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Web-based psychotherapeutic intervention to reduce anxiety levels in patients with an implantable cardioverter defibrillator and co-morbid anxiety after shocks

Submission date
15/06/2015

Recruitment status
No longer recruiting

Registration date
15/06/2015

Overall study status
Completed

Last Edited
15/06/2015

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
Implantation of a cardioverter defibrillator (ICD) is the established treatment to prevent sudden cardiac death for patients who are at increased risk for developing malignant ventricular arrhythmias (dangerously abnormal rapid heart rhythms). The number of patients implanted with an ICD has increased substantially over the last years. However, some of these ICD patients experience become more anxious and depressed after receiving one or multiple therapeutic shocks. According to an own previous study, 19 % of ICD patients suffer from an anxiety disorder. When asked for treatment wishes most of them preferred a psychotherapeutic group setting. Until now there is no evidence-based treatment available for this patient group. In this pilot study, we want to test the feasibility and success of a short psychotherapeutic group treatment for anxious patients receiving ICD shocks using web-based video conferencing technology.

Who can participate?
ICD patients suffering from anxiety who received one or multiple shocks along with their partners or caregivers

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (the control group) are requested to regularly attend medical follow-ups in their cardiology unit and to comply with the medical advices given. Those in group 2 (experimental group) are given the same information in addition to a 10-session-psychotherapy web-based intervention (three single and seven group psychotherapeutic sessions). Anxious, depressive and traumatic symptoms and quality of life are measured using HADS (Hospital Anxiety and Depression Scale), PHQ-D (Patient Health Questionnaire), IES-R (Impact of Event Scale – Revised), GHQ-12 (General Health Questionnaire 12) and SF-36 (Short Form) by all ICD patients and their partners or care givers

before the study begins, immediately after treatment, and then 6 months and 12 months after treatment. A year after the intervention group has finished, the web-based psychotherapy intervention will also be offered to the control group.

What are the possible benefits and risks of participating:
Each patient may benefit in terms of improved coping abilities with anxiety and distress in the future by participating in the intervention. There are no increased risks of physical injury or harm.

Where is the study run from?
The study is run by the Department of General Internal Medicine and Psychosomatics, University Medical Care Center Heidelberg. Recruitment is carried out in the outpatient units of University Medical Centers of Heidelberg and Mannheim and of Clinical Center of Ludwigsburg.

When is the study starting and how long is it expected to run for?
June 2015 to March 2017

Who is funding the study?
German Heart Research Foundation (Deutsche Stiftung für Herzforschung (Frankfurt am Main))

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
Psychotherapeutic web-based intervention for anxious patients after receiving shocks by an implantable cardioverter defibrillator: a randomized wait-list controlled pilot study

Acronym
ESCAAD (Educated Self-Management for Cardiac Arrhythmia and Anxiety Disorder)

Study objectives
The primary objective of this pilot study is to examine the acceptability and feasibility of:
1. The study design
2. The experimental psychotherapeutic intervention for anxious patients receiving shocks by an implantable cardioverter defibrillator (ICD)
The intervention consists of three single and seven group sessions. The secondary objective of this pilot study is to examine the preliminary effect of the intervention on patient and caregiver outcomes. The following are the research hypotheses for the study's secondary objective:
Compared with controls, patients in the intervention group will present:
H1. Fewer anxious symptoms directly after and 6 and 12 months after intervention
H2. Fewer depressive, traumatic symptoms and a better quality of life directly after and 6 and 12 months after intervention
H3. Fewer cardiological treatments in inpatient and outpatient settings
H4. Fewer ICD shocks

Compared with controls, partners of caregivers of ICD patients in the intervention group will present:
H5. Fewer anxious symptoms directly after and 6 and 12 months after intervention
H6. Fewer depressive, traumatic symptoms and a better quality of life directly after and 6 and 12 months after intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Board of the Medical Faculty / Heidelberg University, 10/06/2015, ref: S-543 /2015

Study design
Randomized wait-list controlled pilot study with an allocation ratio of 1:1

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
ICD patients receiving shocks with co-morbid anxiety disorder

Interventions
The intervention consists of three single and seven group psychotherapeutic sessions through a web-based video conference software. For this purpose we created a therapeutic manual including psychoeducational, psychodynamic and behavioral therapeutic elements. The single sessions are to establish a reliable working alliance. The partner or care giver of each study participant is invited to one single session for a closer look on the couple's perspective. Within the group sessions psychoeducation, relaxation techniques and exposition exercises should help the patients to understand and to deal with their anxiety for ICD shocks and teaches them how to cope with anxiety and stress-provoking situations. Furthermore patients can share their concerns and their experiences with other anxious ICD recipients.
The control group is to adhere closely to cardiologists' advices, i.e. they get treatment as usual.

Intervention Type
Behavioural

Primary outcome measure
1. Patients' satisfaction with the intervention on a visual analogue scale directly after treatment
2. The preliminary effect size for change in anxiety level measured by GAD-7
3. Recruitment rate is determined by measuring the percentage of all ICD patients willing to participate in the intervention to all meeting the inclusion criteria

Secondary outcome measures
1. Drop out rates
2. Anxious, depressive and traumatic symptoms and quality of life of ICD patients and their

partners or care givers are measured with HADS, PHQ-D, SF-36, GHQ-12 and IES-R before (T0) and after intervention (T1) and at 6 and 12 month follow-up (T2, T3)
3. Number of cardiological treatments in inpatient and outpatient settings and the frequency of ICD shocks at T0, T1, T2 and T3

Overall study start date
16/06/2015

Completion date
01/03/2017

Eligibility

Key inclusion criteria
1. ICD patients receiving one or multiple shocks
2. Confirmed diagnosis of an anxiety disorder (SCID interview)
3. Sufficient anxiety level : HADS ≥ 8 or GAD-7 ≥ 10 or panic disorder in PHQ-D
4. Age between 18 and 75 years
5. Sufficient knowledge of the German language
6. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Severe dementia or any other psychiatric or cognitive diseases which hampers the capacity to consent
2. Any acute or chronic disease which prevents patients to participate in the intervention
3. No internet accessible

Date of first enrolment
16/06/2015

Date of final enrolment
01/08/2015

Locations

Countries of recruitment
Germany

Study participating centre
University of Heidelberg, Medical Hospital
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Study participating centre
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Sponsor information

Organisation
Department of Internal Medicine II (General Internal and Psychosomatic Medicine)

Sponsor details

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Sponsor type
Hospital/treatment centre

Website
https://www.klinikum.uni-heidelberg.de/Willkommen.1088.0.html

ROR
https://ror.org/038t36y30

Funder(s)

Funder type
Charity

Funder Name
Deutsche Herzstiftung

Alternative Name(s)
German Heart Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Germany

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration