Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Nov 2026

The effect of Balance Training on Cognitive Function and Activity of Daily Living of Elderly People with Heart Failure

Protocol summary

Study aim

Determining the effect of balance exercises on cognitive function and activity daily living in elderly patients with heart failure

Design

Two arm parallel group clinical trial, double blinded and block randomization

Settings and conduct

The intervention will have the effect of balance exercises for eight weeks (60 days). And the blindness will be blind in two ways. The place of study is in Khorramabad and it is in the specialized clinics of Shahid Rahimi Hospital and Shahid Madani Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria including: 1) Male and female patients 60 to 75 years old and residents of Khorramabad 2) Patients with heart failure Class II and III 3) Independent mobility 4) Balance impairment (full tandem standing test < 10 seconds) 5) Having Cognitive dysfunction (based on the MMSE test) 6) Get a score less than 14 based on (IADL) scale 7) No visual or auditory impairment 8) Able to understand and complete questionnaires in Persian 9) Willingness to participate in a 2-month balance training program Exclusion criteria including: 1) Threatening cardiovascular events such as dangerous arrhythmias 2) Unstable hemodynamic status 3) Acute cerebral vascular stroke 4) Participate in other sports and rehabilitation programs such as yoga

Intervention groups

Balance exercises for 60 days are taught to 44 patients in the intervention group. Each balance exercise is repeated and lasts about 3-5 minutes, and the total duration of each daily training session is 30 minutes and four. Times will be weekly for eight weeks. One session per week is supervised by a nurse. Control group,receive only routine care.

Main outcome variables

Cognitive function score based on the Montreal test and activity daily living based on Bartel and Lawton scales

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150919024080N18**
Registration date: **2020-10-12, 1399/07/21**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-12, 1399/07/21**
Update count: **0**

Registration date

2020-10-12, 1399/07/21

Registrant information

Name

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Name of organization / entity

Lorestan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of Balance Training on Cognitive Function and Activity of Daily Living of Elderly People with Heart Failure

Public title
The effect of balance training on the cognition and daily living of the elderly with heart failure

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Class 2 and 3 heart failure based on the diagnosis of the treating physician and the functional class criteria of the New York Heart Association Ability to walk independently and without the use of moving aids (canes and walkers) indoors and outdoors balance impairment (based on the complete tandem standing test in less than 10 seconds) Cognitive dysfunction score below 26 (based on the Montreal Cognitive Functional Disorder Questionnaire) Having a dysfunction in daily activities Gaining a score of 14 from the Barthel questionnaire Ability to make phone calls Lack of restrictive exercises such as visual and auditory impairment Having at least literacy and the ability to understand Persian

Exclusion criteria:
Diabetes mellitus and history of hypoglycemic and hyperglycemic attacks Diabetic nephropathy and retinopathy, hypertensive crises History of acute stroke Dementia Peripheral arterial disease End-stage heart failure requires advanced treatment Acute arthropathy or musculoskeletal disorders Participate in other sports programs

Age
From **60 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
After basic evaluations such as cardiovascular function evaluation tests by a cardiologist, patients are admitted to the study according to the inclusion and exclusion criteria, then by block randomization (Block Randomization) in two groups of treatment and control in a balanced way. Randomization is done using a random number table. In this sampling method, the classes will be based on the New York Heart Association functional class variables and literacy level. Patients will also be matched for age and gender. The sample size is calculated based on the change in the average daily activity or cognitive function of 88 patients with heart failure, of which 44 patients will be in the intervention group and 44 patients in the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Studying on both sides will be blind. Patients are unaware that they are in the control or intervention group and are unaware of the research hypothesis. Data collection is done with the help of a researcher who is unaware of the random allocation of groups. Data analysis is also performed by a researcher who is unaware of the random allocation of groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Lorestan University of Medical Sciences

Street address
Lorestan University of Medical Sciences, Lorestan, Khorram Abad, 5 Km.

City
Khorramabad

Province
Lorestan

Postal code
381351698

Approval date
2020-06-07, 1399/03/18

Ethics committee reference number
IR.LUMS.REC.1399.070

Health conditions studied

1

Description of health condition studied
Elderly patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Cognitive performance score

Timepoint
Before the intervention, and one week after the 60-day treatment period

Method of measurement
Montreal cognitive assessment- Basic (MOCA_Bp) test

2

Description
Activity of Daily Living
Timepoint
Before the intervention, and one week after the 60-day treatment period
Method of measurement
Bartel & Lawton Activities of Daily Living scales

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: There are 44 patients in this group. Balance exercises in this group will be for 30 minutes every day and four times a week for eight weeks. Each balance exercise is repeated and lasts about 3-5 minutes. One session per week. Supervised by a nurse. The first supervision of the nurse will be during the first session and the next supervisions will be performed once a week with the coordination of the patient.
Category
Rehabilitation

2

Description
Control group: There are 44 patients in this group. In this group, no special sports intervention is performed and they receive only the usual care, including period visits by the treating physician.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani Hospital
Full name of responsible person
Faezeh Zahrabi Salari
Street address
Shahid Ayatollah Madani Hospital,Shahid Beheshti St. (Khairabad), Imam Hossein Square,Khorramabad
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2

Recruitment center
Name of recruitment center
Specialty Clinic of Shahid Madani Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
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Ebrahim Falahi
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research@lums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty

Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Khoram-Abad University of Medical Sciences
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Faezeh Zahrabi Salari
Position
Undergraduate Student
Latest degree
A Level or less
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