Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Occupational Performance Coaching on Self-Care Behavior,Participation Level and Depression in Adults With Heart Failure

Protocol summary

Study aim
The effectiveness of occupational performance coaching intervention on self-care behaviors, participation and depression of heart failure patients

Design
Randomized trial with control group, with parallel group, randomized, single blind, in 40 HF patient, Web-based block randomization

Settings and conduct
After receive the ethics code, sampling and intervention will be performed in Hospital. After referring the patients and sign a consent form and confirm with the inclusion and exclusion criteria, the assessments will be done by a blind research assistant . All assessments will be repeated the end of intervention and one month after that. Both groups will receive standard self-care training at Tehran Shahid Rajaei Heart Hospital. The intervention group will also receive occupational performance coaching intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Heart failure(HF) patient aged 18 to 65 who are literate. with HF levels 1, 2 and 3 based on the NYHA classification system.left ventricular ejection fraction less than 40% . Having mild or moderate depression, good cognitive function. scoring less than 70 in the self-care of HF index. Exclusion criteria: receiving other occupational therapy services,severe depression، having vision and hearing problems, living in care institutions, having unstable angina or high blood pressure, having psychiatric treatment and any neurological and psychological disorders, hospitalization and infection with COVID19 virus at the time of intervention.

Intervention groups
Intervention group: in additional to usual care, this group will receive occupational performance coaching. This intervention will be done to achieve the client's goals in 8 sessions for 1 hour maximum. Control group: received the standard self-care criteria of Tehran Shahid Rajaei Heart Hospital

Main outcome variables
Self-care behavior, Participation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120910010806N10**
Registration date: **2021-05-21, 1400/02/31**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-21, 1400/02/31**
Update count: **0**

Registration date
2021-05-21, 1400/02/31

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-20, 1400/02/30

Expected recruitment end date
2022-04-03, 1401/01/14

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Occupational Performance Coaching on Self-Care Behavior,Participation Level and Depression in Adults With Heart Failure

Public title
Occupational Performance Coaching on Self-Care Behavior,Participation Level and Depression in Adults With Heart Failure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged between 18 and 65 years clinical diagnosis of HF levels 1, 2 and 3 according to the New York Heart Association classification system (NYHA) by a cardiologist and left ventricular ejection fraction less than 40% based on echocardiography Have acute coronary artery syndrome for the past 2 weeks or coronary artery bypass graft disease or medical surgery based on a diagnosis made by a cardiologist be able to read, write and fill out questionnaires not having severe depression based on the CDS questionnaire (scoring less than 100) having good cognitive function (score above 22 in MMSE test) having a score less than 70 in self-care behavior scale
Exclusion criteria:
History of claudication, clinical instability, ventricular arrhythmia, primary valve disease, congenital heart disease, hypertrophic or restrictive cardiomyopathy, myocarditis, COPD and pericardial effusion, and history of myocardial infarction in the previous month, acute coronary artery syndrome during the last 2 weeks or patients with coronary artery bypass graft or heart surgery, , , , i Being a recipient of other occupational therapy services Having vision and hearing problems that prevent communication Hospitalization at the time of implementing the intervention, Living in maintenance institutions Having unstable angina or high blood pressure Having any psychiatric disorder treated based on medical documentation Having any neurological or psychological disorders that impair the ability to walk or cognitive function Infection with COVID-19 at the time of intervention Having myocarditis, severe COPD and pericardial effusion and a history of myocardial infarction in the previous month and uncontrolled diabetes and kidney failure based on medical documentation
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized
Randomization description
Blocked randomization, After selecting the samples in a non-probability simple method, participants will be randomly divided into two groups. Random allocation to the two groups in this study will be done using four and six blocks. The order of the blocks will be selected web-based. Randomization in this study will be done by one of the research colleagues and other researchers and the person performing the intervention will not know about the assignment of groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
Assessor and will be blind in this study
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran university of medical sciences and health services
Street address
Iran University of Medical Sciences., Shahid Hemmat highway, Tehran, Iran
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Tehran
Province
Tehran
Postal code
1449614353
Approval date
2021-03-14, 1399/12/24
Ethics committee reference number
IR.IUMS.REC.1399.1414

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
Self-care Behavior
Timepoint
Before the intervention, after the end of the intervention and in the follow-up, one month after the end of the intervention
Method of measurement
self-care of heart failure index

2

Description
Participation
Timepoint
Before the intervention, after the end of the intervention and in the follow-up, one month after the end of the intervention
Method of measurement
Canadian Occupational Performance Measure

Secondary outcomes

1

Description
Self-efficacy
Timepoint
Before the intervention, after the end of the intervention and in the follow-up period one month after the end of the intervention
Method of measurement
Cardiovascular Management Self Efficacy Scale

2

Description
quality of life
Timepoint
Before the intervention, after the end of the intervention and in the follow-up period one month after the end of the intervention
Method of measurement
Minnesota Living with Heart Failure Questionnaire

3

Description
Physical Functional Capacity
Timepoint
Before the intervention, after the end of the intervention and in the follow-up period one month after the end of the intervention
Method of measurement
6 Minute Walk Test

4

Description
activity of Daily Living
Timepoint
Before the intervention, after the end of the intervention and in the follow-up period one month after the end of the intervention
Method of measurement
Lawton questionnaires

5

Description
fatigue
Timepoint
Before the intervention, after the end of the intervention and in the follow-up period one month after the end of the intervention
Method of measurement
Fatigue Severity Scale

6

Description
Depression
Timepoint
Before the intervention, after the end of the intervention and in the follow-up period one month after the end of the intervention
Method of measurement
Beck Depression Inventory-II

7

Description
cognition level
Timepoint
Before the intervention, after the end of the intervention and in the follow-up period one month after the end of the intervention
Method of measurement
Mini Mental Status Examination

8

Description
Social Support
Timepoint
Before the intervention, after the end of the intervention and in the follow-up period one month after the end of the intervention
Method of measurement
Social Support Scale

Intervention groups

1

Description
intervention group: Includes the heart failure patients referred to Rajaie Cardiovascular, Medical and Research Center , which are treated according to the OPC (occupational performance =Coaching) protocol. In the pilot phase, the OPC is performed in 8 sessions individually by the researcher.
Category
Rehabilitation

2

Description
Control group: A standard self-care training session of Rajaie Cardiovascular, Medical and Research Center is performed as a usual care for them.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Rajaie Cardiovascular, Medical and Research Center
Full name of responsible person
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Sponsors / Funding sources

1

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Full name of responsible person
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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
Iran 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
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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
Undecided - It is not yet known if there will be 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
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
Title and more details about the data/document
Article Published
When the data will become available and for how long
6 months after publication
To whom data/document is available
The researchers and Occupational Therapists
Under which criteria data/document could be used
Other research, critics, check and clinical usage
From where data/document is obtainable
First author and corresponding author
What processes are involved for a request to access data/document
Send Request by Email
Comments