular Hospital affiliated to Hamedan University of Medical Sciences in Hamedan city. In addition to routine treatment, intervention group patients will also receive e-health education. The study is one-way blind, the data analyst will not know about the division of patients into test and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria include patients who have been diagnosed with heart failure class I to III by a cardiologist; are over 18 years old; literate; willing to participate in the study; have the access to the internet by patient or a family member who lives with; have been diagnosed with heart failure for at least 6 months; and have no psychiatric diseases; and the exclusion criteria include severe emergency conditions; patient's refusal to continue the study; patient's death; and participation in other educational programs.

Intervention groups
Intervention group: despite receiving routine training, patients will receive remote training through the website for three months using a special password; By entering the website, they benefit from its educational content and are followed up by making phone calls and sending and receiving messages. Control group: Patients will receive routine discharge training according to the current hospital program and no additional training.

Main outcome variables
Self-care; health related quality of life; medication adherence; physical activity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240304061168N1**
Registration date: **2024-05-21, 1403/03/01**
Registration timing: **registered_while_recruiting**

Last update: **2024-05-21, 1403/03/01**
Update count: **0**

Registration date
2024-05-21, 1403/03/01

Registrant information

Name
Mohammad Reza Ghorbani

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-21, 1403/03/01

Expected recruitment end date
2024-11-21, 1403/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of e-health education based on the therapeutic engagement model on the health and behavioral outcomes of patients with heart failure

Public title

The effect of e-health education on patients with heart failure

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of heart failure class I to III confirmed by a cardiologist Reading and writing literacy Over 18 years of age Desire to participate in the study Internet access by patient or a family member who lives with patient Absence of psychiatric diseases Having heart failure for at least 6 months

Exclusion criteria:

Having severe emergency conditions Patient refusal to continue the study Patient’s death Participation in other educational programs

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

First, among the patients who meet the inclusion criteria, they will be selected using the available sampling method and based on the random block method, they will be assigned to either the e-health education group based on the therapeutic engagement model (intervention) or the group receiving routine training (control). For this purpose, the researcher will prepare 4 sheets, with the number "1" written on two sheets for the first group and the number "2" written on two sheets for the second group. The cards will be mixed in a container and randomly drawn one at a time for each patient without replacement until all four cards are drawn. Then four sheets will be returned to the container, and this process will be repeated until the calculated sample volume is reached.

Blinding (investigator's opinion)

Single blinded

Blinding description

The statistical analysis and outcome assessment will not know about the assignment of patients to two intervention and control groups during the analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamedan University of Medical Sciences

Street address

Shahid Fahmideh Blvd., Pajouhesh Sq.

City

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Province

Hamadan

Postal code

6517838698

Approval date

2024-05-11, 1403/02/22

Ethics committee reference number

IR.UMSHA.REC.1403.087

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

Timepoint

Before and 3 months after the end of the intervention

Method of measurement

Using the self-care of heart failure index by Riegel et alia: The self-care of heart failure index was designed and compiled by Riegel et alia in 2004 to measure the self-care in heart failure patients. This questionnaire consists of 3 scales with 22 questions, including 10 questions for self-care maintenance, 6 questions for self-care management, and 6 questions for self-care confidence. Each scale is standardized with a possible score from 0 to 100.

Secondary outcomes

1

Description

Medication adherence

Timepoint

Before and 3 months after the end of the intervention

Method of measurement

Using the medication adherence reporting scale by Yan Chen et alia: The medication adherence reporting scale was compiled by Yan Chen et alia in 2019. This questionnaire contains of 5 questions, and the frequency rating of each behavior in this questionnaire is based on a 5-point scale that is graded from never to always. The total score of the scale ranges from 5, which indicates the lowest level of adherence, to 25, which indicates the highest level of adherence.

2

Description

Physical activity

Timepoint

Before and 3 months after the end of the intervention

Method of measurement

Using the rapid assessment of physical activity questionnaire by Topolski et alia: The rapid assessment of physical activity questionnaire was compiled by Topolski et alia in 2006 in order to measure the physical activity. This questionnaire contains of 9 questions designed to evaluate strength, flexibility and level and intensity of physical activity. The total score of the first seven items is from 1 to 7 points, with the respondent's score categorized into one of five levels of physical activity: 1 = sedentary, 2 = underactive, 3 = regular underactive (light activities), 4 = regular underactive, and 5 = regular active. Responses to the strength training and flexibility items are scored separately, with strength training = 1, flexibility = 2, or both = 3.

3

Description

Health related quality of life

Timepoint

Before and 3 months after the end of the intervention

Method of measurement

Using the MacNew Heart Disease health-related quality of life questionnaire by Valenti et alia: The MacNew Heart Disease health-related quality of life questionnaire was designed and compiled by Valenti et alia in 1996. This questionnaire consists of 27 items which fall into three domains [a 13-item physical limitations domain scale, a 14-item emotional function domain scale, and a 13-item social function domain scale]. There are 5 items that inquire about symptoms: angina/chest pain, shortness of breath, fatigue, dizziness, and aching legs. The maximum possible score in any domain is 7 [high HRQL] and the minimum is 1 [poor HRQL].

Intervention groups

1

Description

Intervention group: After introducing the study and stating its objectives, if desired, the patients will complete the informed consent form, the demographic information form, self-care of heart failure index, medication adherence reporting scale, rapid assessment of physical activity, and MacNew questionnaires. In addition to receiving routine training during discharge that is provided in the hospital, patients will benefit from an educational website about heart failure developed by the research team. Participants in the intervention group are given usernames and passwords specific to each of them, and basic training is provided on how to use each of the website's components. The website will be provided to the intervention group for three months and they will benefit from its educational content by using the website. Different sections of the website include educational modules related to understanding heart failure, the causes and complications of this disease, services that can be provided by the relevant doctor or nurse, self-efficacy and self-management training for the patient, lifestyle modification, the section related to caregivers, warning signs and questions that can be exchanged with the doctor, simple language animations for better visual understanding by patients of the condition, interviews with various patients going through different stages of treatment, practical tools for increasing self-efficacy and adherence to treatment including symptoms and events diary, monitoring chart, appointment record, warning signs, and medicine chart as well as a section for patient question and answer. To follow up and motivate the patients in the intervention group, phone calls will be made to them once a week in the first month and once every two weeks in the next two months. Also, patients can ask the researcher through the website whenever they have a question. The study outcomes will be assessed through questionnaires at pre-study and 3 months after the end of the intervention.

Category

Treatment - Other

2

Description

Control group: In this group, patients will enter the study after receiving informed consent and will complete the questionnaires. These people will only undergo routine training during hospital discharge and will not receive e-health education. At the end of the study, the educational content of the website will be provided to this group in the form of a booklet. The study outcomes will be assessed through questionnaires at pre-study and 3 months after the end of the intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Farshchian Cardiovascular Hospital

Full name of responsible person
Mohammad Reza Ghorbani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Mohammad Reza Ghorbani

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
I must provide all information for the sponsoring institution

Study Protocol
No - There is not 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