

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Investigation of intervention effectiveness based on Health Belief Model on Self-Care Behaviors in Heart Failure Patient

Protocol summary

Study aim

This study examines the effectiveness of intervention based on Health Belief Model on Self-Care Behaviors in patients with Heart Failure in Yasuj.

Design

This study is a Field Trial study that consists of 105 patients with Heart Failure who visit the heart part of Imam Sajjad Hospital and heart clinics in Yasuj. The subjects were randomly divided into intervention and control groups and assigned to each one a code.

Settings and conduct

In this study, The population studied were patients with heart failure in Yasuj. An intervention program tailored to the patients was designed and Trainings were carried out by an experienced trainee and was done with the previous coordination at home. The interval between the training sessions was three days. After two weeks from the last session of the training, the form of evaluation of patients' performance was gathered in form of face-to-face of the patients and data was collected.

Participants/Inclusion and exclusion criteria

Entry conditions 1. Having heart failure that is diagnosed by a cardiologist 2. Resident in Yasuj City 3. Satisfaction for entering the study 4. Ability to communicate effectively with educator Exit Conditions 1. Unwillingness to continue cooperation after entering the study 2. Failure to perform Self-Care skills due to aging or paralysis

Intervention groups

In this study, the Intervention Group included 52 out of 105 Heart Failure Patients that is diagnosed by cardiologist and resident in Yasuj, who Educational Intervention was taken about them.

Main outcome variables

Self-Care Behaviors; Perceived Benefits, Perceived Barriers; Perceived Severity; Perceived Sensitivity; Self-Efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160524028044N2**

Registration date: **2018-02-05, 1396/11/16**

Registration timing: **retrospective**

Last update: **2018-02-05, 1396/11/16**

Update count: **0**

Registration date

2018-02-05, 1396/11/16

Registrant information

Name

hengameh akbari

Name of organization / entity

yasuj university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 917 743 0983

Email address

amlak.akbari@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

vice chancellor for research yasug university of medical sciences

Expected recruitment start date

2016-05-19, 1395/02/30

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Sciences
Scientific title	Street address
Investigation of intervention effectiveness based on Health Belief Model on Self-Care Behaviors in Heart Failure Patient	Motahari Blvd, Yasuj University of Medical Science, Yasuj
Public title	City
Intervention based on Health Belief Model on Self-Care Behaviors in patients with heart failure	Yasuj
Purpose	Province
Health service research	Kohgiluyeh-va-Boyerahmad
Inclusion/Exclusion criteria	Postal code
Inclusion criteria:	7591775114
Having Heart Failure Diagnosed by Plan Consultant Cardiologist Resident in Yasuj City Satisfaction for entering the study Ability to communicate effectively with educator	Approval date
Exclusion criteria:	2016-05-14, 1395/02/25
Unwillingness to continue cooperation after entering the study Failure to perform self-care skills due to aging or paralysis	Ethics committee reference number
Age	IR.yums.REc.1395.32
From 18 years old to 69 years old	
Gender	Health conditions studied
Both	<u>1</u>
Phase	Description of health condition studied
N/A	Heart Failure
Groups that have been masked	ICD-10 code
No information	150
Sample size	ICD-10 code description
Target sample size: 105	omplicating: abortion or ectopic or molar pregnancy (O00-O07, O08.8) obstetric surgery and procedures (O75.4) due to hypertension (I11.0) with renal disease (I13.-) following cardiac surgery or due to presence of card
Randomization (investigator's opinion)	
Randomized	Primary outcomes
Randomization description	<u>1</u>
The type of sampling was selective and the type of assignment was simple random. First, they were enrolled according to the eligibility criteria for a total of 105 patients with heart failure. Then, with a simple random allocation approach allocated in two groups of compared with 53 individuals and intervention group with 52 individuals.	Description
Blinding (investigator's opinion)	Perceived Susceptibility
Not blinded	Timepoint
Blinding description	6 weeks before the intervention and 6weeks after the intervention
Placebo	Method of measurement
Not used	Questionnaire
Assignment	
Factorial	<u>2</u>
Other design features	Description
	Perceived Severity
	Timepoint
	6 weeks before the intervention and 6weeks after the intervention
	Method of measurement
	Questionnaire
Secondary Ids	
empty	<u>3</u>
Ethics committees	Description
<u>1</u>	Perceived Benefits
Ethics committee	Timepoint
Name of ethics committee	6 weeks before the intervention and 6weeks after the intervention
Ethics committee of Yasuj University of Medical	Method of measurement
	Questionnaire

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Description

Perceived Barriers

Timepoint

6 weeks before the intervention and 6weeks after the intervention

Method of measurement

Questionnaire

5

Description

Selfe-Efficacy

Timepoint

6 weeks before the intervention and 6weeks after the intervention

Method of measurement

Questionnaire

6

Description

Selfe -Care Behavior

Timepoint

6 weeks before the intervention and 6weeks after the intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Selfe-Care Behavior

Timepoint

6weeks before the intervention and 6weeks after the intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention Group: Implementation of Educational Intervention by implementing Training Classes in Intervention Group

Category

N/A

2

Description

Control group: No Educational Intervention.

Category

Behavior

Recruitment centers

1

Recruitment center**Name of recruitment center**

CCU Department of Imam Sajjad Hospital

Full name of responsible person

Hengameh Akbari

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Shahid Jalil Ave., Yasuj

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

Vic Chancellor for yasuj university of medical science

Street address

Motahari Blivd vice Chancelloryasuj university of medical science

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Yasuj

Province

Kohgilouyeh-va-Boyerahmad

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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

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Dr Ali Mossavizadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Hengameh Akbari

Position

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Latest degree

Master

Other areas of specialty/work

Health Promotion

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

No - There is not 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

There is no particular explanation.

When the data will become available and for how long

For three years after the publication of the article

To whom data/document is available

Will be available publicly.

Under which criteria data/document could be used

With the written permission of the authors, the data will be usable.

From where data/document is obtainable

Refer to the Responsible Author.

What processes are involved for a request to access data/document

To the address of the Vice-Chancellor of Research, Yasuj University of Medical Sciences, to provide information to

him.

Comments