Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of telephone follow-up methods and group session on quality of life of patients with pacemaker in clinic Investment, Chamran Hospital in Isfahan

Protocol summary

Summary

The purpose of this study was to assess the effect of telephone follow up and group session on different domain of quality of life in patient with pacemaker. The inclusion criterias were the age between 18-85 and the first time implanation and the exclusion criteria was Lack of consent to continue participating in the study. This was a prospective quasi experimental study that covered 60 patient divided into three groups. For 20 patient in intervention group 4 group session were performed one day a week, each session would last 20-40 min. For 20 patient in telephone follow up 12 phone calling were performed for 4 weeks, each call would last 20 min, control group received the routine intervention as a educational material. The data were collected through" AQOL" for physical status and the quality of life questionaries. Physical status and quality of life were evaluated after one month intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138805132289N1**
Registration date: **2011-06-25, 1390/04/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-06-25, 1390/04/04

Registrant information

Name
Fateme Aliakbari
Name of organization / entity
Nursing Midwifery School
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2007-07-25, 1386/05/03

Expected recruitment end date

2008-02-28, 1386/12/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of telephone follow-up methods and group session on quality of life of patients with pacemaker in clinic Investment, Chamran Hospital in Isfahan

Public title

Effect of telephone follow-up methods and group session on quality of life of patients with pacemaker in clinic Investment ,Chamran Hospital in Isfahan

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients are aged 18-80 years; are of both sexes; complete the individual consciousness, awareness of time, place and person possible Drmtalh companies have; For the first time pacemaker is embedded; Patients who have the ability to participate in

the meetings are; have a telephone at home; mental disorder is not known in this field do not use drugs; speech and hearing problems are not known; during pregnancy and lactation not; surgery, while there is no pacemaker fitted; or physical mental disability which prevents the ability not participate in session. Exclusion criteria: patient's unwillingness to continue participating in the study

Age
From **18 years** old to **85 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **65**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
Aliakbari

Secondary trial Id
386352

Registration date
2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan University of Medical Science

Street address
Hezarjrib street, Midwifery Dept, Nursing and Midwifery Faculty, Univ of Medical Science, Isfahan, Iran.

City
Isfahan

Postal code

Approval date
2007-09-23, 1386/07/01

Ethics committee reference number
386352

Health conditions studied

1

Description of health condition studied
Pacemaker Implatation

ICD-10 code
Y83.1

ICD-10 code description
Surgical operation with implant of artificial internal device

Primary outcomes

1

Description
Quality of life

Timepoint
One month

Method of measurement
SF-36 questionaries

Secondary outcomes

1

Description
Physical condition

Timepoint
one month

Method of measurement
AQOL questionaries

Intervention groups

1

Description
For 20 patient in telephone follow up 12 phone calling were performed for 4 weeks, each call would last 20 min.

Category
Other

2

Description
For 20 patient in group session group 4 group session were performed one day a week, each session would last 20-40 min.

Category
Other

3

Description
For 20 patient in control group the routine intervention(giving educational material) was done.

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Chamran Hospital, Pace implatation clinic
Full name of responsible person
Street address
Salman-e Farsi street, Pace implatation clinic, Chamran Hospital, Isfahan, Iran
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Science
Full name of responsible person
Research Assistant
Street address
Hezarjrib street, Research Assistant, Univ of Medical Science, Isfahan, Iran.
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan University of Medical Science
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

2

Sponsor
Name of organization / entity
Isfahan University of Medical Science
Full name of responsible person
Peyman Adibi
Street address
Hezarjrib street, Research Assistant, Univ of Medical Science, Isfahan, Iran.
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan University of Medical Science
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty