Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Effectiveness of Educational Intervention Based on Roy's Adaptation model on the Psychosocial Adjustment of patients with Permanent Pacemaker

Protocol summary

Study aim
Determining the Effectiveness of Educational Intervention Based on ROY Adaptation Model on Psychosocial Adjustment of Patients with Permanent Pace maker Shahid Madani Hospital, Khorramabad, Iran.

Design
Semi-experimental clinical practice, without independent control group, before and after, sampling available, without blinding

Settings and conduct
A study on the Adaptation of Patients with Pace maker in the Khorramabad Madani Hospital. Patients will be selected with the introduction of the arrhythmia Doctor. On the first day, providing clear explanations about the purpose of the study and obtaining written consent and the next month when the patient is referred to the doctor for analysis of the battery, three forms are filled by the researcher. Within one week, the researcher will pay attention to the Roy model to analyze the information and the general and specific training program will be implemented for each person in the hospital, and immediately after the training, a compatibility questionnaire will be filled. A month and three months later, the compatibility questionnaire will be filled again

Participants/Inclusion and exclusion criteria
Log-in: Patients with Permanent Pacemaker in their body and One month after the pacemaker has been used in the patient's body and are pleased to participate in the study. Non arrival: 1- 1. Not having Patient's tendency to assist in research. 2.Un Favorable physical condition. 3. Participation in any kind of effective workshop on the level of compatibility 4. Using Drugs that are effective on your Mental health

Intervention groups
All Patients with Permanent Pacemakers referring to Khorramabad Madani Hospital in 1397form the community under study

Main outcome variables
Psychosocial compatibility

General information

Reason for update

Acronym
PSAKH

IRCT registration information
IRCT registration number: **IRCT20181023041426N1**
Registration date: **2019-03-11, 1397/12/20**
Registration timing: **retrospective**

Last update: **2019-03-11, 1397/12/20**
Update count: **0**

Registration date
2019-03-11, 1397/12/20

Registrant information

Name
Elham Nasiri

Name of organization / entity

Country
Iran (Islamic Republic of)

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Email address
nasirielham55@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-23, 1397/05/01

Expected recruitment end date
2018-11-22, 1397/09/01

Actual recruitment start date
2018-07-23, 1397/05/01

Actual recruitment end date
2018-11-22, 1397/09/01
Trial completion date
2018-11-22, 1397/09/01

Scientific title
Effectiveness of Educational Intervention Based on Roy's Adaptation model on the Psychosocial Adjustment of patients with Permanent Pacemaker

Public title
Effectiveness of Educational Intervention Based on Roy's Adaptation model on the Psychosocial Adjustment of patients with Permanent Pacemaker
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
1. Patients who have Permanent Pace maker in their bodies . 2. One month after the pacemaker has been used in the patient's body. 3. the patient should express his consent to participate in the training program . 4. Patient should be introduced by the doctor to participate in the research 5. A person can understand Give the subject. 6. Age between 20-70 years 7. Lack of serious disabling illness, such as COPD - Blindness - Cancer . 8. Lack of any psychological problem 9. Lack of any hearing impairment - Vision - Speech 10. To Know Farsi language 11. Having a mobile or phone
Exclusion criteria:
1. Not having Patient's tendency to assist in research. 2. Unfavorable physical condition 3. Participating in any kind of effective workshop on the level of compatibility 4. Use of drugs that affect fluency
Age
From **20 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
The Study is Based on the ROY Adaptation Model, which is a nursing compatibility model.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Khorramabad University of Medical Sciences
Street address
Khorram Abad Mole Student, Shahid Anooshirvan Rezaei Square, Medical Sciences University
City
Khoram abad
Province
Lorestan
Postal code
6813833946
Approval date
2018-07-23, 1397/05/01
Ethics committee reference number
IR.LUMS.REC.1397.046

Health conditions studied

1

Description of health condition studied
Psychosocial Adjustment
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Psychosicial Adjustment
Timepoint
The Demographic Characteristics and the form of examination and recognition on the first session and the Psychosocial Adjustment to Illness Scale immediately After the intervention, one month and three months later After the intervention, will be completed by questioning the patient through the researcher's assistance (four times the questionnaire will be completed).
Method of measurement
Including Demographic Specification Form - Standard Questionnaire on Knowledge of ROY - Psychosocial Adjustment to Illness Scale

Secondary outcomes

1

Description
Compatibility time
Timepoint
Beginning of the study (before the intervention) - Immediately after the intervention - one month after the intervention - three months after the intervention
Method of measurement

Psychosocial Adjustment to Illness Scale

Intervention groups

1

Description

Intervention group: Patients with Pacemakers. The intervention will be conducted in accordance with a training protocol prepared by the care team (Researcher Nurse, relevant Physician, and Psychologist). The theoretical and practical program with lecture notes and lectures, with the help of slides and short films, include: (teaching patients about: heart function, definition of an Arrhythmia, Pacemaker function and physical risk factors And non-physical with illness and Pacemaker - in Psychological problems such as depression - Anxiety - Disturbance in the body of mind - decentralization - isolation and ... also social problems such as job loss - communicating with family and others - Participating in communities - adapting to the social environment ...) in 4 training sessions of 40 minutes and during 2 weeks in the conference hall Shaheed Madani Hospital will be offered. Meanwhile, after the end of the sessions, they will be in constant contact with the patients once a month (for one month) and their questions will be answered about their situation.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Madani Hospital, Khorram Abad Lorestan

Full name of responsible person

Dr. Tahereh Tolabai

Street address

Imam Hossein Square, Kheirabad Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Dr.Morovat Taheri Kalani

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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

Khoram-Abad University of Medical Sciences

Proportion provided by this source

50

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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Elham Nasiri

Position

MSc Student Specialist Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All participants' data are shareable in the study. However, the outcomes of the study are more relevant
When the data will become available and for how long
Access is available 6 months after the results are published.
To whom data/document is available
Scientific and academic Nursing researchers from Medical Sciences have access to the documentation.
Under which criteria data/document could be used
Any Analysis is allowed by the Professor. Use for research and research in Nursing and Medical Sciences is allowed. The requirements for sending Nursing and Medical Science groups can be provided.
From where data/document is obtainable
Khorram Abad University of Medical Sciences - Boroujerd Road 4 - Pardis University Campus - Faculty of Nursing - Dr. Tahereh Toloabi Mailbox: 381351698 Telex: 33120140-066 E-mail: Tolabi.t@lums.ac.ir College Education: 33120155-066- 33120166-066 - Internal 403 and 403
What processes are involved for a request to access data/document
First, Contact by email with Dr. Tolabi office to get permission to access the next document if Dr. Tolabi's permission is granted. Documentation will be sent by him or by Elham Nassiri's student.
Comments
This Study is based on Nursing Models. It is widely used in studies that are supposed to work on patients based on Nursing Models or to work on adaptation in chronic patients.