

# 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

**Street address**

East Nusrat st. Tohid sq

**City**

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**Province**

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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

**Street address**

North Kargar, corner of Jalal Al Ahmad highway

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**Province**

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**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****Contact****Name of organization / entity**

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Elham Navab

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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Tehran University of Medical Sciences

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**Position**

PhD Candidate in Nursing

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

East Nosrat st. Tohid sq

**City**

Tehran

**Province**

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