

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Investigation of the effect of cardiac rehabilitation via telenursing on sexual satisfaction and fatigue of patients with different types of heart rhythm management devices and their spouses at arrhythmias clinics affiliated to Shiraz University of Medical Sciences

Protocol summary

Study aim

Determination of the effect of cardiac rehabilitation through telenursing on sexual satisfaction and fatigue in patients with different types of heart rhythm management devices and their spouses

Design

A randomized controlled clinical trial, with parallel groups and single blind

Settings and conduct

At arrhythmias clinics affiliated to Shiraz University of Medical Sciences Training and counseling (about fatigue and sexual satisfaction) during in person and non in-person session. Single blind: Outcome evaluator, Data analyzer

Participants/Inclusion and exclusion criteria

Married and sexually active patient (only one spouse) aged 18 to 70 years old and has one of a different types of heart rhythm management devices and has been implanted at least three months.

Intervention groups

Intervention group (patient plus his / her spouse) during an 8-week period including 8 sessions of cardiac rehabilitation: 2 in-person sessions including training and counseling on fatigue and sexual satisfaction for two weeks (one session per week) and after in-person sessions starting with the third week of the intervention, 6 non-face-to-face sessions will be followed by 6-week telephone follow ups (one call per week by the nurse). Also, educational-motivational text messages will be sent three times a week from the beginning of the rehabilitation period. Patients will perform exercise sessions at home according to the cardiac electrophysiology practitioner and based on the instruction booklet we will provide. In the control group, there is no intervention, and patients will receive only routine training and routine care.

Main outcome variables

Sexual satisfaction and fatigue in patients with different types of heart rhythm management devices and their spouses

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200302046662N1**

Registration date: **2020-03-07, 1398/12/17**

Registration timing: **prospective**

Last update: **2020-03-07, 1398/12/17**

Update count: **0**

Registration date

2020-03-07, 1398/12/17

Registrant information

Name

Fatemeh Sabetghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3837 0559

Email address

f_sabetghadam@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation of the effect of cardiac rehabilitation via telenursing on sexual satisfaction and fatigue of patients with different types of heart rhythm management devices and their spouses at arrhythmias clinics affiliated to Shiraz University of Medical Sciences

Public title
Investigation of the effect of cardiac rehabilitation on patients with different types of heart rhythm management devices and their spouses

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Has one of a different types of heart rhythm management devices and has been implanted for at least three months Be married Only have one spouse 18 to 70 years old Not diagnosed mental illness and acute cognitive disorders Not having severe orthopedic, neurological, visual and hearing problems Ability to understand and speak and read and write Persian language Phone access (fixed and mobile) after discharge Have sexual activity
Exclusion criteria:
Incidence of unstable angina Uncontrolled blood pressure, resting systole greater than 180 mmHg or diastolic resting time greater than 110 mmHg Severe neurological, orthopedic and musculoskeletal problems that occur during the study and prevent them from being active The patient's unwillingness to continue attending the study Not attending one of the pre- or post-test sessions Not attending one of the in person sessions

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the stratified random sampling method, here are the classes of Cardiac resynchronization therapy, implantable cardiac defibrillator and pacemaker to fit each class, 14 patients with Cardiac resynchronization therapy, 22 patients with implantable cardiac defibrillator and 32 patients with Pacemakers will first be

selected as available sampling in the aforementioned classes, and then random allocation using Random allocation Software to generate block randomization lists of each block size 2 or 4 2 blocks of 7, floor implantable cardioverter defibrillator The size of 2 blocks of 11 blocks and the pacemaker class 4 blocks of 8 blocks will be divided into control and patient groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to single blind , questionnaires will be collected by the first researcher and assigned to intervention and control groups by the second researcher, so the outcome assessor will be kept blind. Also, the person analyzing the data will not be aware of the intervention and control groups.

Placebo

Not used

Assignment

Parallel

Other design features

The present study will be conducted on couples and patients' spouses will be included. Therefore, the intervention group (34 patients plus 34 spouses) and the control group (34 patients plus 34 spouses) will total 68 couples (136 persons).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Fatemeh(P.B.U.H)School of Nursing and Midwifery, Namazi Hospital, Namazi Square

City

Shiraz

Province

Fars

Postal code

۷۱۹۳۶ - ۷۱۱۹

Approval date

2020-01-15, 1398/10/25

Ethics committee reference number

IR.SUMS.REC.1398.1195

Health conditions studied

1

Description of health condition studied

Patients with different types of heart rhythm management devices

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Spouses of patients with different types of heart rhythm management devices

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Level of sexual satisfaction in Hudson Index of Sexual Satisfaction questionnaire

Timepoint

At baseline (before intervention) and 2 months after intervention

Method of measurement

Hudson Index of Sexual Satisfaction

2

Description

Fatigue score on the Fatigue Severity Scale Questionnaire

Timepoint

At baseline (before intervention) and 2 months after intervention

Method of measurement

Fatigue Severity Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group (patient plus his / her spouse) during an 8-week period including 8 sessions of cardiac rehabilitation: 2 in-person sessions including training and counseling on fatigue and sexual satisfaction for two weeks (one session per week) and after in-person sessions starting with the third week of the intervention, 6 non-face-to-face sessions will be followed by 6-week telephone follow_ups (one call per week by the nurse). Also, educational-motivational text messages will be sent three times a week from the beginning of the rehabilitation period. Patients will perform exercise sessions at home according to the cardiac electrophysiology practitioner and based on the instruction booklet we will provide.

Category

Rehabilitation

2

Description

Control group: There is no intervention, and patients will receive only routine training and routine care.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arrhythmia clinic of Alzahra Heart Hospital

Full name of responsible person

Fatemeh Sabetghadam

Street address

Sibouyeh Boulevard, Astana Three Way, Alzahra Heart Charity Hospital

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2

Recruitment center

Name of recruitment center

Arrhythmia clinic of Shahid Faghihi Hospital

Full name of responsible person

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3

Recruitment center

Name of recruitment center

Imam Reza Clinic

Full name of responsible person

Fatemeh Sabetghadam

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Doctor Younes Ghasemi

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mahnaz Rakhshan

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Phone

0098 7136474254-8

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mahnaz Rakhshan

Position

Associate Professor

Latest degree

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Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Sabetghadam

Position

Master of Adult Critical Care Nursing Student

Latest degree

Bachelor

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

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

Undecided - It is not yet known if there will be 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

- Obtaining an official letter from the Fatemeh School of

Nursing and Midwifery of Shiraz and obtaining permission from the authorities of Shiraz University of Medical Sciences. - Obtain written consent from the sample to participate in the study. - Ensure that the research units are confident of the information received. - Freely and voluntarily participate in the research and consider the right to opt out of research. - Creating a private environment for interviewing the patient and completing the questionnaire. - Providing research results if desired by the training center where the researcher has sampled.

When the data will become available and for how long

After completing the study and publishing the results

To whom data/document is available

Private and public hospitals Cardiac rehabilitation centers The training center where the researcher has sampled.

Under which criteria data/document could be used

- Obtain the permission of the respected authorities at the College, University and Hospital. - Confidentiality of participants' information

From where data/document is obtainable

Shiraz. Zand Street, Library of Shiraz School of Nursing and Midwifery. Phone: 0098 7136474254

What processes are involved for a request to access data/document

Requests for results are sent to the library of Shiraz School of Nursing and Midwifery. They will be provided with the coordination.

Comments