Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessing the effect of nursing care plan according “one care program “on Quality Of Life(QOL) in patients with Atrial Fibrillation(AF) Hospitalized to the Coronary Care Unit(CCU)

Protocol summary

Study aim

Determine the effect of a care plan on the quality of life of the patients with atrial fibrillation

Design

This is a randomized two-group clinical trial that was conducted on 50 patients diagnosed with atrial fibrillation and hospitalized in Coronary Care Unit(CCU). Fifty patients were selected through convenient sampling and were randomly assigned to intervention (n=25) and control (n=25) groups. a code was allocated to each one of them.

Settings and conduct

This is randomized two-group two- step clinical trial , conducted on 50 patients with atrial fibrillation hospitalized in Coronary Care Unit of Nour hospital , affiliated to Isfahan University of Medical Sciences, Iran . For the intervention group, a planned care program was performed and performed routine care for the control group. Quality of life was measured using a SF36 quality of life questionnaire before and one month after the end of the intervention.

Participants/Inclusion and exclusion criteria

Conditions for entering the research:patients with diagnosed atrial fibrillation hospitalized in CCU of Nour hospital , affiliated to Isfahan University of Medical Sciences, Iran. The patient's willingness to participate in the research project. Exclusion Consciouslessness of the Subjects Having Pacemaker and Implantable cardiovertion Defibrillasion No patients who live in Isfahan Unwillingness of the Patient to Continue to Participate in the Research Project life Threatening Physical Condition and Acute Psychotic Disorders.

Intervention groups

Control group : Control group underwent routine care including routine control of cardiac rate and rhythm , and prevention of thromboemboli , mostly administrated through oral and non-identical instructions ,and often, with educational pamphlets by the nurses in the ward . Intervention group : In study group, a care plan was designed based on previous studies , forcing the nurses to administrate care according to a checklist including control of cardiac rhythm and rate , prevention of thromboemboli and atrial fibrillation and their treatment strategies, complications and educational program. Researcher precisely checked administration of the checklist by nurses.

Main outcome variables

The dependent variable was the quality of life and its dimensions, which was measured.’quality of life(QOL) and domains of physical function, physical role, emotional role, happiness, mental health , social function, pain ,and general health.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160316027073N3**
Registration date: **2018-03-02, 1396/12/11**
Registration timing: **retrospective**

Last update: **2018-03-02, 1396/12/11**
Update count: **0**

Registration date

2018-03-02, 1396/12/11

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete
Funding source
vice chancellor for research,Isfahan University of Medical Sciences

Expected recruitment start date
2015-06-10, 1394/03/20
Expected recruitment end date
2015-09-23, 1394/07/01
Actual recruitment start date
2015-06-10, 1394/03/20
Actual recruitment end date
2015-09-23, 1394/07/01
Trial completion date
empty

Scientific title
Assessing the effect of nursing care plan according “one care program “on Quality Of Life(QOL) in patients with Atrial Fibrillation(AF) Hospitalized to the Coronary Care Unit(CCU)

Public title
Effect of Nursing Care Program on Quality Of Life in patients with Atrial Fibrillation
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
patients with diagnosed atrial fibrillation hospitalized in CCU of Nour hospital , affiliated to Isfahan University of Medical Sciences, Iran . The patient's willingness to participate in the research project.
Exclusion criteria:
Consciouslessness of the Subjects Having Pacemaker and Implantable cardiovertion Defibrillasion No patients who live in Isfahan Unwillingness of the Patient to Continue to Participate in the Research Project life Threatening Physical Condition and Acute Psychotic Disorders
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Actual sample size reached: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
The research units with inclusion criteria were entered into the study by simple sampling method and were randomly assigned to two groups of test and control using the random numbers table.

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 Committe of Isfahan University of Medical Sciences
Street address
Isfahan, Shiraz gate, 1000 Jreib Street, Isfahan University of Medical Sciences
City
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Isfehan
Postal code
8174673461
Approval date
2015-04-21, 1394/02/01
Ethics committee reference number
IR.Mui.Rec.1394.3.270شماره مجوز

Health conditions studied

1

Description of health condition studied
Atrial Fibrilation
ICD-10 code
I48
ICD-10 code description
Atrial fibrillation and flutter

Primary outcomes

1

Description
quality of life
Timepoint
pre intervention and after one month post intervention
Method of measurement
Quality of life SF36 questionnaire

Secondary outcomes

1

Description
Ejection Fraction
Timepoint
before and one month after study
Method of measurement
Echocardiogram

Intervention groups

1

Description
In study group, a care plan was designed based on previous studies , forcing the nurses to administrate care according to a checklist including control of cardiac rhythm and rate, prevention of Thromboembolism and atrial fibrillation and their treatment strategies, complications and educational program. Care plan also contained medical cardioversion. checklist and heparin and warfarin thromboembolism prevention checklist .
Category
Rehabilitation

2

Description
Control grop:Firstly, demographic characteristics and QOL questionnaires were completed by the researcher for all the subjects in both groups . Control group underwent routine care including routine control of cardiac rate and rhythm , and prevention of thromboembolism , mostly administrated through oral and non-identical instructions ,and often, with educational pamphlets by the nurses in the ward .
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
CCU of Nour hospital , affiliated to Isfahan University of Medical Sciences, Iran
Full name of responsible person
Dr.Jafar Golshahi
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Ostandary Ave ,Nour Hospital,Isfahan,Iran.
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Sponsors / Funding sources

1

Sponsor
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Research Deputy for Isfahan University of Medical Sciences
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Web page address
http://research.mui.ac.ir
Grant name
Isfahan Medical Science University
Grant code / Reference number
دانشگاه علوم پزشکی اصفهان
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
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Full name of responsible person
Asghar khalifehzadeh Esfahani
Position
Lecturer department of Critical nursing,Faculty of Nursing and Midwifery, Isfahan University of M
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Disagreement with the research sponsor until the paper is submitted
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available