

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Effect of Caring Program Based on Pender Health Promotion Model on Quality of Life and Self-Care of Patients with Chronic Heart Failure

#### Protocol summary

##### Study aim

Effect of Caring Program Based on Pender Health Promotion Model on Quality of Life and Self-Care of Patients Undergoing Chronic Heart Failure

##### Design

In this study, 48 patients with heart failure referred to cardiac clinics of AJA hospitals were randomly selected and subjected to control and intervention in two groups of 24. And each participant was assigned a code.

##### Settings and conduct

The method of this study was to test the program based on the Pender Health Promotion Pattern and then the impact of this program was evaluated by valid quality of life and self-care questionnaires. While the control group has not implemented any specific and edited program. The place of the study was Aja Hospital (Golestan Patient Heart Clinic).

##### Participants/Inclusion and exclusion criteria

Input criteria: Having congestive heart failure diagnosed by a cardiologist Exit criteria: acute phase of the disease

##### Intervention groups

The intervention group consisted of 24 people whose program was based on Pender Health Promotion Pattern on this group. The control group included 24 people who did not receive any specific program during the study period.

##### Main outcome variables

Improving the health and quality of life of subjects  
Provide a family-centered empowerment model Providing suggestions for hospital nurses and educational planners

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150801023446N17**

Registration date: **2018-01-30, 1396/11/10**

Registration timing: **retrospective**

Last update: **2018-01-30, 1396/11/10**

Update count: **0**

##### Registration date

2018-01-30, 1396/11/10

##### Registrant information

###### Name

Fatemeh Teymouri

###### Name of organization / entity

AJA University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 5588 0283

###### Email address

z.farsi@ajaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Deputy of Research and Technology of AJ University of Medical Sciences

##### Expected recruitment start date

2016-06-21, 1395/04/01

##### Expected recruitment end date

2016-08-22, 1395/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Caring Program Based on Pender Health Promotion Model on Quality of Life and Self-Care of Patients with Chronic Heart Failure

##### Public title

"Effect of Caring Program Based on Pender Health Promotion Model on Quality of Life and Self-Care"

## Purpose

Health service research

## Inclusion/Exclusion criteria

### Inclusion criteria:

Ability to Read and Write Age Range 31 to 51 Years  
Having a known physical disease that affects the quality of life of patients. Having a known mental disease that affects the quality of life of patients. Having congenital Heart Failure with Diagnosis of Cardiologist Ability to Write

### Exclusion criteria:

Absence more than Twice the Intervention Sessions  
Failure to Follow the Training Sessions in the Test Group more than Two Sessions Participate in other Educational Programs Acute Phase of the Disease

## Age

From **31 years** old to **51 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **48**

Actual sample size reached: **48**

## Randomization (investigator's opinion)

Randomized

## Randomization description

patients were first selected using purpose-based sampling. They were then randomly assigned to two intervention and control groups.

## 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

The Research Council and the Research Ethics Committee in the Army University of Medical Sciences

##### Street address

No.1, West Fatemi St., Shahid Etemadzadeh ., Army University of Medical Sciences of the Islamic Republic of Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1645793914

## Approval date

2017-01-19, 1395/10/30

## Ethics committee reference number

IR.AJAUMS.REC.1396017

## Health conditions studied

### 1

#### Description of health condition studied

Congestive heart failure

#### ICD-10 code

I50.4

#### ICD-10 code description

Combined systolic (congestive) and diastolic (congestive) heart failure

## Primary outcomes

### 1

#### Description

Lifestyle Improvement Health

#### Timepoint

Before the intervention - after intervention

#### Method of measurement

questionnaire

### 2

#### Description

Self care

#### Timepoint

Before the intervention - after intervention

#### Method of measurement

questionnaire

### 3

#### Description

Quality of Life

#### Timepoint

Before the intervention - after intervention

#### Method of measurement

questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

"Intervention group:" was conducted in group and individual sessions in the form of conversation and interviews and presentation of personal pamphlets.

#### Category

Lifestyle

## 2

### Description

"Control group:" have not received any intervention.

### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tehran Military Selection Hospitals

##### Full name of responsible person

Masoud Chehri

##### Street address

No.1, West Fatemi St., Shahid Etemadzadeh ., Army University of Medical Sciences of the Islamic Republic of Iran

##### City

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##### Province

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##### Postal code

1645793914

##### Phone

+98 21 8864 4547

##### Email

Biseton67@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Artesh University of Medical Sciences

##### Full name of responsible person

Kamran Azma

##### Street address

AJA University of Medical Sciences, Etemadzadeh St, Fatemi St, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1645793914

##### Phone

+98 21 8864 4547

##### Email

biseton67@yahoo.com

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Artesh 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

Artesh University of Medical Sciences

##### Full name of responsible person

Masoud Chehri

##### Position

Master of Nursing

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

##### Street address

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##### Phone

+98 919 445 6348

##### Fax

##### Email

biseton67@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Artesh University of Medical Sciences

##### Full name of responsible person

Masoud Chehri

##### Position

Master of nursing

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

Masoud Chehri

**Position**

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**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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of Iran**City**

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**Phone**

+98 21 8864 4547

**Fax****Email**

Biseton67@yahoo.com

**Web page address****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**A portion of the data will be available after being  
unidentifiable**When the data will become available and for how long**

Get started 6 months after printing results

**To whom data/document is available**

Students and professors of medical universities

**Under which criteria data/document could be used**There is no other specific condition for obtaining  
information**From where data/document is obtainable**masoud chehri Tel no: 09194456348 biseton  
67@yahoo.com Library of the Army Medical University**What processes are involved for a request to access data/document**Refer to the Library of the Army Medical University and  
receive the necessary information and questionnaires**Comments**

No other specific explanation is required