

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Roy's Adaptation Model-Based Patient Education on The Quality of Life of Patients with Heart Failure

Protocol summary

Summary

This single-blind clinical study aims to determine the effect of adaptation-based educational program on heart failure patients' quality of life. Research subjects will be selected using purposive sampling technique based on inclusion criteria. They will be divided blocked randomly into two groups. Inclusion criteria include: diagnosis of class I, II, III heart failure by a physician, according to the American Heart Association and clinical and laboratory evidence, at least 6 months before the study; ejection fraction of 40% or below; no mental disorder; normal hearing, vision and mental capabilities that allow making communication; age range from 18 to 65 years; no contraction of other chronic diseases such as kidney or liver failure, chronic pulmonary obstructive diseases, neural and motor disorders, except diabetes; having access to patients for follow-up controls; walking capability; and not receiving the same training in other centers. Exclusion criteria include: unwillingness to participate for any reason; moving from the research region during the study; and more than two times absence from training sessions. In this study, 38 cardiac patients will receive group training intervention based on the Roy's Adaptation Model for one month And since the beginning of the intervention period up to one month after a group training, individual training on the telephone and physically will receive based maladaptive behaviors; in addition, another 38 patients will receive routine training. One month after the intervention, the quality of life of both groups will be measured based on the Roy's inventory and Minnesota's questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010625880N1**

Registration date: **2016-05-12, 1395/02/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-12, 1395/02/23

Registrant information

Name

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Name of organization / entity

Ahvaz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Ahvaz University of Medical Sciences

Expected recruitment start date

2015-12-19, 1394/09/28

Expected recruitment end date

2016-01-10, 1394/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Roy's Adaptation Model-Based Patient Education on The Quality of Life of Patients with Heart Failure

Public title

The Effect of Education on Quality of Life in Patients With Heart Failure

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria are: diagnosis of class I, II, III heart failure by a physician, according to the American Heart Association and clinical and laboratory evidence, at least 6 months before the study; ejection fraction of 40% or below; no mental disorder; normal hearing, vision and mental capabilities that allow making communication; age range from 18 to 65 years; no contraction of other chronic diseases such as kidney or liver failure, chronic pulmonary obstructive diseases, and neural and motor disorders, except diabetes; having access to patients for follow-up controls; walking capability; and not receiving the same training in other centers. Exclusion criteria include: unwillingness to participate for any reason; moving from the research region during the study; and more than two times absence from training sessions.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaze University of Medical Sciences

Street address

Ahvaze University of Medical Sciences, Gholestan Square, Ahvaze, Khuzestan, Iran

City

Ahvaze

Postal code

00986133361983

Approval date

2015-12-19, 1394/09/28

Ethics committee reference number

IR.AJUMS.REC.1394.504

Health conditions studied

1

Description of health condition studied

Heart Failure

ICD-10 code

I50.20150,

ICD-10 code description

Chronic Systolic (Congestive) Heart Failure

Primary outcomes

1

Description

Quality of Life

Timepoint

Before Intervention and one Month After Intervention

Method of measurement

Minnesota Questionnaire, Roy Questionnaire

Secondary outcomes

1

Description

Adaptation

Timepoint

before intervention and one month after intervention

Method of measurement

Roy Questionnaire

Intervention groups

1

Description

Control Group Did not Receive Behavioral Intervention and Receive only Treatment Routine Care.

Category

Behavior

2

Description

Type of Intervention Is Behavioral, In addition to routine medical cares, the intervention group will receive weekly 45-minute sessions of Roy's Adaptation Model-based training for one month. This group will also receive a follow-up procedure through phone contact, during which the positive behaviors of the patients will be encouraged and strengthened by stating the advantages of such behaviors; whereas, their negative behaviors will be undermined by mentioning their complications and disadvantages. The intervention group will also receive telephone and physically individual consultation. The educational content will be gathered and developed based on nursing and medical literature review. Presentation of educational content during the 4 sessions will be as follows: • The first session: definition of heart

failure, signs and symptoms of the disease, how to perform exercise and physical activities. • The second session: diet and fluid intake, tobacco use, alcohol consumption, daily weighing and its interpretation. • The third session: training in medications, their complications, and how to adjust drug dosing. • The fourth session: Management of and adaptation to symptoms, sexual problems, and stresses. If patients need more help to shape adaptation behaviors, they will be referred to other treatment team members based on the type of behavior and its stimulator (e.g. referral to a specialized physician for drug dosing adjustment). The researcher will provide patients with continuous follow-ups from the beginning of the intervention onward. In fact, these telephone follow-ups and the time spent on visiting patients physically and individually, will create a sense of support in them, which is associated with psychologically positive effect. During the whole program, patients will be encouraged to have one companion in training sessions. A handout, entitled

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized Therapy Clinics of Shushtar

Full name of responsible person

Mohsen Jmali

Street address

Khatamolanbia Hospital, Farhang High way, Shoushtar, Khuzestan, Iran

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Shoushtar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaze University of Medical Sciences

Full name of responsible person

Mr Shahram Baraz

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Ahvaze University of Medical Sciences, Gholstan Highway, Ahvaze, Khuzestan, Iran

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Ahvaze

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaze 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

Doctor Shahram Baraz

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Assistant Professor

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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