Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 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
Street address
East Nusrat st. Tohid sq
City
Tehran
Province
Tehran
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

Street address

North Kargar, corner of Jalal Al Ahmad highway

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1411713138

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fatemeh.gheiasi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Alireza Nikbakht Nasrabadi

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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

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Full name of responsible person

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Associate Professor

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Person responsible for updating data

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Tehran University of Medical Sciences
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Latest degree
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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
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