

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Malahat Akbarfahimi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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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

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Iran University of Medical Sciences., Shahid Hemmat highway, Tehran, Iran

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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

Sepideh Taghavi

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Shaheed Rajaie Cardiovascular Medical and Research Center Valiasr Ave Niayesh Intersection

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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

Iran University of Medical Sciences

Full name of responsible person

Zahra Ahmadizadeh

Position

PhD candidate of occupational therapy

Latest degree

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Other areas of specialty/work

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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**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Zahra Ahmadizadeh

Position

PhD. candidate of Occupational Therapy

Latest degree

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Other areas of specialty/work

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