

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Effect of face-to-face education versus virtual education on self-care and quality of life in patients with heart failure: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of face-to-face education versus virtual education on self-care and quality of life in patients with heart failure

Design

This is a randomized clinical trial with control group, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct

This study will be performed in the Farshchian Heart Hospital in Hamadan city on 80 eligible patients. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 25 to 70 years Heart failure Heart ejection fraction less than 40% Exclusion criteria: Psychological problems Physical disability (hearing or visual)

Intervention groups

Intervention group: Sending recorded self-care training files through WhatsApp for 30 minutes once a day for 8 days, including: explanation of heart function, understanding heart disease and its complications, diet and medication management, sodium and fluid restriction, importance and how to weigh daily, regular exercise, monitoring of signs and symptoms of exacerbation of the disease, non-smoking, social activities, sexual activity, taking medications, following medical instructions and avoiding self-medication. Control group: Face-to-face self-care training for 60 minutes every other day for 8 days including: explanation of heart function, understanding heart disease and its complications, diet and medication management, sodium and fluid restriction, importance and how to weigh daily, regular exercise, monitoring of signs and symptoms of exacerbation of the disease, non-smoking, social activities, sexual activity, taking

medications, following medical instructions and avoiding self-medication.

Main outcome variables

Primary outcome: Self-care, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N430**

Registration date: **2022-06-15, 1401/03/25**

Registration timing: **prospective**

Last update: **2022-06-15, 1401/03/25**

Update count: **0**

Registration date

2022-06-15, 1401/03/25

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-10-25, 1401/08/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of face-to-face education versus virtual education on self-care and quality of life in patients with heart failure: a randomized clinical trial

Public title

Effect of face-to-face education versus virtual education on self-care and quality of life in patients with heart failure

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 25 to 70 years Heart failure Heart ejection fraction less than 40%

Exclusion criteria:

Psychological problems Physical disability (hearing or visual) Having a medical education

Age

From **25 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Sending recorded self-care training files through WhatsApp for 30 minutes once a day for 8 days, including: explanation of heart function, understanding heart disease and its complications, diet and medication management, sodium and fluid restriction, importance and how to weigh daily, regular exercise, monitoring of signs and symptoms of exacerbation of the disease, non-smoking, social activities, sexual activity, taking medications, following medical instructions and avoiding self-medication.

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**

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2022-06-11, 1401/03/21

Ethics committee reference number

IR.UMSHA.REC.1401.224

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**

Evaluation of patients' self-care

Timepoint

Before and 2 months after the intervention

Method of measurement

using Jarasma standard questionnaire

2**Description**

Evaluation of patients' quality of life

Timepoint

Before and 2 months after the intervention

Method of measurement

Using the standard Minnesota questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Sending recorded self-care training files through WhatsApp for 30 minutes once a day for 8 days, including: explanation of heart function, understanding heart disease and its complications, diet and medication management, sodium and fluid restriction, importance and how to weigh daily, regular exercise, monitoring of signs and symptoms of exacerbation of the disease, non-smoking, social activities, sexual activity, taking medications, following medical instructions and avoiding self-medication.

Category

Treatment - Other

2

Description

Control group: Face-to-face self-care training for 60 minutes every other day for 8 days including: explanation of heart function, understanding heart disease and its complications, diet and medication management, sodium and fluid restriction, importance and how to weigh daily, regular exercise, monitoring of signs and symptoms of exacerbation of the disease, non-smoking, social activities, sexual activity, taking medications, following medical instructions and avoiding self-medication.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Heart Hospital in Hamadan city

Full name of responsible person

Mohsen Ahmadi

Street address

Farshchian Heart Hospital, Shahid Fahmideh Ave.

City

Hamadan

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6517838695

Phone

+98 81 3838 1740

Email

pedonconurse69@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

Street address

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info.research@umsha.ac.ir

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

Mohsen Ahmadi

Position

Student of Nursery

Latest degree

Master

Other areas of specialty/work

Nursery

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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Azim Azizi

Position

PhD in Nursery

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

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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