WEB-based distress management program for implantable CARdioverter dEfibrillator patients.

Published: 08-09-2009
Last updated: 06-05-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON37227

Source
ToetsingOnline

Brief title
WEBCARE

Condition

- Cardiac arrhythmias

Synonym
life threatening arrhythmias, ventricular fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Distress, Implantable cardioverter defibrillator, Internet interventie

Outcome measures

Primary outcome

Anxiety; depression; ICD concerns; ICD acceptance; quality of life; health care

utilization;

cost-effectiveness of the intervention.

Secondary outcome

Ventricular arrhythmias; cortisol awakening response

Study description

Background summary

The implantable cardioverter defibrillator (ICD) constitutes the treatment of choice in patients who have experienced life-threatening cardiac arrhythmias and in patients at risk for these cardiac arrhythmias. Several clinical trials have shown that the ICD is superior to antiarrhythmic drugs in the prevention of sudden cardiac death. The ICD can terminate life-threatening arrhythmias by antitachycardia pacing or shocks.

Despite the medical benefits of ICD treatment, 25-35% of ICD patients experience clinical levels of anxiety and poor quality of life. Adaptation problems have several causes, including the experience of resuscitation and the unpredictable reoccurrence of life-threatening arrhythmias and ICD therapies. For these patients, behavioral intervention may be warranted in order to reduce distress and secondary outcomes, such as avoidance behavior, physical inactivity, and poor quality of life. In addition, preliminary evidence indicates that emotional distress may precipitate life-threatening arrhythmic events, with a successful reduction in distress potentially leading to a decrease in these arrhythmias. Given the exponential rise in ICD implantations and the projected increase in the future, knowledge of the efficacy of behavioral interventions is important in order to optimize clinical management of these patients.

Study objective

The general objective of the intervention trial will be to evaluate the effect of this web-based behavioral intervention on psychological outcomes (i.e., anxiety and quality of life), physiological parameters (i.e., ventricular arrhythmias and salivary cortisol levels), and self-care and health-care utilization. In addition, the potential moderating influence of psychological (i.e., personality and positive affect) and clinical (i.e., cardiac synchronization therapy) factors on the effectiveness of the intervention will be determined. Finally, the cost-effectiveness of the intervention will be evaluated.

Specific objectives:

Primary
1. To investigate whether the web-based intervention is superior to usual care in terms of reducing anxiety and ICD concerns as well as improving ICD acceptance and quality of life.
2. To investigate whether the web-based intervention is cost-effective and leads to a reduction in health-care utilization in the intervention group as compared to the usual care group.

Secondary
1. To examine whether psychological (i.e., Type D personality and positive affect) and clinical factors (i.e., cardiac resynchronization therapy) moderate the effect of the intervention, with a view to developing risk profiles of patients who are less likely to benefit from the intervention.

Exploratory
1. To explore whether the web-based intervention influences physiological parameters (i.e., ventricular arrhythmias and the cortisol awakening response).

Study design

The study design is a prospective, multi-center, multi-disciplinary, randomized controlled web-based behavioral intervention trial, with usual care comprising the comparison group.

Standardized and validated questionnaires will be administered at four time points. At baseline (i.e., 1 day prior to implantation and randomization), 3 months (i.e., at the end of the intervention), and 6 and 12 months. Salivary cortisol will be assessed at the majority of these time points. Information on the occurrence of life-threatening arrhythmias will be obtained from the patients' medical records.

Intervention

The proposed behavioral intervention will be web-based, comprising 8 modules

with a duration of 3 months starting two weeks after ICD implantation. The main components include education about the ICD, cognitive restructuring and problem-solving skills, and relaxation training.

Study burden and risks

Given that a web-based behavioral intervention is provided to the treatment arm, and no invasive medical procedures nor withholding medical treatment are done, there are no risks associated with participation in the study. The burden to patients is comprised of completing a set of standardized and validated questionnaires at 4 time points and providing saliva samples at 3 time points. It is estimated that it will take 45 minutes to complete the set of questionnaires at each time point. No extra scheduled visits to the hospitals are nessary for patients participating in the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Patients receiving an ICD implantation.
- Age between 21 and 75 years.
- Speaking and understanding Dutch.
- Access to internet.
- Ability to use internet.
- Providing written informed consent.

Exclusion criteria

- Patients with a life expectancy less than 1 year.
- Patients with a history of psychiatric illness other than affective/anxiety disorders.
- Patients on the waiting list for heart transplantation.
- Patients with insufficient knowledge of the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-04-2010
Enrollment:	350
Type:	Actual

Ethics review

Approved WMO Date:	08-09-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-09-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-05-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT00895700
CCMO	NL25617.078.09