Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of progressive muscle relaxation on the quality of life of patients with heart failure

Protocol summary

Study aim
Determine the effect of progressive muscle relaxation on the quality of life in patients with heart failure
Design
The clinical trial has a community-based and pragmatic control group, with parallel groups, randomized and has 70 samples
Settings and conduct
In this clinical trial, 70 patients who were referred to Amiralmomenin Hospital were selected through available sampling. They were then randomly assigned to control and test groups, and demographic characteristics questionnaire and Minnesota Living with Heart Failure Questionnaire (MLHFQ) were completed for both groups. After 5 sessions of Jacobson progressive muscle relaxation program in the test group and one month follow up, the Minnesota questionnaire was again given to the patients in both groups to complete it.
Participants/Inclusion and exclusion criteria
Patients with heart failure with ejection fraction less than 40%
Intervention groups
The experimental group received an intervention with progressive muscle relaxation and the control group under routine care
Main outcome variables
Improving the quality of life of patients with heart failure

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180206038650N1**
Registration date: **2018-02-18, 1396/11/29**
Registration timing: **prospective**

Last update: **2018-02-18, 1396/11/29**
Update count: **0**
Registration date
2018-02-18, 1396/11/29

Registrant information
Name
Samira Rasouli
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-02-20, 1396/12/01
Expected recruitment end date
2018-03-20, 1396/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of progressive muscle relaxation on the quality of life of patients with heart failure

Public title
The effect of relaxation on heart failure
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Having a functional level of 3 and 4 based on the category of New York Heart Association Heart ejection

fraction (EF) less than 40%

Exclusion criteria:

Having a known psychiatric disorder Having Malignant disease and other chronic diseases

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

A list of all patients was prepared and numbered within one month from the start of the sampling, which included the criteria for entering the study, giving each patient a certain number. They were then randomly assigned into two groups using the random number table in the sample statistics books.

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 the Islamic Azad University, Tehran Medical Branch

Street address

khaghani st, shariati Ave

City

Tehran

Province

Tehran

Postal code

19395/1495

Approval date

2017-07-26, 1396/05/04

Ethics committee reference number

IR.IAU.TMU.REC.1396.59

Health conditions studied

1

Description of health condition studied

Heart Failure

ICD-10 code

I50.9

ICD-10 code description

Heart failure, unspecified

Primary outcomes

1

Description

Quality of Life Score in the Minnesota Questionnaire

Timepoint

Before and one month after the intervention

Method of measurement

Minnesota Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Implementation of progressive muscle relaxation in 5 sessions

Category

Rehabilitation

2

Description

Control group: Routine care

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir al Momenin Hospital

Full name of responsible person

Samira Rasoli

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Deputy of Medical Sciences
Street address
Khaghani Avenue, Shariati Street
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iautmu@iautmu.ac.ir
Web page address
http://www.iautmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
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Position
Student
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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
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
Not applicable
Title and more details about the data/document
Only data analysis results will be shared and individual sample data will not be provided
When the data will become available and for how long
Start the access period one year after the print results
To whom data/document is available
All patients and researchers
Under which criteria data/document could be used
The final results of the analysis of patients' quality of life will be usable
From where data/document is obtainable
To Samira Rasoli with this email: srasoli@iautmu.ac.ir
What processes are involved for a request to access data/document
Send the request to the email and the results will be sent in less than a week
Comments