Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 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

Detemining 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 Hadon's strategy Training in three sessions of group training for 60 minutes . Hadon'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 Hadon's strategy Training in three sessions for 60 minutes. Hadon'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
Age
From **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 Hadon's strategy Training in three sessions for 60 minutes . Hadon'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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Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

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

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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

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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
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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