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Behavioral interventions in patients with an implantable cardioverter defibrillator: Lessons learned and where to go from here?

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Abstract

Background—The implantable cardioverter defibrillator (ICD) is the first line treatment for primary and secondary prevention of sudden cardiac death. A subgroup of patients experiences psychological distress post implant, and no clear evidence base exists regarding how best to address patients' needs. The aim of this critical review is to provide an overview of behavioral interventions in ICD patients to date, and to delineate directions for future research using lessons learned from the ongoing RISTA and WEBCARE trials.

Methods—We searched the PubMed and PsycInfo databases to identify reports of behavioral trials targeting distress and related factors in ICD patients published between 1980 and April 2012.

Results—We identified 17 trials for the review. Generally, compared to usual care, behavioral interventions were associated with reduced anxiety and depression, and improved physical functioning, with effect sizes ranging from small to moderate-large (0.10 – 1.79 for anxiety; 0.23 – 1.20 for depression). Important limitations were small sample sizes and potential selection bias, hampering generalizability of the results. In addition to a need for larger trials, experiences from the RISTA and WEBCARE trials suggest that intervention trials tailored to the individual patient may be the way forward..

Conclusions—Behavioral interventions show promise with respect to reducing distress in ICD patients. Large-scale intervention trials targeted to the individual needs and preferences of patients are warranted, as a 'one size fits all' approach is unlikely to work for all ICD patients.

Keywords

Implantable cardioverter defibrillator; randomized controlled trials; psychological interventions

Introduction

The implantable cardioverter defibrillator (ICD) is the treatment of choice for patients who have experienced a sudden cardiac arrest (SCA) or are at risk of SCA due to impaired left ventricular function^{1, 2}. The ICD is generally well accepted by the majority of patients and is

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perceived as a life saving device³. A subgroup of patients (25–33%), however, experience psychological distress after implantation, including anxiety, depression, posttraumatic stress disorder, and impaired quality of life^{3–56}. Distress may increase the risk for ventricular arrhythmias and ICD shocks, and lead to even more distress in a feed forward cycle. An anxious patient who has experienced a shock might become even more anxious about shock, this anxiety could then lead to experiencing additional shocks etc^{7, 8}. Besides ICD shocks^{9, 10}, other factors, including personality^{11, 12}, symptomatic heart failure¹³, and pre-implantation illness beliefs¹⁴ may increase the risk of distress. The further importance of distress beyond its impact on quality of life is demonstrated by the association between distress and mortality in ICD patients^{4, 15}.

Preliminary evidence suggests that despite the association with adverse health outcomes, distress, anxiety, and depression are still undertreated in ICD patients¹⁶. Two previously published reviews addressing the effectiveness of behavioral interventions in reducing these psychological sequelae among ICD patients concluded that the results of Phase-II and early Phase-III clinical trials that utilized these interventions are promising¹⁷. These reviews also advised caution, due to considerable limitations of the trials reviewed, which were notable with respect to small sample sizes potentially reduced statistical power, selection bias, and questionable generalizability^{17, 18}. While these prior reviews provided a thorough assessment of trial effectiveness to their time of publication, there has since been an over 40% increase in the number of published randomized clinical trials testing a behavioral intervention to improve psychological outcomes in ICD patients. Furthermore, neither of the reviews provided recommendations with respect to how to proceed with the larger Phase-III and Phase-IV trials that are needed for the establishment of a sufficient evidence base to inform clinical practice.

In this critical review and evaluation of the behavioral trials literature in ICD patients to date, we will focus more on the recent trials, with particular attention to “lessons learned” overall. Furthermore, we will utilize our own experiences from the ongoing ‘*Reducing Vulnerability to ICD-Shock Treated ventricular Arrhythmias Trial*’ (RISTA)¹⁹ and the ‘*WEB-based distress management program for implantable CARDiovert dEFibrillator patients*’ (WEBCARE)²⁰ trials to help illustrate directions for future research.

Methods

The databases PubMed and PsycInfo were searched for the period between January 1980 and April 2012. A combination of the following search terms was used: *Implantable cardioverter defibrillator; psychosocial; psychological; behavioral; intervention; therapy; treatment; rehabilitation*. All studies with an experimental design, including evaluation of an intervention with a psychological component, which were published in a peer-reviewed English language journal were included. Reviews, case studies, and descriptive studies were excluded. The search resulted in 517 hits, with 444 from PubMed and 73 from PsychInfo. After removing double hits and evaluation of the title and abstract, 501 studies did not meet the inclusion criteria and were excluded, resulting in a total number of 16 studies. A hand search of the reference list of these studies identified 1 additional study. A total number of 17 studies was identified, 5 of which had not been published at the time of the prior reviews¹⁷. Each of these more recent trials was then examined. For each of these trials, the effect sizes were calculated with respect to the impact of the trial intervention on anxiety and/or depression (if data were available). For the calculation of the effect sizes, we only focused on anxiety and depression, as these have been the most common endpoints reported. An effect size index (indicated by Cohen’s *d*) of .20 is considered small, .50 medium, and .80 or higher as large²¹.

Recent findings

In Table 1, an overview of the main characteristics of the 17 randomized controlled trials (RCTs) is displayed. Focusing on the five more recently published trials, we found that the results are comparable to those of the previously published trials¹⁷. The number of patients that were included in these five more recent trials ranged from 14 to 96 for the intervention group and 15 to 97 for the controls^{22–26} (as compared to 6–84 and 5–121 in previous trials). Four out of five trials showed significant improvement in psychological distress^{23–26} (e.g., (shock) anxiety, depression, posttraumatic stress disorder (PTSD)), while in one study no significant effect of the intervention compared to usual care was observed²². Furthermore, no significant change in cardiac outcomes (shocks and anti-tachycardia pacing (ATP)) was observed²⁴. The effect sizes in these trials ranged from 0.10 to 0.72 for anxiety, and 0.23 to 0.61 for depression (Table 2), indicating a low to moderate-large effect. For three of the five trials, the intervention was comprised mainly of psycho-educational sessions^{22, 23, 25} (information about the ICD and psychological impact was provided in written form or face-to-face at the time of implantation) with or without additional training in cognitive behavioral therapy (CBT) and techniques to improve coping skills. Two remaining studies used CBT with, among other components, psychoeducation and relaxation exercises, as part of the treatment^{24, 26}. Three of the studies defined the control condition as “usual care”,^{22–24} with the remaining two using a wait-list control group which received the treatment at the end of the study^{25, 26}. A detailed description of the study components is displayed in Table 3.

Overall, the design of these five RCTs was comparable to the 12 previously published trials¹⁷, with all recruiting patients at the time of implantation or shortly thereafter. Furthermore, the effect sizes for the five more current trials were comparable to the effect sizes published in the prior trials, indicating that behavioral interventions for ICD patients that include CBT components, psychoeducation, relaxation techniques, and means to improve coping skills, are promising for reducing anxiety, depression, and psychological distress^{23–26}. At the same time, these trials utilized relatively small samples, and thus with the same methodological limitations as earlier published trials, necessitating caution when interpreting the findings^{17, 18}. In particular, generalizability continues to be an issue, and it remains to be demonstrated that the interventions being tested are acceptable to the broader ICD population. Therefore, the establishment of sufficient evidence base to inform clinical practice on how to manage anxiety, depression, and distress in ICD patients remains an important research imperative.

Behavioral interventions in ICD patients

When we consider all trials published to date, we find that the majority of the studies (12/17) were based on sample sizes of 35 patients in both the intervention and control groups. The mainstay of treatment in these trials has been CBT, focusing on correction of common misconceptions and problem solving skills, comparing this to care as usual, whereby patients receive information about the ICD provided by the manufacturer along with a standard follow-up of the device (for a detailed description of the intervention components and the control groups see Table 3). Particularly strong effects are shown for reductions in anxiety symptoms^{23, 26–32} with effect sizes ranging between 0.10 to 1.79, as indicated by Cohen's *d* (Table 2), but improvements in depression^{23, 29–31} (effect size range from 0.23 to 1.20), exercise capacity³³, and posttraumatic stress symptoms²⁴ are also reported. A number of trials have examined the effects of the intervention on cardiovascular endpoints, including ICD shocks, arrhythmias, ATP, heart rate variability (HRV), salivary cortisol, and the inflammatory markers tumor necrosis factor (TNF)- α and interleukin (IL)-6^{24, 27, 29, 31–34}. Only one trial found an effect of the intervention on these endpoints, showing a significant improvement in HRV for the CBT group as compared to the care as usual group²⁷. Thus,

while behavioral interventions appear promising for improving psychosocial outcomes in ICD patients, any improvements in cardiovascular outcomes remain to be demonstrated.

Issues for the establishment of an evidence base

Despite promising trends towards improvement in psychosocial outcomes in ICD patients following behavioral intervention, and an increase in the number of trials conducted over the past 20 years, significant concerns about study power and validity remain, with the majority of these trials being statistically underpowered for the findings to be considered as an evidence base to inform clinical practice^{22, 25–27, 29, 30, 32, 33, 35–37}. The low recruitment rate and high attrition rate described in the literature may contribute to studies being underpowered, highlighting difficulties with participant engagement that must be addressed for the field to advance. Specific obstacles include the need for patients to travel to a central site for receipt of the intervention, and the logistics of accomplishing this^{29, 30, 33}, with patients describing a preference for treatment closer to their home³⁰. With these issues, the trial literature is likely biased towards the more motivated patients, and thus may only be applicable to those who are likely to actively seek care for psychological distress. If this bias holds, implementation of tested interventions in clinical practice would not be as successful as the study findings might suggest.

An associated problem with respect to the development of a sufficient evidence base concerns the severity of disease among the greater ICD population that is to be enrolled in behavioral trials. The primary indication for an ICD implant is significant impairment in left ventricular function¹. Therefore, the majority of the ICD population have heart failure. Indeed, it is patients with more impaired left ventricular function who are at highest risk for ICD shock and thus for potential psychological sequelae, such as anxiety, distress, and depression^{13, 38}. Yet, it is this patient group who are more likely to decline trial participation^{22, 23}. Due to low response rate and high drop-out – particularly in this sub-group – the generalizability of the trial findings to date for the larger ICD population remains to be demonstrated.

While these issues comprise important limitations to the behavioral trials literature in ICD patients, we can learn important lessons from these trials with respect to advancing the field. Two recent and ongoing trials (RISTA and WEBCARE) have taken different approaches to addressing these issues. Lessons learned from these trials will be described in detail next. We will discuss our experiences from these trials illustrating the problems that were encountered, how they were dealt with, and how this experience can inform future trials that aim to establish an evidence base for treating psychological distress and thereby optimizing the management and care of ICD patients in clinical practice.

RISTA

RISTA is an RCT conducted in the US that aims to test the effects of a cognitive behavioral stress reduction intervention (SRT) on the prevalence of shock treated ventricular arrhythmia compared to usual care control among patients with an ICD. Secondary outcomes include quality of life, and autonomic and electrophysiological arrhythmogenic indices during a standardized laboratory mental stress protocol, and during 24-hr holter monitoring. RISTA recruited 318 patients between February 2008 and February 2012. Patients recruited were within 6-months of a first ICD implantation and/or were prior ICD recipients who had received appropriate device therapy (shock, ATP) for a ventricular arrhythmia in the prior 6 months (a group at higher risk for subsequent arrhythmias). Follow-up is for up to 2-years from randomization. The RISTA trial design has been published previously¹⁹.

RISTA intervention—The SRT protocol developed for RISTA was modeled after the group therapy component of the intervention used in the ENRICHD clinical trial³⁹ and consists of 8, 90 minute group sessions delivered over a 10 week period by a licensed clinical psychologist or social worker. Briefly, it utilizes a cognitive-behavioral model of stress that emphasizes the interactive relationship of cognition, emotion, physiology and behavior. SRT targets each aspect of this model to provide patients with several different tools they can utilize to prevent or reduce stress. Content material is presented in a didactic format with skill guidelines and in-session exercises and includes: cognitive stress model; relaxation strategies (e.g. diaphragmatic breathing, breath counting meditation, progressive muscle relaxation, visualization, self-hypnosis, and autogenic training); cognitive restructuring; skills training in problem solving, communication and assertiveness, and goal setting/time management. Homework assignments are presented at the end of each session to facilitate practice of new skills. Participants are provided with workbooks that include both information sheets on material covered in the sessions, and monitoring forms to facilitate acquisition of skills and home practice. The intervention has elsewhere previously been described in detail¹⁹.

To address some of the limitations discussed previously, patients randomized to the intervention have been able to “conference in” to group sessions by telephone if circumstances (e.g., travel difficulties, poor health) precluded their physical attendance. These efforts were made at the outset to facilitate participation and thereby promote a more representative patient population in the trial.

Issues of Recruitment and Protocol Delivery—At approximately the time that RISTA began recruitment, a number of issues with ICD devices and leads were identified. This had a significant impact on the number of new implants performed at the trial recruitment centers and thus the number of patients available for the RISTA trial. Despite adding additional centers, the overall population to sample from was lower than had been projected, slowing down the overall rate of recruitment for the trial.

A second issue arose as a consequence of the reduced population from which to recruit. Since a cohort of at least 3 patients was required to form a treatment group, the study needed to recruit approximately twice that many to initiate a group, assuming equal randomization to intervention and usual care conditions. Thus, because of the slower than anticipated recruitment rate, patients randomized to receive the intervention often had to wait several months before there were enough patients for the intervention to be initiated. During this intervening period, many patients returned to previous commitments, initiated new commitments, moved, or experienced exacerbations of congestive heart failure, each of which reduced their continued enthusiasm for being in the trial.

Taken together, this highlights that: 1) interventions should be made easily available to ICD patients (i.e., requiring limited time and travel, and can be fit into their daily routine); 2) delivery of interventions involve a minimal wait for implementation; and 3) interventions match the need of the individual patient, where the intensity and “dose” of treatment can be increased or decreased according to the patient’s needs.

WEBCARE

WEBCARE is a behavioral RCT testing the effects of web-delivered intervention targeting symptoms of anxiety, depression, ICD concerns, ICD acceptance, and quality of life²⁰. Secondary outcomes include investigating whether psychological (e.g. Type D personality, positive affect) and clinical factors (e.g. heart failure, indication) moderate the effect of the intervention, and whether the intervention influences physiological parameters (e.g. ventricular arrhythmias, cortisol awakening response). Study participants are consecutively

first-time implanted ICD patients, with one of the primary eligibility criteria being internet access and a requisite level of internet skills. Patients are recruited from seven university medical centers or peripheral hospitals in the Netherlands. The study design of WEBCARE has been published elsewhere²⁰.

WEBCARE intervention—The web-delivered intervention is based on a previously developed and evaluated online intervention for a depressed healthy population ‘*Everything Under Control*’ (‘*Alles Onder Controle*’)⁴⁷ that we adapted to ICD patients. The intervention utilizes problem solving therapy and consists of 6 online lessons. Patients randomized to the intervention condition are required to do the homework assignments that accompany 5 of the 6 lessons and are provided with personalized feedback by a therapist within 2–3 days via the computer. In addition, intervention patients are provided with relaxation training exercises on CD, which they are encouraged to use. Internet interventions tend to have a low threshold accessibility, require no extra hospital visits, result in less stigma, and are accessible when-and wherever the patients want it⁴⁸. Knowing that a proportion of the ICD patients may be part of a relatively sick population, an intervention which does not require additional hospital visits but is accessible to a large number of patients was expected to result in a higher response rate and also provide support to an underserved group.

Issues of recruitment—Recruitment of patients started in April 2010 and is still ongoing, with the targeted number of patients being 350. Initially, three hospitals were involved, where a total number of 870 new ICD implants are performed on an annual basis. Both cardiologists and ICD nurses from the participating centres are actively involved in patient recruitment. Briefly after recruitment was initiated, we encountered several problems. First, the number of eligible patients was much lower than expected. More than 50% of patients were excluded because they 1) did not have internet access or skills, 2) were older than 75 years, and 3) did not speak Dutch. A significant number of patients were lost to competing clinical trials being performed at the recruiting centres, as patients are only allowed to be included in one clinical trial at a time. Thus, using a web-based approach as in WEBCARE has not substantially increased the number of ICD patients that can participate.

To optimize the recruitment rate, we decided to expand the number of participating centers from three to seven. In addition to this expansion, we invested more time in providing extra information to recruiting personnel and motivating them by organizing steering committee meetings, introducing a newsletter that is mailed to all parties involved in the study every 3 months, and visiting the recruitment sites on a regular basis.

Attrition—Patients who met the inclusion criteria have generally been positive about the study and expressed this to the recruitment personnel. The fact that no extra hospital visits are required and that patients can decide when and where they access the intervention is described by participants as a major advantage. Despite this early enthusiasm, a significant drop-out has still been observed in the intervention group. The reasons given by patients include that participation is too time consuming, too much work, too confronting, and too much to think about at this time point, with some patients also stating that they would prefer face-to-face treatment, or that they feel just fine and thus do not see the need. The intervention is offered within 2 weeks after ICD implantation, which might be too soon, as patients might be more focused on other aspects, such as their heart disease (e.g. for those patients receiving the ICD after a sudden cardiac arrest or an acute myocardial infarction) and not being allowed to drive and the implications that this has for their daily lives,. Perhaps introducing a watchful waiting period in the intervention as described in previous studies within the cardiac population^{51, 52} would have been helpful in reducing the attrition rate.

Discussion

Behavioral intervention trials in ICD patients have shown promising results with respect to reductions in psychological distress¹⁷, although effect sizes (Cohen's *d*) vary widely from 0.10 (negligible) to 1.79 (large) for anxiety symptoms and between 0.23 (small) to 1.20 (large) for depression symptoms. Significant decreases in PTSD symptoms have also been reported in one study²⁴. However, effects on cardiovascular endpoints (e.g. shocks and arrhythmias) remain elusive^{24, 27, 29–31, 33, 34}. Generally, inclusion of CBT as one of the core components seems to have a beneficial effect on the outcomes of behavioral interventions in ICD patients. Nevertheless, despite these promising results large scale trials that can help establish evidence-based medical practice are generally lacking⁵³.

The ongoing RISTA and WEBCARE trials included a larger sample size and evaluated the feasibility of an e-health intervention to address some of the limitations reported in previous studies. Still the RISTA and WEBCARE trials have been faced with significant challenges related to patient recruitment and drop-out, overestimation of the prevalence of end points (e.g. shocks) as well as changes to device therapy and the management of ICD patients in clinical practice. This demonstrates the complexity of performing intervention trials in the ICD population in a field that from a technological vantage point is continuously evolving.

Recommendations

Based on lessons learned from earlier trials and the ongoing RISTA and WEBCARE trials, recommendations for future research in this area are outlined in Table 4. Given the findings from previous trials, the use of CBT components is also recommended for future RCTs. The addition of behavioral activation⁵⁴ to a treatment “package” containing these components could furthermore help patients engage in previous daily activities and thereby support post-implant normalization and improved quality of life. We also recommend that future RCTs take into account patient preferences (as the ICD population is diverse) and use interventions that are targeted to the individual patient using a collaborative, stepped care, patient tailored approach. To make the intervention more patient tailored one could consider targeting different subgroups of patients, for example: primary versus secondary patients, patients with heart failure versus patients without heart failure, and younger patients versus older patients. This way patient' psychological needs could be better met also leading to higher recruitment rates. In addition, a stepped care, patient tailored approach, with a attention control group could also provide us with more insight in the effectiveness of the specific CBT components that are included in the intervention.

In order to enhance our knowledge from future trials, it is important that current guidelines for reporting on clinical trials (i.e., the Consolidated Standards for Reporting Trials (CONSORT) Statement (www.consort-statement.org) be followed⁵⁵. The CONSORT statement covers 22 guidelines on how to report the findings from a clinical trial⁵⁶. Adherence to these guidelines enhances transparency and replicability, and allows the reader to learn from not only the positive aspects but also the challenges encountered when conducting the trial and address these issues in future studies.

Patient recruitment and retention strategies are not well understood within the ICD population and deserve more attention in future studies. The high drop-out in some studies is generally attributed to travel burden^{33, 37}. The burden of baseline and follow-up assessment has also been described as a reason for drop out³⁴. Understanding and addressing a priori the reasons for refusing to participate or for drop-out is of utmost importance for the development of recruitment strategies for larger future trials. A number of recommendations for improving patient recruitment can be made based on our experiences from the WEBCARE trial. We have learnt that having health care providers (e.g. ICD nurses) take an

active part in the recruitment process helps to increase the response rate. Patients are more willing to participate if approached by a familiar health care professional with whom they already have a good rapport and trust. Another way of reaching patients and keeping them in the study is to tailor the intervention to their needs and preferences, and to deliver it in a manner that makes it more accessible to them, whether this is by phone, internet, or other modality. The application of new technological developments in research such as the use of mobile applications (using mobile phones or tablets) appears promising and warrants further attention.

Patients may or may not be distressed at the time of implantation. Some patients will perhaps become distressed later on rather at the time of implant. The timing of the intervention is therefore crucial. An intervention that is tailored to the individual patient's needs (both psychological and logistical needs) is therefore more likely to be effective and to result in lower attrition rates and higher patient satisfaction⁵¹. As distress levels in ICD patients tend to decrease after the ICD implant⁵⁷, it might be useful to introduce a watchful waiting period in the study design in order to avoid targeting distress related to the implant itself that will remit spontaneously, thus providing treatment to those patients who need it the most.

Another important question remains whether future trials should have ICD therapy (e.g., ATP and shock) as outcomes. Previous trials showed that behavioral interventions did not successfully reduce these outcomes^{24, 27, 29–31, 33, 34}. However, these results should be interpreted with caution as these trials were generally not powered to answer this question. Another issue influencing the inclusion of (appropriate) shock as an endpoint is the enhanced programming of the ICD which results in a decreased prevalence of appropriate shocks. This in turn leads to a lower number of eligible patients to include in studies with shocks as an endpoint. Hence, shock or fear of shocks may be better targeted in a general intervention for ICD patients that, for example, make use of relaxation therapy and developing a 'shock plan'⁵⁸ as one of the components of the intervention. Focusing on patient centred outcomes with age, gender, personality, patients' expectations with respect to living with an ICD, and physical activity as mediators/moderators in addition to disease severity, would also be worthwhile examining in future studies. Finally, there is a need to examine the cost-effectiveness of behavioral interventions in ICD patients in order to increase the chance that they be implemented in standard care models. To date, no such information is available.

Conclusions

Behavioral RCTs in ICD patients show promise with respect to reducing psychological distress in this patient cohort. However, considering lessons learned from the RISTA and WEBCARE trials, patient variability in distress levels in terms of severity, time of onset, and chronicity, and the heterogeneity of the population in terms of indication for ICD implantation (i.e., primary versus secondary) suggest that a 'one size fits all approach' to intervention may not be the way to advance the field in order to optimize the management and care of these patients. A collaborative, stepped care approach provides an important alternative to the standard approach, allowing patients with less severe distress to be supported to engage in self-help treatment, while patients with higher levels of distress could get a more intensified and personalized approach that would be tailored to their specific needs. This approach has previously proven to be successful in reducing distress in other cardiac populations^{51, 52}. In addition, in order to perform large scale trials, it seems crucial that we gain more knowledge about how to successfully recruit patients, while minimizing patient drop-out.

For future studies, use of CBT components, the integration of modern technology (e.g. mobile phone applications) with a stepped care approach could prove to be an effective intervention for the majority of ICD patients. Although in WEBCARE the majority of patients had to be excluded due to lack of internet access or knowledge how to use the internet, we believe that in the future this problem will resolve itself as the next generation of ICD patients grow up with internet and associated technologies such as smart phones and their applications.

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Abbreviations

ICD	Implantable Cardioverter Defibrillator
SCA	Sudden Cardiac Arrest
RCT	Randomized controlled trial
PTSD	Posttraumatic stress disorder
ATP	Anti-tachycardia pacing
CBR	Cognitive Behavioral Rehabilitation
CBT	Cognitive Behavioral Therapy
CCR	Comprehensive Cardiac Rehabilitation
HRV	Heart rate variability
TNF-	Tumor Necrosis Factor –
IL-6	Interleukin -6
SRT	Stress Reduction Training

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Table 1

Overview of the included studies

Author	N _{Int}	N _{Con} [*]	Study design	Controls	Intervention	End points	Significant overall effect on end points
Badger and Morris (1989) ³⁵	6	6	Comparative study	Support group	Support group	QoL	NO
Carlsson et al., (2002) ⁵⁹	10	10	RCT	Usual Care	Education	QoL	NO
Chevalier et al., (2006) ²⁷	35	35	RCT	Usual Care	CBT	Shocks, HRV, QoL, anxiety, depression, defibrillator tolerance	Reduction in mean anxiety scores at 3 and 12 months in intervention vs control; improvement in HRV variability in the CBT group
Crössmann et al., (2010) ²²	56	63	RCT	Usual Care	Education, telephone support	QoL, psychological distress, anxiety, depression, fear and attitude regarding heart, ICD related concerns	NO
Dougherty et al., (2004, 2005) ^{28, 34}	84	84	RCT	Usual Care	Telephone support	Physical functioning, shocks, QoL, anxiety, depression, health care use, ICD-related knowledge	Reduction in physical symptoms at 1 month, anxiety at 3 months, increased knowledge at 3 months, Reduction in physical symptoms, anxiety, fear of dying, and enhanced knowledge at 12 months.
Dunbar et al., (2009) ²³	83/85 [*]	78	RCT	Usual Care	Education, counseling, symptom management, coping skills	Anxiety, depression, physical functioning, health resource use	Reduction in anxiety at 3 months, reduction in depressive symptoms at 3 and 12 months,
Edelman et al., (2008) ³⁶	13	9	RCT	Usual Care	Education	Anxiety, depression, stress, hostility	NO
Fitchet et al., (2003) ²⁹	8	8	RCT	Usual Care	CCR [*]	Arrhythmia, shocks, exercise, anxiety, depression	Reduction in anxiety pre- and post-treatment, reduction in depression.
Frizelle et al., (2004) ³³	12	10	RCT	Waiting-list	CCR	Shocks, ATP, QoL, exercise, anxiety, depression, ICD concerns, health status	Improvement on all exercise ability and psychological outcomes.
Irvine et al., (2011) ²⁴	96	97	RCT	Usual Care	CBT	Shocks, ATP, QoL, anxiety, PTSD, depression	Reduction in PTSD and improvement in QoL and depression (only in women).
Kohn et al., (2000) ³⁰	25	24	RCT	Usual Care	CBT	Shocks, anxiety, depression, psychosocial adjustment	Reduction in trait anxiety mean scores at 9 months, reduction in mean depression scores.

Author	N _{int}	N _{con} *	Study design	Controls	Intervention	End points	Significant overall effect on end points
Kuhl et al., (2009) ²⁵	15	15	RCT	Wait-list control	Education (computer)	QoL, trait anxiety, ICD acceptance, shock anxiety, cardiac specific QoL	Increased ICD acceptance in patients who demonstrated increase in learning
Lewin et al., (2007) ³¹	71	121	RCT	Usual Care	CBR**	Shocks, exercise, anxiety, depression, emergency hospitalization, health care costs	Reduction in number of patients with anxiety and depression in intervention vs control group.
Molchany and Peterson (2004) ³⁷	11	5	Comparative study	Usual Care	Support group	QoL, anxiety	NO
Sears et al., (2007) ³²	Total sample N=30		RCT	One-day workshop group	Education, relaxation, CBT, social support ("ICD-SSMP")	QoL, anxiety, ICD acceptance, salivary cortisol, TNFa, IL-6	Reduction in anxiety pre- and post-treatment, no difference at 4 months. Increase in mental health pre- and post treatment, no difference at 4 months.
Sneed et al., (1997) ⁴⁰	17	17	RCT	Usual Care	Counseling, telephone support, support group	Mood state, psychosocial adjustment	NO
Vazquez et al., (2010) ⁴⁶	14	15	RCT	Wait-list control	CBT	Shock anxiety, device acceptance	Reduction in shock anxiety and increase in device acceptance.

* Comprehensive Cardiac Rehabilitation

** Cognitive Behavioral Rehabilitation

Table 2
Effect sizes (Cohen's *d*) for impact of intervention versus usual care on anxiety and depression

Author	Follow-up	Effect size intervention		Effect size controls		Measures	
		ANX	DEP	ANX	DEP	ANX	DEP
Badger and Morris (1989) ³⁵	2 months	-	-	-	-	-	-
Carlsson et al., (2002) ⁵⁹	1 month	-	-	-	-	-	-
Chevalier et al., (2006) ²⁷	12 months	0.72	0.38	-0.84	-0.38	HAM-A	BDI
Crössmann et al., (2010) ²²	6 months	0.13 -0.39*	-0.04 -0.07*	-0.25 0.15*	-0.16 -0.12*	HADS	HADS
Dougherty et al., (2004, 2005) ^{28, 34}	12 months	0.38	0.33	0.15	0.08	STAI-S	CES-D
Dunbar et al., (2009) ²³	12 months	0.23/-0.02	0.23/0.23**	0.11	0.03	STAI	BDI
Edelman et al., (2008) ³⁶	6 months	-	-	-	-	DASS	DASS
Fichet et al. (2003) ²⁹	3 months	1.79	1.20	-	-	HADS	HADS
Frizelle et al., (2004) ³³	3 months	0.34	0.52	-	-	HADS	HADS
Irvine et al. (2011) ²⁴	12 months	0.10/0.28 [†]	-0.01/0.61	0.11/-0.05	0.05/-0.15	HADS	HADS
Kohn et al., (2000) ³⁰	9 months	0.89	-	0.30	-	STAI-S	BDI
Kühl et al., (2009) ²⁵	1 month	-0.22/0.10	-	0.40/0.30	-	STAI-T/FSAS	-
Lewin et al., (2007) ³¹	6 months	-	-	-	-	HADS	HADS
Molchany and Peterson (2004) ³⁷	9 months	0.14	-	0.20	-	STAI-S	-
Sears et al., (2007) ³²	4 months	1.13	1.11	0.37	0.39	STAI	CES-D
Sneed et al., (1997) ⁶⁰	4 months	-	-	-	-	POMS	POMS
Vazquez et al., (2010) ²⁶	1 month	0.56	-	0.07	-	FSAS	-

Cohen's *d*/effect size: .20=small; .50=medium; .80=large

* Patients >65

** compared support group and telephone counselling to usual care

[†] male/female

ANX=anxiety; DEP=depression; HAM-A= Hamilton Anxiety Scale; BDI= Back Depression Inventory; HADS= Hospital Anxiety Depression Scale; STAI(-S/T)= State-Trait Anxiety inventory, CES-D= Center for Epidemiologic Studies Depression Scale; DASS= Depression Anxiety Stress Scale; FSAS= Florida Shock Anxiety Survey; POMS= Profile of Mood State

Table 3

Characteristics of study intervention and control groups

Author	Intervention components	Control group
Badger and Morris (1989) ³⁵	Support group for patient and spouse with focus on patient education about the ICD, emotional support, sharing of experiences and coping strategies, clarifying common misconceptions about the ICD	UC* – patients who lived to far away from the including center formed the control group
Carlsson et al., (2002) ⁵⁹	Repeated contact with the nurse and received a planned education program based on information provided by ICD companies.	UC – not specified
Chevalier et al., (2006) ²⁷	CBT: stress and relaxation, cognitive restructuring, positive interindividual communication, problem solving methods, dealing with everyday stress	UC – not specified
Crössmann et al., (2010) ²²	Information booklet about technical a psychological aspects of wearing an ICD and appropriate coping strategies. Supportive, semistructured, phone calls up to 6 months post implant aiming at reduction of avoidance behaviour, reducing cognitive bias, reducing anxiety	UC – routine medical check up at 1, 3, and 6 months after implantation; booklet with technical aspects of wearing an ICD (provided by the manufacturer)
Dougherty et al., (2004, 2005) ^{28, 34}	Based on Bandura's Social Cognitive Theory Structured information: recovery experiences, behavioral strategies, anxiety reduction strategies, practice of new behavior Nursing telephone support: physical symptoms, activity and exercise, emotional reactions, ICD shocks, partner relationship, safety of ICD, and health care providers	UC – standardized information about the ICD provided via a booklet, videotape or a health care provider. The booklets were constructed by the manufacturer
Dunbar et al., (2009) ²³	Education and information about the device: maintaining a healthy lifestyle, dealing with fear and anxiety, practical aspects of wearing an ICD Symptom management training CBT: improving proactive coping skills and illness appraisal, relaxation techniques, reducing negative thoughts, activity goals, managing depressive symptoms, reaching out for social support	UC – standard discharge teaching form and an audiotape with the same information as found in standard information booklets provided by manufacturers
Edelman et al., (2008) ³⁶	General information about the ICD, satisfaction with ICD by other patients, device discharge, safety and potential hazard of the ICD, lifestyle changes, regular exercise, open communication with others, normalizing patients feelings, contacting health care providers if needed	UC – verbal information from the cardiologist and a booklet constructed by the manufacturer
Fitchet et al., (2003) ²⁹	Individually prescribed aerobic exercise Information: benefits of exercise, cardiovascular disease, ICD technology, diet CBT: explaining link between thoughts, feelings and behaviors, group sessions which address management of anxiety, anger and depression, self-help strategies (e.g. relaxation and self hypnosis)	UC – not specified
Frizelle et al., (2004) ³³	Home-based exercise programme, cardiac misconceptions and concerns, relaxation and breathing training, weekly goal setting for enjoyable activities, educational session about anxiety, phobia and panic, educational session about recognizing and challenging negative thoughts, education about the working of the ICD, sharing experiences and questions with cardiac nurses and other ICD patients	Waiting-list controls (routine care)
Irvine et al., (2011) ²⁴	CBT: cognitive theory of anxiety, focus on misconceptions that cause distress with 8 telephone counselling sessions, psychoeducation, mindfulness-based exercise and muscle relaxation on CD, additional counselling was offered for patient who have experienced an ICD shock	UC – what is routinely offered by the participating center to all ICD patients (standard education material and follow-up appointments for device interrogation and problem-shooting)
Kohn et al., (2000) ³⁰	CBT: education about anxiety and apprehensions, avoidance behaviour, fear of shock, stress management, ability to resume work and social activities, and distorted cognitions	UC – not specified
Kuhl et al., (2009) ²⁵	CD-ROM-based psychoeducational CBT with topics on coping, mood, relationships, and device functioning. Deep breathing techniques is demonstrated via a video component	Waiting-list controls
Lewin et al., (2007) ³¹	Booklet with common fears experienced by ICD patients prior to implantation, relaxation and breathing exercise, cognitive behavioral rehabilitation programme in self-help form (how to get back to normal and avoid further problems)	UC – received an informational booklet developed by the British Heart Foundation and were contacted about postoperative progress
Molchany and Peterson (2004) ³⁷	Daily activity planning, maintaining social contacts, ongoing education, support groups	UC – standard symptom management information

Author	Intervention components	Control group
Sears et al., (2007) ³²	ICD specific education: health education and stress management Relaxation and stress reduction management: breathing, muscle relaxing exercises, and guided imagery CBT: identification of automatic thoughts, cognitive distortions, cognitive restructuring, development of alternative thoughts, exposure, activity planning	Condensed information what was received by the treatment group
Sneed et al., (1997) ⁶⁰	Counselling: focused on identifying concerns e.g. fear, dependency, lifestyle changes, body image, physical activity etc. Support group: sharing of experiences Relaxation training	UC – preoperative teaching by case manager and daily visits to discuss any concerns, standardized discharge information and instruction to contact the case manager in case of any questions
Vazquez et al., (2010) ²⁶	Group session of 4 hours, focus on: heart health, stress and anxiety including relaxation strategies, specific gender related issues (e.g. changes in your body)	Waiting-list controls

* Usual Care

Table 4

Recommendations for future research

- Large scale trials (>100 patients in each group)
- Using CONSORT guidelines for better reporting
- Improve participant engagement (focus on recruitment and attrition)
- Develop an easily available treatment (using internet and mobile applications)
- Patient tailored approach matching the intervention to patient needs and preferences (stepped care approach)
- Examine the most opportune timing of the intervention
- Using CBT components as part of the intervention
- Involving medical staff in patient recruitment (i.e., cardiologists and nurses)
- Motivating recruiting personnel (organizing project and steering committee meetings, introducing a newsletter)