

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of an Educational Intervention Based on PRECEDE - PROCEED Model on treatment adherence and readmission rate among Patients with heart failure

Protocol summary

Study aim

Determining the effect of educational intervention based on PRECEDE-PROCEED model on treatment adherence and readmission rate in heart failure patients

Design

A controlled clinical trial with parallel groups, without blinding, 72 patients, randomized, randomization by www.randomization.com

Settings and conduct

The research setting is a cardiac clinic in Dehdasht associated with Yasouj University of Medical Sciences. 72 patients are selected according to the inclusion criteria and after randomisation, 36 people are placed in the intervention group and receive educational intervention; The control group receives routine care.

Participants/Inclusion and exclusion criteria

Inclusion criteria; Patients with heart failure, age over 50 years, history of hospitalization at least once, heart failure of one year and more; Exclusion criteria; Having a psychological illness, Chronic diseases other than hypertension and diabetes

Intervention groups

Intervention group: The educational intervention is designed based on the third phase of the Precede-Proceed Model, educational assessment, among the predisposing, enabling, and reinforcing constructs. Before and after the intervention, a demographic questionnaire, the Madanloo treatment adherence questionnaire, and a researcher-made readmission inventory will be completed. Post-test will be conducted one and three months after training, respectively. The intervention is performed for the experimental group in a month (two sessions per week). Researchers will use PowerPoint slides and educational posters in all sessions. During this time, the intervention group will join a virtual educational channel, and the educational materials will be shared in this channel. Spouse or key person of a

meeting Will receive training. control group; The control group will only receive their usual care.

Main outcome variables

treatment Adherence, Readmission

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200922048806N1**

Registration date: **2021-03-30, 1400/01/10**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-30, 1400/01/10**

Update count: **0**

Registration date

2021-03-30, 1400/01/10

Registrant information

Name

Fereshte Eskandari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3226 5907

Email address

8238fereshte.eskandari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-05, 1399/12/15

Expected recruitment end date

2021-04-04, 1400/01/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of an Educational Intervention Based on PRECEDE – PROCEED Model on treatment adherence and readmission rate among Patients with heart failure

Public title
The effect of an Education on treatment adherence and readmission in Patients with heart failure

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
History of hospitalization at least once Have at least one year of heart failure Have Class II (mild) and III (moderate) heart failure based on the New York Heart Association classification scale and specialist physician approval Age over 50 years Minimum literacy Living with family The ability to use smartphones
Exclusion criteria:
Having psychological illnesses Chronic diseases other than hypertension and diabetes

Age
From **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
A total of 72 samples are selected based on the inclusion criteria and by convenience sampling method, and are allocated to the control and intervention groups using block random allocation method.. Depending on the sample size, 18 blocks of 4 are required for random block allocation. The intervention group will be displayed with A and the control group with B. Samples can be placed in blocks in 6 different modes. The website <https://www.Randomization.com> will be used to determine the random sequence of blocks. In order to allocation concealment from the researcher, 72 dark envelopes were prepared and each of the random sequences created was recorded on a card and placed inside the envelope, and finally the envelope lid was pasted. At the beginning of the registration of individuals, according to the order of arrival of the samples, one of the envelopes is opened in order and the assigned group of that sample is specified.

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 the School of Nursing and Midwifery and the School of Rehabilitation, Tehran Uni

Street address

Tehran University of Medical Sciences., ghods Ave., Keshavarz BLvd., Tehran

City

Tehran

Province

Tehran

Postal code

1417863181

Approval date

2020-09-07, 1399/06/17

Ethics committee reference number

IR.TUMS.FNM.REC.1399.096

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

Score of treatment adherence in madanloo questionnaire

Timepoint

Before study, One month after study and Three month after study

Method of measurement

Madanloo treatment adherence questionnaire

2

Description

Percentage of people with readmission

Timepoint

One month after study and Three month after study

Method of measurement

Researcher-made questionnaire on readmission rate

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The educational intervention is designed based on the third phase of the Precede-Proceed Model, educational assessment, among the predisposing, enabling, and reinforcing constructs. Then, impact evaluation is carried out to examine the immediate effect of the program, including therapy adherence and readmission. Predisposing factors include the knowledge, attitudes, and beliefs of the affected person. Two 60-minute face-to-face sessions will be held to promote patients' awareness. In the first training session, we will discuss the following themes: familiarity of patients with adherence to treatment and medication, their knowledge about the benefits of treatment adherence and how to use medication, the definition of adherence to medication and therapy, and factors affecting these variables, appropriate dietary and lifestyle changes in heart failure according to the existing recommendations, and approaches to control these variables. There will be two 60-minute discussion sessions to assess patients' attitudes and provide the researcher's opinion to the participants. Reinforcing factors in this study include encouragement from the spouse or a family member (a key figure in a person's life). A 60-minute face-to-face meeting will be held with the key person to discuss the family's role in the disease process, encouragement strategies, and methods to motivate the patient. The enabling factors include two 60-minute training sessions to discuss the role of mass media in treatment adherence and the importance of quality of life improvement. Also, the authors will use a virtual social network. Finally, there will be a session to review the issues and resolve the problems and any ambiguities. Researchers will use PowerPoint slides and educational posters in all sessions. The intervention is performed for the experimental group in a month (two sessions per week). During this time, the intervention group will join a virtual educational channel, and the educational materials will be shared in this channel. Before and after the intervention, a demographic questionnaire, the Madanloo treatment adherence questionnaire, and a researcher-made readmission inventory will be completed. Post-test will be conducted one and three months after training, respectively.

Category

Lifestyle

2

Description

Control group: The control group will not receive any intervention and receive routine care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiac clinic in Dehdasht associated with Yasouj University of Medical Sciences

Full name of responsible person

Ali akbar Akbarpoor

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Emam Khomeini Hospital., Sepah Ave., Parastar Blvd., Dehdasht, Yasouj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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

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
Fereshte Eskandari
Position
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Person responsible for updating data

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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

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