

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 Amirmomenin 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

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2200 6660

Email address

srasoli@iautmu.ac.ir

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

Street address

Opposite of Sardar Jangal Park, Nazi Abad

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55346301

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info@amhos.ir

Web page address

http://amhos.ir/(S(clctopw412tielzkxhcpoapf))/index.aspx

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

City

Tehran

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1916893813

Phone

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Email

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

Samira Rasouli

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Faculty of Nursing and Midwifery- Azad University
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Person responsible for updating data**Contact****Name of organization / entity**

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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