

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

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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

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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

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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

Latest degree

Bachelor

Other areas of specialty/work

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Fax**Email**

biseton67@yahoo.com

Web page address**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 biseton67@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

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

Artesh University of Medical Sciences

Full name of responsible person

Masoud Chehri

Position

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Latest degree

Master

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