

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Trial of effect of hospital-based training program to improve self-care behaviors in heart failure patients using the Health Belief Model

Protocol summary

Summary

Objectives: To determine the effects of hospital-based training program on self-care behaviors based on health belief model in patients with heart failure and to offer quality improvement programs for self-care to patients.

Design: At first, a 70-subject sample size was determined for the study. However, considering a 20% loss rate, the sample size was increased to 84 subjects (42 in each group). **Setting and conduct:** In order to prevent information exchange between the patients during the intervention, randomization was done based on hospitals rather than individuals (The hospitals were selected using sealed envelopes). The patients were assessed regarding the inclusion and exclusion criteria and were entered into the study after signing written informed consents. **Inclusion criteria:** suffering from heart failure, being literate, and being able to communicate. **Exclusion criteria:** having underlying diseases such as chronic kidney disease and diabetes, being educated in medical sciences, withdrawal from the study due to personal reasons, and failure to participate in training sessions (over 2 sessions) or exams. **Intervention:** The patients participated in four 15-30-minute training sessions. In the first two sessions, the concept, importance, and method of self-care behaviors were taught. The patients were also provided with leaflets and videos. The subsequent sessions were held in form of question and answer. The study questionnaire was completed in three steps (before the intervention and 2 weeks and 2 months after discharge). **Main outcome measures:** To compare the mean scores of the health belief model structures (knowledge, perceived susceptibility, perceived severity, perceived barriers, perceived benefits, cues to action, self-efficacy, and behavior) between the two groups before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506136261N11**

Registration date: **2015-11-04, 1394/08/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-11-04, 1394/08/13

Registrant information

Name

Mohammad Hussein Kaveh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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kaveh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-08-06, 1394/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Trial of effect of hospital-based training program to improve self-care behaviors in heart failure patients

using the Health Belief Model

Public title

The impact of hospital-based training to improve the treatment of patients with heart failure

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with heart failure who are literate and able to communicate. Exclusion criteria: underlying disease includes chronic kidney disease or diabetes, a degree in medical science, Exclusion of study due to personal reasons or failure to participate in training sessions (over 2 sessions) or exams.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 94

Randomization (investigator's opinion)

Randomized

Randomization description

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

Ethics Committee of Shiraz University of Medical Sciences

Street address

Research Ethics Committee of the Department of Shiraz University of Medical Sciences, 7 floor, Shiraz University of Medical Sciences, Karim Khan Zand Blvd, Shiraz, Iran

City

Shiraz

Postal code

7134814336

Approval date

2015-04-19, 1394/01/30

Ethics committee reference number

IR.SUMS.REC.1394.17

Health conditions studied

1

Description of health condition studied

heart failure

ICD-10 code

I50

ICD-10 code description

Excl.:complicating:•abortion or ectopic or molar pregnancy (O00-O07, O08.8)

2

Description of health condition studied

congestive heart failure

ICD-10 code

I50.0

ICD-10 code description

Congestive heart failure;Congestive heart disease;Right ventricular failure (secondary to left heart failure)

3

Description of health condition studied

Left ventricular failure

ICD-10 code

I50.1

ICD-10 code description

Cardiac asthma;Left heart failure;Oedema of lung;Pulmonary oedema(with mention of heart disease NOS or heart failure)

4

Description of health condition studied

Heart failure, unspecified

ICD-10 code

I50.9

ICD-10 code description

Cardiac, heart or myocardial failure NOS

Primary outcomes

1

Description

Knowledge

Timepoint

Before the intervention, two weeks and two months after the first intervention

Method of measurement

European Heart Failure Self-care Behaviour questionnaire

2

Description

Perceived susceptibility

Timepoint

Before the intervention, two weeks and two months after the first intervention

Method of measurement

European Heart Failure Self-care Behaviour questionnaire

3

Description

Perceived barriers

Timepoint

Before the intervention, two weeks and two months after the first intervention

Method of measurement

European Heart Failure Self-care Behaviour questionnaire

4

Description

Perceived benefits

Timepoint

Before the intervention, two weeks and two months after the first intervention

Method of measurement

European Heart Failure Self-care Behaviour questionnaire

5

Description

Perceived severity

Timepoint

Before the intervention, two weeks and two months after the first intervention

Method of measurement

European Heart Failure Self-care Behaviour questionnaire

6

Description

Efficacy

Timepoint

Before the intervention, two weeks and two months after the first intervention

Method of measurement

European Heart Failure Self-care Behaviour questionnaire

7

Description

cues to action

Timepoint

Before the intervention, two weeks and two months after the first intervention

Method of measurement

European Heart Failure Self-care Behaviour questionnaire

8

Description

behavior

Timepoint

Before the intervention, two weeks and two months after the first intervention

Method of measurement

European Heart Failure Self-care Behaviour questionnaire

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Due to ethical considerations regarding the control group to obtain his address, educational booklets and CD with phone and e-mail address to respond to their questions, they will be available after completion of the study.

Category

N/A

2

Description

Educational interventions with scientific content approved by professors are conducted in four sessions. The first session held on admission includes providing the patients with a brief introduction about the study objectives and their conditions, collecting information about their training needs, providing educational pamphlets, and face-to-face training for 10 minutes. The second session held during discharge includes their familiarization with self-care behaviors through face-to-face training for 20 minutes and presentation of educational clips in form of CD. The third session held two weeks after discharge includes questions about performance of the intended behaviors at home, responding to the patients' questions by meeting them in the clinic (considering the physicians' visit), and collecting information. Finally, the last training session held at the end of the fifth and sixth weeks after discharge (considering the physicians' next visit) includes review of the previously learnt issues, question and answer, and problem solving. The patients will be reminded to attend the meeting through making phone calls and sending SMS. This session will be held for groups of 7 to 10 subjects for one hour. The third stage of data collection will be carried out within the ninth and tenth weeks after discharge (considering the physicians' next visit in the clinic).

Category

Behavior

Recruitment centers

1

Recruitment center**Name of recruitment center**

Hospital Martyr Doctor Faghihi

Full name of responsible person

Zakieh Khoramaki

Street address

Hospital Martyr Doctor Faghihi, Zand Blvd, Shiraz,
Iran

City

Shiraz

2**Recruitment center****Name of recruitment center**

Namazi Hospital

Full name of responsible person

Zakieh Khoramaki

Street address

Hospital Namazi, Zand Blvd, Shiraz, Iran.

City

Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Shiraz University of
Medical Sciences

Full name of responsible person

Vice Chancellor for research of Shiraz University of
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Street address

Vice Chancellor for research of Shiraz University of
Medical Sciences, 7 Floor, Shiraz, Iran

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for research of Shiraz 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**

School of Public Health

Full name of responsible person

Dr mohammad Hosein Kaveh

Position

Associate Professor

Other areas of specialty/work**Street address**

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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