Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

the effect of family center empowerment modle on activity daily living and quaility of life in clients chamran heart hospital isfahan

Protocol summary

Summary

The goal of this clinical intervention is to empower clients with family-centered empowerment to improve quality of life andactivity daily living . This study was designed based on a family-centered empowerment model on quality of life and activity daily living of clients with permanent pacemaker. A clinical trial was double blind (Related to study subjects (patients), Committee for the Study of Study Information (Information analysts are in the middle or end stages of the study)that conducted on 60clients that contrive permanent pacemaker who had entered the study, randomly divided into two groups of intervention and control.Interventions during family-oriented sessions A family-centered empowerment model has a step-by-step implementation phase that should be interconnected and integrated. These four main steps, which are based on the family-center empowerment model, are: Includes: 1. Increased perceived threat by increasing knowledge. 2. Promoting self-efficacy by using problem-solving method. 3. Increasing self-esteem through educational participation. Step 4-Evaluation. Prior to the start of the steps, a questionnaire for quality of life and activitiy daily living is carried out by two groups of control and after 8weeks educated, we filling the questionaries of activity daily living and quality of life from two group for analyze. finally I get control group education in one sesstion and get them pamphelats and books.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017103137143N1**
Registration date: **2017-11-19, 1396/08/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-11-19, 1396/08/28

Registrant information

Name
manejeh toraby
Name of organization / entity
Hospital
Country
Iran (Islamic Republic of)
Phone
+98 913 287 0676
Email address
st-toraby.m@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-10-12, 1396/07/20

Expected recruitment end date

2018-02-09, 1396/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of family center empowerment modle on activity daily living and quaility of life in clients chamran heart hospital isfahan

Public title

the effect of family-center empowerment modle on activity daily living and quiality of life in clients with per manent pace maker

Purpose

Supportive

Inclusion/Exclusion criteria

Entry criterion:1.the clients have permanent pace maker.2.the clients agree to participate in. 3.they didn,t have any sychology problem.4.the client have 18until80 years old.5.the clients could have comunication.6.the clients didn,t have auditory problem.7.one of the family person agree to particicipate to intervention.8.they have minimum ability of reading and writing. .9the nearst family that care from client have nesessory khnowledge about his or her client,s illnessand could make disition. outgoing ceriterion: the clients dont like percipitate in intervention.2if the clientswii die.3.the client have another problemfor example get sycho sochial problems that dont abble to continue this case.4.any problem that influence on quality of life and activity daily living,for example dieing nearst family or getting another problems with his or her heathy.

Age

From **17 years** old to **79 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

after I meet the client that who has entry requirements i get consent letter and I get client agroup cards that provide them enough to clients and mix them . the client randomly pick up one of the gruop cards .if the card is A the client is in the intervention group and if the client is the Bgroup she or he is in the control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

MEDICAL SURGICAL SCIENTS

Street address

CHAHAR MAHAL AND BAKHTIARI

City

SHAHREKORD

Postal code

Approval date

2017-10-12, 1396/07/20

Ethics committee reference number

IR.SKUMS.REC1396.172

2

Ethics committee

Name of ethics committee

IR.SKUMS.REC.1396.172

Street address

SHAHREKORD MEDICAL SCIENCE

City

CHAHARMAHAL AND BAKHTIARI

Postal code

Approval date

2017-10-12, 1396/07/20

Ethics committee reference number

IR.SKUMS.REC1396.172

Health conditions studied

1

Description of health condition studied

the clints with permanent pace maker

ICD-10 code

152

ICD-10 code description

Other heart disorders in diseases classified elsewhere

Primary outcomes

1

Description

family center impowerment modle

Timepoint

15daiy until one month

Method of measurement

QUISTIONARY

Secondary outcomes

1

Description

activity daily living and quality of life

Timepoint

8weeks

Method of measurement

QUISTIONARY

Intervention groups

1

Description

the intervention will be in the interventional group.at first we tell clients how pace maker works and what should or shouldnt they do. then in some session we want the

clients tell what they know about pacemaker to one of person in their family that in client,s treatment is active. then we evaluate them with questionarys after 8weeks.but control groupwill get ruling eduction in hospitaland after 8weekswe we will evalute they, then we,ll compare two group.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

chamran heart hospital in esfahan

Full name of responsible person

mrs doctor shirani

Street address

esfahan

City

esfahan

2

Recruitment center

Name of recruitment center

chamran heart hospital in esfahan

Full name of responsible person

doctor rezvan normand

Street address

esfahan

City

esfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, shahrekord University of Medical Sciences

Full name of responsible person

doctor solati

Street address

shahrekord

City

shahrekord

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, shahrekord University of Medical Sciences

Proportion provided by this source

100

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

shah rekord univercity

Full name of responsible person

manejeh toraby kharaji

Position

master of medical surgical nursing student

Other areas of specialty/work

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shahrekord medical science

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manejeh.toraby@gmil.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

medical surgical univercity shahrekord

Full name of responsible person

doctor fatemeh ali akbari

Position

nursing doctor

Other areas of specialty/work

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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