Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

The effect of lifestyle modification on the readmission of patients with heart failure

Protocol summary

Study aim
Determining the effect of lifestyle modification on the readmission of patients with heart failure

Design
Clinical trial with control group, with parallel groups,Two blind, randomized, with a sample size of 174.

Settings and conduct
The lifestyle modification program in the Intervention group starts at the time of admitting the patient at Torbat Heydarieh Hospital. During the period of admission, nutrition education, medical education, education for light stomatal improvement, etc. are given. Training is provided by the nurse and with the help of a pamphlet, a drug booklet, and so on. Trainings are performed after telephone service and continue until 12 weeks after discharge.

Participants/Inclusion and exclusion criteria
"Inclusion criteria" 1- age 18 to 90 year old 2-patient access to the telephone 3-No known psychological illness 4-patient and none of his family members have medical education and related fields 5-Have full satisfaction to cooperate 6-known patients in class 2 and 3 of heart failure. "Exclusion criteria" 1'-Unwillingness to participate in study

Intervention groups
"Intervention group" The lifestyle modification program in the Intervention group starts from the time of admission and continues until 12 weeks after discharge from the hospital. Each patient in the Intervention group will be required to undergo a visit at least two times according to the need for training. After discharge, the researcher will contact the patients in the Intervention group every two weeks for 12 weeks and will examine the patient's progress and achieve goals and adherence to the curriculum. The first telephone call is made by the researcher within the first 24 hours after discharge. "control group" Except for the usual self-care education that all patients receive, no further action will be taken

Main outcome variables
Blood Pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180727040610N1**
Registration date: **2019-01-02, 1397/10/12**
Registration timing: **retrospective**

Last update: **2019-01-02, 1397/10/12**
Update count: **0**

Registration date
2019-01-02, 1397/10/12

Registrant information

Name
Tahere Sarboozi Hosein Abadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 5414 3311

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sarboozit1@thums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-11-11, 1396/08/20

Expected recruitment end date
2018-11-11, 1397/08/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of lifestyle modification on the readmission of patients with heart failure

Public title
Lifestyle modification and readmission of patients with heart failure

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age 90-18 years The patient has access to the telephone Not known to have a known psychological illness The patient and none of his family have medical education and related disciplines Complete satisfaction for cooperation Have at least reading and writing skills

Exclusion criteria:
Do not want to participate in research.

Age
From **18 years** old to **90 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **174**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization: Simple randomization, using 174-bit Random Excel software with Excel, is generated sequentially with A and B bursts. The reader now has a patient range of 1 to 174, depending on whether he is in either of the A or B grades, in either of these two groups of patients.

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 Torbat Heydarieh University of Medical Sciences

Street address
THUMS Building., Razi St., Ferdawsi St.

City
Torbat Heydarieh

Province
Razavi Khorasan

Postal code
95196-33787

Approval date
2016-07-17, 1395/04/27

Ethics committee reference number
IR.THUMS.REC.1395.27

Health conditions studied

1

Description of health condition studied
Heart failure

ICD-10 code
I50.2

ICD-10 code description
Systolic (congestive) heart failure

Primary outcomes

1

Description
Blood Pressure

Timepoint
Blood Pressure will be measured once before the first intervention and once after the last intervention session.

Method of measurement
Mercury pressure gauge device

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group: The lifestyle modification program in the Intervention group starts from the time of admission and continues until 12 weeks after discharge from the hospital. Each patient in the Intervention group will be required to undergo a pre-discharge test at least two times (within 24 hours) according to the need for training. After discharge, the researcher will contact the patients in the Intervention group every two weeks for 12 weeks and will examine the patient's progress and achieve goals and adherence to the curriculum. The first telephone call is made by the researcher within the first 24 hours after discharge. Each phone call will be divided into two parts: the first part will include routine recommendations regarding the care required in patients with heart failure, and the second part will be determined based on the specific needs and underlying illnesses of the patient. During the call, patients will be encouraged and supported in relation to the individual risk reduction plan, including exercise, diet, smoking

cessation and adherence to drugs. The last phone call for each individual patient will be established in the 12th week after the discharge, during which, in addition to the counseling, coordination will be required for the last appointment. The patients will have a total of 3 face-to-face meetings (2 sessions at the beginning of the study and 1 The end of the study) and five sessions of telephone training will be held every two weeks with the researcher.

Category
Lifestyle

2

Description
control group: Except for the usual self-care education that all patients receive, no further action will be taken.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Nohome day Hospital, Torbat Heydarieh University of Medical Sciences

Full name of responsible person
Tahereh Sarbuzi Hossein Abadi

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THUMS Building., Razi St., Ferdawsi St.

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DeyHospital@thums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Torbate-Heidaria University of Medical Sciences

Full name of responsible person
Dr Hasann Azhdari Zarmehri

Street address
THUMS Building., Razi St., Ferdawsi St.

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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
Torbate-Heidaria 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
Torbate-Heidaria University of Medical Sciences

Full name of responsible person
Tahereh Sarbuzi Hossein Abadi

Position
Member of the faculty of Torbat Heydarieh University of Medical Sciences

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Latest degree
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Other areas of specialty/work

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Person responsible for updating data

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Master

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is 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
Information about the main consequence after being unidentified will be shared.

When the data will become available and for how long
Start the access period 6 months after Publish results

To whom data/document is available
Everyone

Under which criteria data/document could be used
The results obtained in this study can be used without restriction by researchers.

From where data/document is obtainable
Referring to Torbat Heidarieh Nursing and Midwifery Faculty

What processes are involved for a request to access data/document
After sending the email to the person responsible for the response process begins.

Comments