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Evaluation of the PROCARE nursing intervention on device acceptance in patients with newly implanted cardiac defibrillators

Submission date
19/01/2013

Recruitment status
No longer recruiting

Registration date
30/01/2014

Overall study status
Completed

Last Edited
19/01/2015

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Patients with an Implanted Cardiac Defibrillator (ICD) have less risk of death from cardiac arrhythmias (irregular heartbeat). However, there are many concerns about this device, including ICD shocks, which may result in increased anxiety and limitation in performing everyday activities. Due to these emotional reactions and behavioural changes patients may not accept this device. The purpose of this study was to find the feasibility, acceptability and initial effectiveness of an individualized nursing intervention aimed at improving device acceptance and performance in everyday activities and decreasing anxiety in patients with newly implanted ICDs.

Who can participate?
Adult patients with a first-time ICD implanted can take part in the study.

What does the study involve?
For all participants, data are collected at the start and 1 month after hospital discharge. Patients are randomly allocated to two groups. Those in the experimental group received three interventions, with the first being a face-to-face encounter before hospital discharge, followed by two subsequent telephone interventions at 7 and 14 days post-discharge. Those in the control group received usual care in the hospital.

What are the possible benefits and risks of participating?
There are no known risks to the participants. However, time is needed for face-to-face encounters (for those in the experimental group) and to respond to questionnaires for participants in both groups.

Where is the study run from?
Montreal Heart Institute, Canada.

When is study starting and how long is it expected to run for?
The recruitment started in June 2011 and ended in April 2012, including a one month follow-up.

Who is funding the study?
Quebecs Ministry of Education, Recreation and Sports, Canada.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluation of a caring and cognitive behavioural nursing intervention on device acceptance in patients with newly implanted cardiac defibrillators

Acronym
PROCARE

Study objectives

The purpose of this randomized controlled pilot study was to evaluate the feasibility, acceptability and preliminary efficacy of an individualized nursing intervention on device acceptance in patients with newly implanted cardiac defibrillators.

The study hypothesis was that at one month post hospital discharge patients who received the intervention would demonstrate better device acceptance and performance of everyday activities, as well as less defibrillator shock and general anxiety compared to the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Montreal Heart Institute, 11/05/2011, ref: 11-1294

Study design
Randomized pilot study two groups

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Patients with Newly Implanted Cardiac Defibrillators

Interventions
Experimental intervention (three encounters):
At the start of each encounter, the nurse encouraged the patient to express their major concerns /worries about the ICD. Then the research nurse proposed an individualized intervention, based on Human Caring theory and a cognitive behavioural approach. From the reported concerns, the nurse focused the intervention on the patients dysfunctional beliefs that can lead to anxiety and avoidance behaviours.
The research nurse undertook this assessment-intervention process three times:
1. Face-to-face encounter before hospital discharge, after ICD implantation;
2. By telephone 7 ± 2 days following discharge, and;
3. By telephone 14 ± 2 days following discharge.

Control group:
The control group continued to benefit from usual hospital care and follow-up.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Acceptability and feasibility of the intervention and the methodological aspects of the study

Secondary outcome measures
1. Device acceptance - Florida Patient Acceptance Survey (FPAS), Burns, Serber, Keim, & Sears, 2005.
2. Performance in everyday activities - Functional Performance Inventory (FPI)- Short Form, Leidy, 1999; Leidy & Knebel, 2010.
3. Defibrillator shock anxiety - Florida Shock Anxiety Survey (FSAS), Kuhl, Dixit, Walker, Conti, & Sears, 2006.
4. General anxiety - Hospital Anxiety and Depression (HAD) Scale (anxiety sub-scale only), Zigmond & Snaith, 1983.

Data were collected at baseline and 1 month after hospital discharge.

Overall study start date
01/06/2011

Completion date
01/12/2012

Eligibility

Key inclusion criteria
1. Aged 18 years or older, no upper age limit and either sex
2. Patients with first-time implantable cardiac defibrillators (ICD)
3. Speak, read and understand French
4. Physical and cognitive capabilities to participate
5. Hospital length of stay of two weeks or less after ICD implantation
6. Returning home after hospital discharge (not to long-term care, rehabilitation or other health care facilities)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Having a regular and specialized follow-up (e.g., every week or every month) in a Heart Failure Clinic or an Adult Congenital Heart Center
2. Participate in another clinical research project, or regular follow-up by a specialist such as a psychiatrist or nurse practitioner, to avoid doubling the interventions by different professionals
3. Being referred or followed in palliative care or similar, or being in end-stage heart failure [New York Heart Association (NYHA) class IV]

Date of first enrolment
01/06/2011

Date of final enrolment
01/04/2012

Locations

Countries of recruitment
Canada

Study participating centre
Montreal Heart Institute Research Centre
Montreal
Canada
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Sponsor information

Organisation
Montreal Heart Institute Research Center (Canada)

Sponsor details
c/o Gilles Lefebvre
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Sponsor type
Hospital/treatment centre

Website
http://www.icm-mhi.org/en/index.html

ROR
https://ror.org/03vs03g62

Funder(s)

Funder type
Government

Funder Name
Quebec Interuniversity Nursing Intervention Research Group [Groupe de recherche interuniversitaire en interventions en sciences infirmières du Québec (GRIISIQ)] (Canada)

Funder Name
Quebecs Ministry of Education, Recreation and Sports [Ministère de lÉducation, du Loisir et du Sport (MELS)] (Canada)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		01/10/2010		No	No
Abstract results		01/09/2011		No	No
Abstract results		01/09/2012		No	No