

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Investigating the effect of the educational program based on the participatory care model on treatment adherence of patients with heart failure

Protocol summary

Study aim

Determining the effect of the educational program based on the participatory care model on treatment adherence of patients with heart failure

Design

Clinical trial with control group, with parallel groups, double blind, randomized, phase 3 on 100 patients. Random allocation of samples to study groups is performed by block randomization method and by using R statistical software.

Settings and conduct

This double-blind randomized clinical trial study will be conducted on 100 patients with heart failure (in intervention and control group) in the heart failure clinic of Tehran Heart Center. Random allocation of samples is performing by block method and using statistical software. Random allocation of samples is performing by block method and using statistical software. The treatment adherence of patient with heart failure questionnaire will be used to collect data.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age > 18 years, a diagnosis of heart failure class I to III (according to New York Heart Association Classification) approved by the fellowship, history of heart failure for at least 6 months, having at least reading and writing literacy Non-inclusion criteria: Participation in other educational programs

Intervention groups

In intervention group, the patients with heart failure will receive an educational program based on participatory care model, including 4 sessions of participatory educational visits (weekly) and 2 sessions of continuous participatory visits (monthly) by the fellowship and nurse. Educational sessions will be held in groups with a contribution of family caregivers for 45-60 minutes. An educational booklet will be provided to patients. In control group, patients with heart failure will receive

routine clinic care.

Main outcome variables

Treatment adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200910048678N3**

Registration date: **2022-12-25, 1401/10/04**

Registration timing: **prospective**

Last update: **2022-12-25, 1401/10/04**

Update count: **0**

Registration date

2022-12-25, 1401/10/04

Registrant information

Name

seyede fatemeh gheiasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3314 8338

Email address

fatemeh.gheiasi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-31, 1401/10/10

Expected recruitment end date

2023-03-11, 1401/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of the educational program based on the participatory care model on treatment adherence of patients with heart failure

Public title

Investigating the effect of a participatory education program on treatment adherence of patients with heart failure

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Age > 18 years A diagnosis of heart failure class I to III (according to New York Heart Association Classification) approved by the fellowship History of heart failure for at least 6 months Having at least reading and writing literacy

Exclusion criteria:

Participation in other educational programs

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization block method was used in this study. The size of all the blocks was equal and in this trial two groups of 4 blocks (including 2 interventions and 2 control) were formed. A random sequence was created by a statistician using R software and it was provided to the researcher and based on the code assigned to each group (A, B), people were divided into two groups without researcher's interference.

Blinding (investigator's opinion)

Double blinded

Blinding description

The random allocation of samples in two groups was done by the collaborator of the project who had no conflict of interest. The samples were marked with code A and B, and the outcome evaluator and statistician did not know about it.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

School of Nursing and Midwifery & Rehabilitation -
Tehran University of Medical Sciences

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East Nusrat st. Tohid sq

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Postal code

141973317

Approval date

2020-02-12, 1398/11/23

Ethics committee reference number

IR.TUMS.FNM.REC.1398.174

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**

Mean score of treatment adherence

Timepoint

Before and after the intervention

Method of measurement

Treatment adherence of patient with heart failure questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The patients with heart failure will receive an educational program based on participatory care model, including 4 sessions of participatory educational visits (weekly) and 2 sessions of continuous participatory visits (monthly) by the fellowship and

nurse. Educational sessions will be held in groups with a contribution of family caregivers for 45-60 minutes. An educational booklet will be provided to patients.

Category

Lifestyle

2**Description**

Control group:Patients with heart failure will receive routine clinic care.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Heart failure clinic, Tehran heart center

Full name of responsible person

Seyede Fatemeh Gheiasi

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North Kargar, corner of Jalal Al Ahmad highway

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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

Seyede Fatemeh Gheiasi

Position

PhD Candidate in Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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**

Tehran University of Medical Sciences

Full name of responsible person

Seyede Fatemeh Gheiasi

Position

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Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Tehran

Postal code**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

Not applicable

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

Not applicable