Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Investigating the Effect of Adherence to Therapeutic Regimen program on the Quality of Life in Patients with Atrial Fibrillation

Protocol summary

Study aim

Determining the effect of an adherence to a therapeutic regimen program on the quality of life of patients with atrial fibrillation arrhythmia hospitalized in the Shahid Chamran Educational-Medical hospital of Isfahan in 2018

Design

Randomised, superiority, parallel group trial with blinded outcome assessment. Randomisation was centralised and computerised with concealed

Settings and conduct

The study environment is the CCU, Post CCU, and Internal Cardiology units of Isfahan, Shahid Chamran Educational-Medical Center.

Participants/Inclusion and exclusion criteria

Those patients with atrial fibrillation arrhythmia diagnosed and treated by the cardiologist specialists.

Intervention groups

The intervention group: A compiled therapeutic regimen program which is a synthesis of personal training and practicing in two 45-minute successive sessions. On the second and third days of hospitalization, during the hours 9 to 11, and with the aid of illustrated pictures of an educational booklet, there will be face to face discussions between the patients and the researcher on the arrhythmia type, the therapeutic method, the used drugs and their side effects, the amount of activity, how to face psychological problems, the significance of conducting coagulation tests, the type of nourishing, and a plan to correctly face probable problems. The control group: This group will receive the usual cares besides a personal 30-minute session concerning the atrial fibrillation disease. One month after the intervention, a researcher colleague possessing no information on the study purposes will fill out the questionnaire via the questioning method and by the use of data included in the histories of the experimental and control groups.

Main outcome variables

The enhancement of the quality of life of patients with atrial fibrillation, the enhancement of the management in face of disease signs and symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190203042608N1**
Registration date: **2019-12-29, 1398/10/08**
Registration timing: **retrospective**

Last update: **2019-12-29, 1398/10/08**
Update count: **0**

Registration date

2019-12-29, 1398/10/08

Registrant information

Name

fatemeh Yazdizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3624 8911

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-15, 1396/10/25

Expected recruitment end date

2018-06-15, 1397/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the Effect of Adherence to Therapeutic Regimen program on the Quality of Life in Patients with Atrial Fibrillation

Public title
Investigating the Effect of Adherence to Therapeutic Regimen program on the Quality of Life in Patients with Atrial Fibrillation

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
7- The Main Inclusion criteria in the Study before Randomization Those patients with atrial fibrillation arrhythmia diagnosed and treated by cardiologist specialists. Those patients with atrial fibrillation arrhythmia hospitalized for the first time. Those patients that are in the age range between 35 and 70 years old

Exclusion criteria:
Patients' disinclination to participate in the intervention Patients' with physical and psychological problems leading to their disabilities 3. Patients below 35 years old and above 70 years old

Age
From **35 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
To collect data, having obtained the required permissions accompanied with the authorities' agreement and cooperation, the researcher refers to the CCU, Post CCU, and internal cardiology units of the Chamran Hospital and extracts the list of patients with atrial fibrillation arrhythmia introduced by the cardiologist specialists in these units. Then, she talks to all patients having the inclusion criteria, and, in addition to introducing herself, she explains them the purpose of the study. Finally, the qualified samples for the study are simply selected, and, having acquired their written informed consent, we will include them in the study. The randomization is implemented as the following: the samples are given numbers from the list of random numbers, and, according to the numbers, the even ones are assigned to the experimental group and the odd ones are assigned to the control group. This task continues until the considered sample number is achieved.

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
The Ethics Committee of Isfahan, University of Medical Sciences

Street address
The Headquarters, Isfahan, University of Medical Sciences and Healthcare Services, Hezarjarib Street

City
Isfahan

Province
Isfehan

Postal code
7346181746

Approval date
2018-01-14, 1396/10/24

Ethics committee reference number
IR.MUI.REC.396635

Health conditions studied

1

Description of health condition studied
Atrial Fibrillation

ICD-10 code
I48.1

ICD-10 code description
Persistent atrial fibrillation

Primary outcomes

1

Description
The quality-of-life in patients with atrial fibrillation in the AFEQT questionnaire

Timepoint
Investigating the quality of life at the study outset, one month and three months after the intervention

Method of measurement
The atrial fibrillation effect on the quality-of-life questionnaire

Secondary outcomes

1

Description
The atrial fibrillation symptoms including heartbeat,

chest pain, shortness of breath, and vertigo

Timepoint

All items accomplished before the intervention, and one month and three months after the intervention

Method of measurement

All items are from the atrial fibrillation effect on the quality-of-life questionnaire for the patients with atrial fibrillation

Intervention groups

1

Description

A compiled therapeutic regimen program which is a synthesis of personal training and practicing in two 45-minute successive sessions. On the second and third days of hospitalization, during the hours 9 to 11, and with the aid of illustrated pictures of an educational booklet, there will be face to face discussions between the patients and the researcher on the arrhythmia type, the therapeutic method, the used drugs and their side effects, the amount of activity, how to face psychological problems, the significance of conducting coagulation tests, the type of nourishing, and a plan to correctly face probable problems. At the end of the second session, the experimental group will be given an educational booklet concerning the presented issues in adherence to a therapeutic regimen program. The telephone call happens between 8 in the morning and 8 at night on certain dates and times according to the agreement between the researcher and the patient and its content is encouraging the presented discussions in the sessions, question and answer, reinforcing the lessons, and the disease management power. Then, there will be no intervention for 8 weeks. Finally, 12 weeks after the intervention, the questionnaire will be filled out by the educational colleague.

Category

Diagnosis

2

Description

Control group: This group will receive the usual cares besides a personal 30-minute session concerning the atrial fibrillation disease. One month after the intervention, a researcher colleague possessing no information on the study purposes will fill out the questionnaire via the questioning method and by the use of data included in the histories of the experimental and control groups

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan, Shahid Chamran Educational-Medical Center

Full name of responsible person

Fatemh Yazdizadeh

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Salman Farsi Street after the city bridge

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahin Moeini

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Central headquarters, Isfahan, University of Medical Sciences and Healthcare Services, Hezarjarib Street

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Fatemeh Yazdizadeh
Position
An M.A. Student
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Person responsible for updating data

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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
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
Yes - There is a plan to make this available
Title and more details about the data/document
The entire data present in the questionnaire is sharable after it becomes unidentifiable
When the data will become available and for how long
The accessibility onset is up to 5 years after printing the results
To whom data/document is available
It will be accessible to all researchers working in scientific and academic institutions
Under which criteria data/document could be used
The resultant documents can be referred to in similar studies on the patients with atrial fibrillation, the effect of regimen according to demographic variables, and similar issues
From where data/document is obtainable
Referring to the library of the nursing faculty and receiving the electronic file of the thesis The personal e-mail of the researcher Fatima Yazdizadeh: yazdizadeh.f71@gmail.com
What processes are involved for a request to access data/document
The document appliers should have valid student number from their university or ethics code from the respected university. Moreover, they should present the full specifications of their advisors while they receive the documents so that they can hold them for two weeks.
Comments