

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/06/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/06/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

Dr. Sascha Wohnsland

Sascha.Wohnsland@med.uni-heidelberg.de

Contact information

Type(s)

Scientific

Contact name

Dr Sascha Wohnsland

ORCID ID

<http://orcid.org/0000-0003-3564-1273>

Contact details

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

University of Heidelberg, Medical Hospital

Heidelberg

Germany

69120

004962215637357

Sascha.Wohnsland@med.uni-heidelberg

Type(s)

Public

Contact name

Dr Sascha Wohnsland

Contact details

Department of Internal Medicine II (General Internal and Psychosomatic Medicine)
University of Heidelberg, Medical Hospital
Heidelberg
Germany
69120
004962215637357
Sascha.Wohnsland@med.uni-heidelberg.de

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

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

Im Neuenheimer Feld 410

Heidelberg

Germany

69120

Study participating centre

University of Heidelberg, Medical Hospital

Department of Internal Medicine III (Cardiology, Angiology, Pulmonology),

Im Neuenheimer Feld 410

Heidelberg

Germany

69120

Study participating centre

1st Department of Medicine – Cardiology, University Medical Centre Mannheim

Theodor-Kutzer-Ufer 1-3

Mannheim

68167

Study participating centre

Clinical Center Ludwigsburg

Department of Internal Medicine (Cardiology, Nephrology, Intensive Care)

Posilipostraße 4

Ludwigsburg

Germany

71640

Sponsor information

Organisation

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

Sponsor details

University of Heidelberg, Medical Hospital
Im Neuenheimer Feld 410
Heidelberg
Germany
69120

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