

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The effect of preventive behavioral training with Haddon's strategy on self-care behavior and the consequences of disease in heart failure patients.

Protocol summary

Study aim

Determining the effect of preventive behavioral training on Haddon's strategy on self-care behavior and the consequences of disease in heart failure patients

Design

A randomized clinical trial with a control group, with two parallel groups

Settings and conduct

The present study will be a randomized clinical trial involving 96 patients with heart failure admitted to Farshchian hospital in Hamadan. Patients will be randomly divided into experimental and control groups. In the experimental group, the researcher will present the Haddon's strategy Training in three sessions of group training for 60 minutes. Haddon's strategy is to educate self-care behavior to reduce risk factors and complications of the disease. The first session will provide an overview of the nature and causes of the disease and warning signs. In the second session, the focus will be on the training of the diet and medication. The third session will focus on teaching balance between activity and rest, daily weighing and monitoring of symptoms of exacerbation, stress control and urinary output.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having literacy of reading and writing, Diagnosis of heart failure confirmed by a cardiologist, Patients over the age of 18 years
Exclusion criteria: Unwilling to continue participating in the study, Failure to attend more than two training sessions

Intervention groups

In the intervention group, the researcher will deliver the Haddon's strategy Training in three sessions for 60 minutes. Haddon's strategy is to educate self-care behavior to reduce risk factors, severity and complications of the disease (shortness of breath, lower extremity edema, rest and activity disorder, chest pain,

memory impairment and alertness and judgment) and rehabilitation. The control group will receive only routine training.

Main outcome variables

Self-care, complications of the disease

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160110025929N26**

Registration date: **2019-08-02, 1398/05/11**

Registration timing: **prospective**

Last update: **2019-08-02, 1398/05/11**

Update count: **0**

Registration date

2019-08-02, 1398/05/11

Registrant information

Name

Mehdi Molavi Vardanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3422 5056

Email address

m.molavi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-22, 1398/05/31

Expected recruitment end date

2020-08-21, 1399/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of preventive behavioral training with Haddon's strategy on self-care behavior and the consequences of disease in heart failure patients.

Public title

effect of preventive behavioral training with Haddon's strategy on self-care behavior and the consequences of disease

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients over the age of 18 years
Diagnosis of heart failure confirmed by a cardiologist
Having literacy of reading and writing

Exclusion criteria:

Failure to attend more than two training sessions
Unwilling to continue participating in the study

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **96****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization will be performed using 6-point
permutational block method by computer software

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 Hamadan University of Medical
Sciences

Street address

Shahid Fahmideh St., Hamadan University of Medical
Sciences, Hamadan

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Approval date

2019-07-20, 1398/04/29

Ethics committee reference number

IR.umsha.REC.1398.339

Health conditions studied**1****Description of health condition studied**

Heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes**1****Description**

Complications of the disease

Timepoint

Before and after educational intervention

Method of measurement

Complications checklist

Secondary outcomes**1****Description**

Self-care

Timepoint

Before and after educational intervention

Method of measurement

Self-Care of Heart Failure patients Index

Intervention groups**1****Description**

Intervention group: In the intervention group, the researcher will present the Haddon's strategy Training in three sessions for 60 minutes . Haddon's strategy is to educate self-care behavior to reduce risk factors and complications of the disease. The first session will provide an overview of the nature and causes of the disease and warning signs. In the second session, the focus will be on the training of the diet and medication. The third session will focus on teaching

balance between activity and rest, daily weighing and monitoring of symptoms of exacerbation, stress control and urinary output.

Category

N/A

2

Description

Control group: Patients in the control group will receive only routine care and training.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Arezoo Karampourian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

No

Title of funding source

Deputy of research and technology

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

Hamedan University of Medical Sciences

Full name of responsible person

Arezoo Karampourian

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health in Emergency and Disaster

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Arezoo Karampourian

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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

Hamedan University of Medical Sciences

Full name of responsible person

Afsaneh Hoseini

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

City

Hamadan

Province

Hamadan

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available