Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of continuous care pattern on self-care behaviors of hospitalized heart failure patients

Protocol summary

Summary

Objectives: The aim of this study is to determine the effect of continuous care model on self-care behaviors in patients with heart failure in the Abbasi hospital of Miyandoab. Design: randomized, single blinded, controlled trial in which patients with heart failure will be included in the study by convenient sampling method and then assigned to the experiment and control groups using random allocation, without placebo. The study is a quasi-experimental clinical trial with pre- and post-test design. The experiment group will receive follow-up based on continuous care model during 3 months of the study period and the control group will received only routine cares. Inclusion criteria: subjects over 30 years with heart failure based on clinical symptoms; ECG and echocardiography; classification in level II and III heart failure based on category system of New York Heart Association; availability for follow up during the study, and informed consent to participate in the study. Exclusion criteria: patients with severe mental or cognitive disorders; patients with a history of working in therapeutic centers; receiving information about self-care of heart failure disease. Intervention: after completing the research forms, the experiment group will be followed-up based on self-care model for three months. Control group will receive the routine care without any education. Then the items related to self-care behaviors will be assessed in both groups by a questionnaire and compared. Main outcome variable: maintenance, management, and assuring of self-care behaviors among patients with heart failure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111930963N1**
Registration date: **2017-02-09, 1395/11/21**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-02-09, 1395/11/21

Registrant information

Name

Khadijeh Aghakarimi

Name of organization / entity

Urmia University of medical sciences, Urmia Faculty of Nursing

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Deputy of Urmia University of Medical Sciences

Expected recruitment start date

2016-03-29, 1395/01/10

Expected recruitment end date

2016-06-14, 1395/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of continuous care pattern on self-care behaviors of hospitalized heart failure patients

Public title

The impact of education on self-care behaviors in patients with heart failure

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: subjects over 30 years with heart failure based on clinical symptoms; ECG and echocardiography which represent ejection deficiency less than 40 percent; classification in level II and III heart failure based on categorization system of New York Heart Association; availability for follow up during the study; informed consent to participate in the study. Exclusion criteria: patients with severe mental or cognitive disorders; patients with a history of working in therapeutic centers; receiving information about self-care of heart failure disease.

Age

From **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

40 red cards and 40 yellow cards will be prepared and put into a bag. Then the patients will be allocated to the intervention group or the control group according to the chosen card

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Urmia University of Medical Sciences

Street address

Ethics Committee of Urmia University of Medical Sciences, Resalat St., Urmia, Iran Urmia

City

Urmia

Postal code

5714783734

Approval date

2016-04-04, 1395/01/16

Ethics committee reference number

Ir.umsu.rec.1395.11

Health conditions studied

1

Description of health condition studied

heart failure

ICD-10 code

150

ICD-10 code description

Heart failure

Primary outcomes

1

Description

Maintenance (keeping) of self-care

Timepoint

Three months

Method of measurement

Specific questionnaire of indicators self-care in patients with heart failure

2

Description

Management of self-care

Timepoint

Three months

Method of measurement

Specific questionnaire of indicators self-care in patients with heart failure

3

Description

Specific questionnaire of indicators self-care in patients with heart failure

Timepoint

Three months

Method of measurement

Specific questionnaire of indicators self-care in patients with heart failure

Secondary outcomes

1

Description

Self-care behaviors

Timepoint

Three months

Method of measurement

Chek list

Intervention groups

1

Description

Experiment group: this group will complete specific questionnaire of self-care indicators. The continuous care

model consisting of 4 stages of orientation,sensitization,implementation and evaluation will be deployed. The first stage will be orientation stage and providing the background the necessary sensitivity. Sessions of 30 to 45 minutes will be attended by the patients and their families. Demographic characteristics as well as specific questionnaire of self-care indicators in patients with heart failure will be completed.

Category

Prevention

2

Description

Control group will receive routine cares without any educational program. After three months, again the items related to self-care behaviors will be assessed by the questionnaire.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Miyandoab Abbassi Hospital

Full name of responsible person

Khadijeh Aghakarimi

Street address

Abbassi hospital, Shohadayeh Garaveran street, Miyandoab, West Azarbijan province, Iran

City

Miyan doab

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Urmia University of Medical Sciences

Full name of responsible person

Rahim Baghaei

Street address

Vice chancellor for research, Urmia University of Medical Sciences, Resalat St., Urmia, Iran Urmia

City

Urmia

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Research Deputy of Urmia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

Khadijeh Aghakarimi

Position

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Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty