

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of health literacy promotion through virtual education on the self-care of heart failure patients

Protocol summary

Study aim

Determining the impact of health literacy promotion on self-care in patients with heart failure

Design

Randomized clinical trial, control and intervention groups

Settings and conduct

In this study, patients will be divided into two groups of intervention and control, through table of random numbers. For both groups, intervention and control, before and after study, Self-care and demographics questionnaire will be completed. This study will be done in oil and Rajaie hospitals and private clinics of Gachsaran

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age 35 to 75 2. Ability to speak Persian, having reading and writing skills 3. The ejection fraction of less than 45% 4. Satisfaction to participate in the research 5. Access to WhatsApp and the ability to use Cyberspace. Exclusion criteria: 1. Cases of other diseases such as chronic kidney disease, liver cirrhosis and cancers 2. Having a mental illness

Intervention groups

the intervention, will be provided 4section to the intervention group through electronic cyber (software ispring)The control group received only routine training.

Main outcome variables

Self-care

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190311043021N1**

Registration date: **2020-05-02, 1399/02/13**

Registration timing: **retrospective**

Last update: **2020-05-02, 1399/02/13**

Update count: **0**

Registration date

2020-05-02, 1399/02/13

Registrant information

Name

Khadijeh Saberi nejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3233 3728

Email address

khadijeh.saberi428@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-08-22, 1398/05/31

Actual recruitment start date

2019-05-22, 1398/03/01

Actual recruitment end date

2019-09-22, 1398/06/31

Trial completion date

2019-12-06, 1398/09/15

Scientific title

The effect of health literacy promotion through virtual education on the self-care of heart failure patients

Public title

effect of health literacy promotion on heart failure patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age 35 to 75 Cyberspace. Ability to speak Persian,

having reading and writing skills³. The ejection fraction of less than 45% based on the patient's echocardiography Satisfaction to participate in the research Access to WhatsApp and the ability to use

Exclusion criteria:

Cases of other diseases such as chronic kidney disease, liver cirrhosis and cancers Inability to take care of yourself Having a mental illness

Age

From **35 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

Actual sample size reached: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, table of random numbers and an online software (from www.random.org/integers website) will be used to divided patients into two groups of intervention and control.

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

Islamic Azad University - Isfahan (Khorasgan) Branch

Street address

Department of Nursing, School of Medical Science,
Yazd Branch, Islamic Azad University, Gomham
Shohaday Bolvar, Safaey Yazd, Iran

City

yazd

Province

Yazd

Postal code

8915813135

Approval date

2019-05-15, 1398/02/25

Ethics committee reference number

IR.IAU.KHUISF.REC.1398.062

Health conditions studied

1

Description of health condition studied

heart failure

ICD-10 code

I50.9

ICD-10 code description

Heart failure, unspecified

Primary outcomes

1

Description

Self-care

Timepoint

Self-care measurement before intervention and one month after training

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Educational content will be provided for intervention group through electronic cyberspace (ispring software) in four sessions. In first sessions, definition of heart failure, mechanism, reasons and the cause of heart failure symptoms and also under what circumstances should the patient see his or her doctor, will be explained. Second session will contain symptoms, diagnosis, general principles of treatment of heart failure, which contains pharmacological and surgical treatment, non-pharmacological management of heart failure and increasing factors of heart failure Risk. Third session Includes activity and rest in heart failure patients, contact or visiting a doctor and How to control daily weight. In fourth session, diet in heart failure patients, obesity control, smoking, Influenza injection time, will be studied.

Category

Lifestyle

2

Description

Control group will only receive routine training which includes training given by nurses while the patients are admitted in hospitals or when they visit a doctor private clinic.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialty Clinics of Rajaei Hospital and Oil Hospital

Full name of responsible person

Masoumeh Barkhordari sharifabad

Street address

Sharghi 5 jazireh, 12 Beasat, Beasat Bolvar, Dastgah
Pansad, Gachsaran, Iran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Masoumeh Barkhordari Sharifabad

Street address

Department of Nursing, School of Medical Science,
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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

Islamic Azad University

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

Yazd Branch, Islamic Azad University, Yazd, Iran

Full name of responsible person

Masoumeh Barkhordari Sharifabad

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Department of Nursing, School of Medical Science,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is shared after unidentifiable people

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

This data will be of use to medical science researchers for further analysis

From where data/document is obtainable

(Yazd Azad University, School of Nursing)

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

Applicant from the Research Department of the University of Origin Apply to the Research Department of the destination university (Yazd Azad University, School of Nursing)

Comments