

Tilburg University

Psychological intervention following implantation of an implantable defibrillator

Pedersen, S.S.; van den Broek, K.C.; Sears, S.F.

Published in:
PACE. Pacing and Clinical Electrophysiology

Publication date:
2007

Document Version
Publisher's PDF, also known as Version of record

[Link to publication in Tilburg University Research Portal](#)

Citation for published version (APA):
Pedersen, S. S., van den Broek, K. C., & Sears, S. F. (2007). Psychological intervention following implantation of an implantable defibrillator: A review and future recommendations. *PACE. Pacing and Clinical Electrophysiology*, 30(12), 1546-1554.

General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal

Take down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

REVIEW

Psychological Intervention Following Implantation of an Implantable Defibrillator: A Review and Future Recommendations

SUSANNE S. PEDERSEN, PH.D.,*†, KRISTA C. VAN DEN BROEK, M.A.,* and SAMUEL F. SEARS JR, PH.D.‡

From *CoRPS—Center of Research on Psychology in Somatic diseases, Tilburg University, Tilburg, The Netherlands, †Department of Cardiology, Thoraxcenter, Erasmus Medical Centre, Rotterdam, The Netherlands, and ‡Department of Psychology, East Carolina University Greenville, North Carolina

Background: *The medical benefits of the implantable cardioverter defibrillator (ICD) are unequivocal, but a subgroup of patients experiences emotional difficulties following implantation. For this subgroup, some form of psychological intervention may be warranted. This review provides an overview of current evidence on the efficacy of psychological intervention in ICD patients and recommendations for future research.*

Methods: *We searched the PubMed and PsycInfo databases in the period between January 1980 and April 2007, using a set of a priori determined keywords. Based on the search and a hand search of the reference lists of the included articles, we identified nine studies that fulfilled the inclusion criteria.*

Results: *The majority of studies used a randomized controlled trial design, but studies varied considerably in sample size, response, attrition rate, and type of intervention. However, most interventions were multifactorial, using cognitive behavioral therapy as one of the mainstays of treatment. Overall, psychological interventions seem to have little impact on shocks and heart rate variability. Some studies found a decrease in depressive symptoms and gains in quality of life, but the most notable effects are seen in improved exercise capacity and reductions in anxiety. Effect sizes for changes in anxiety in the intervention group ranged from small to large compared to small in the usual care group, using Cohen's effect size index.*

Conclusions: *Preliminary evidence from small-scale intervention trials suggests that psychological intervention is worthwhile in ICD patients. Nevertheless, large-scale, well-designed trials are warranted to substantiate these findings. A multifactorial approach using a cognitive behavioral component paired with exercise training is likely to be the most successful. (PACE 2007; 30:1546–1554)*

implantable cardioverter defibrillator, intervention, psychological, review.

Introduction

The superiority of the implantable cardioverter defibrillator (ICD) compared to antiarrhythmic drugs for the prevention of sudden cardiac death (SCD) both in primary^{1,2} and secondary prevention is well established,^{3,4} with risk reductions ranging from 50–63%.⁵ Nevertheless, a subgroup of patients experiences emotional difficulties, with symptoms of anxiety and depression varying from 24–87%.⁶ Anxiety may exist on a

continuum from normalized fear, generalized anxiety, and panic disorder to posttraumatic stress disorder,^{6,7} with 13–38% of ICD patients experiencing clinical levels.⁸

Generally, the manifestation of emotional distress in ICD patients has been attributed to shocks.⁶ However, the Canadian Implantable Defibrillator Study (CIDS) indicated that a threshold ≥ 5 shocks is required,³ whereas the Antiarrhythmics Versus Implantable Defibrillators (AVID) trial showed that one shock is sufficient to lead to decreased quality of life (QoL) and increased patient concerns.⁹ Other studies show that catastrophic cognitions, such as attributing ICD shocks to the progression of disease and impending risk of SCD,¹⁰ concerns about the ICD firing,^{10,11} and the distressed (type-D) personality (i.e. the tendency to experience increased negative emotions paired with the non-expression of these emotions) may be more important determinants of emotional distress than shocks.¹²

This research was supported with a VENI grant (451-05-001) to Dr. SS Pedersen from the Netherlands Organization for Scientific Research (NWO), The Hague, The Netherlands.

Address for reprints: Susanne S. Pedersen, Ph.D., CoRPS, Department of Medical Psychology, Room P506, Tilburg University, Warandelaan 2, PO Box 90153, 5000 LE Tilburg, The Netherlands. Fax: +31-13-466-2067; e-mail: s.s.pedersen@uvt.nl

Received March 15, 2007; revised May 2, 2007; accepted May 21, 2007.

There is also preliminary evidence to suggest that distress may precipitate arrhythmic events.^{13,14} For some patients, a vicious cycle may ensue, with ICD implantation leading to anxiety and depression in turn precipitating arrhythmic events and leading to more distress. ICD patients may be particularly prone to developing anxiety post implantation due to fears of the ICD firing and associated catastrophic cognitions, with some patients interpreting a shock as a sign of danger and progression of disease.⁶ Being caught in this vicious cycle may lead to detrimental effects of a secondary nature, including avoidance behavior, not returning to work, reduced sexual activity, physical inactivity, and impaired QoL.^{6,8}

Both anxiety and depression comprise risk factors for adverse prognosis in coronary artery disease.^{15,16} More importantly, emotional distress in some ICD patients does not remit spontaneously but persists over time.^{17,18} For these patients, psychological intervention on its own or combined with pharmacotherapy may be warranted in order to reduce distress and adverse secondary outcomes. Given the exponential rise in ICD implantations and its projected increase in the future,¹⁹ knowledge of psychological interventions and their efficacy is important for secondary prevention in this distinct patient group.

The only review on psychological interventions in ICD patients was published in 2003.²⁰ However, the search period extended only until 2002, with new studies having been published since then. The current review (1) provides an up-to-date overview of psychological intervention studies in ICD patients, (2) evaluates their efficacy in terms of reducing distress and the occurrence of ventricular arrhythmias, and (3) provides recommendations for future research.

Methods

The databases PubMed and PsycInfo were searched in the period between January 1980 and April 2007, using a combination of the following search terms: *Implantable defibrillator, psychological, psychosocial, intervention, rehabilitation, therapy, and treatment outcome*. We included articles in the review irrespective of their design, as long as the study was empirical, included an intervention and a comparison group, the intervention had a psychological component, and the article was published in a peer-reviewed English journal. Hence, studies that evaluated multifactorial interventions (e.g. comprising psychotherapy and/or exercise in addition to a psychological component) also qualified for inclusion. Reviews, case studies, and descriptive studies were excluded, as were studies based on mixed patient groups (i.e. if only part of the patients had received an ICD).

In addition to the computer search, the reference list of the included articles was hand searched. The second author (KCB) conducted the computer search and eliminated double hits; subsequently, the first (SSP) and the second authors (KCB) reviewed the abstracts and decided on whether an article qualified for inclusion based on the inclusion criteria. The hand search was conducted by the first (SSP) and the second authors (KCB). No other hand searches were conducted.

The search resulted in 232 hits. After removing double hits, the number of studies was reduced to 137. Weighing the remaining studies against the inclusion criteria reduced the number to eight. A hand search of the reference list of these studies identified one additional study. See Figure 1 for an overview of the selection. Due to the limited number of studies, their heterogeneity, and the relatively small sample sizes, it was not possible to conduct a meta-analysis. However, we aimed to comply with the criteria for the reporting of meta-analysis of observational studies in epidemiology (MOOSE) to the extent that it was possible.²¹ We chose to use the MOOSE criteria given that studies used a mix of designs (i.e. experimental or observational).

Results

The current review is based on nine studies, with studies reporting on the same sample in different publications being listed under the first author and as one study. See Table I for an overview. In the following section, we provide a description of the included studies in relation to design, sample size, patient characteristics, and the intervention used. Subsequently, we evaluate the effect of the intervention on the primary outcome measures of the studies, divided into two main categories (i.e. cardiac and patient-centered). For the patient-centered outcomes, we focus on QoL, anxiety, and depression, given that they were the outcome measures most frequently used across studies.

Description of included studies

Design

The majority of studies (7/9) used a randomized controlled trial (RCT) design,²²⁻²⁸ with two of these studies employing an RCT with a case-crossover design.^{25,26} The RCT is considered the gold standard in medicine and the most powerful design in terms of providing the strongest evidence for the efficacy of a given intervention.²⁹ In two studies, an observational design was employed.^{30,31}

In several studies, the participant rate was low, with 26% of eligible patients participating in

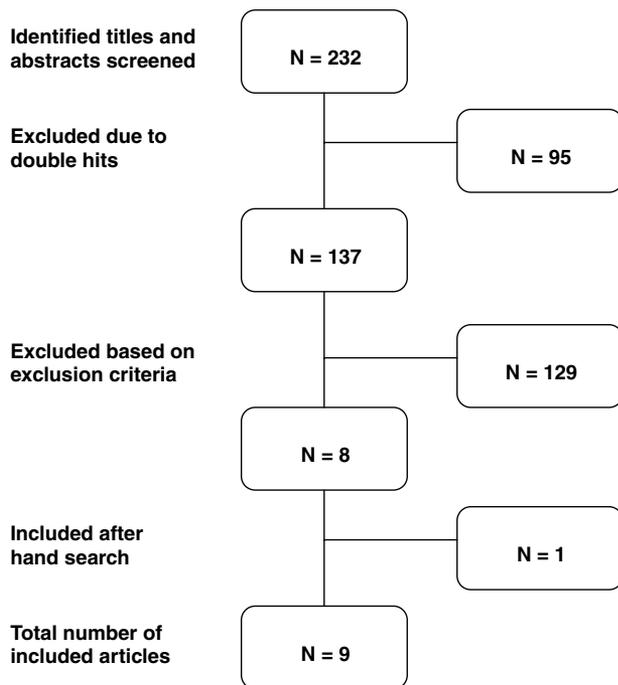


Figure 1. Flowchart of the literature selection.

the Frizelle et al. study,²⁶ 35% in the Chevalier et al. study,²³ and 47% in the Fitchet et al. study,²⁵ although in the latter study a random sample of 16 patients was drawn from those who agreed to participate ($n = 34$). Molchany and colleagues included a convenience sample of ICD patients and their significant other and did not report the initial number of patients and significant others approached.³¹ In some,^{24–26} but not all studies²³ with a low participant rate, responders and nonresponders were compared on baseline characteristics to rule out systematic differences. Such a comparison is important, in particular in studies with a low-response rate, as systematic differences between responders and nonresponders jeopardize the external validity of the study.

In four studies, patients were included during hospitalization for ICD implantation, with three studies including prior to implantation^{22,27,28} and one study at the time of discharge from the hospital.²⁴ One study included patients who had their ICD implanted prior to or during the study.²³ The other four studies recruited patients who had their ICD implantation for some time. In these studies, the mean time since implantation was 8–12.5 months³⁰ and 20 months.²⁵ One study did not provide information on the time since implantation,²⁶ and one study only reported the range (i.e. 5–24 months).³¹

The follow-up periods for evaluating the endpoints varied widely between studies from one²² to 12 months.^{23,32}

Sample Size

Sample sizes varied considerably across studies, ranging for the total sample from 12–168, 6–84 in the intervention and 5–84 in the control group, respectively.^{22–28,30,31} Generally, sample sizes were small, with ≤ 35 patients in the intervention and usual care groups, respectively, in all but one study.²⁴

Patient Characteristics

The majority of patients were men,^{22–25,27,30,31} with two studies not providing information on sex.^{26,28} The mean age was between 57 and 66 years,^{22–28} with a range of 28–83 years.^{22,25,27,30,31} When reported, mean left ventricular ejection fraction varied from 30–44%.^{23–25,28,30} Only four studies provided information on the reason for ICD implantation, including coronary artery disease etiology.^{22–25,32}

Interventions

The interventions employed across studies were heterogeneous, although the majority of studies used a multifactorial approach. Four studies included a cognitive behavioral component,^{23,25–27} with cognitive behavioral therapy (CBT) being the mainstay of treatment. Using a CBT framework, anxiety, apprehensions, avoidance behavior, fear of shocks, and distorted cognitions were targeted, with stress management and relaxation therapy often forming adjunctive therapies.^{23,25,26} In two studies, patients also engaged in aerobic exercise, as part of a comprehensive cardiac rehabilitation program.^{25,26}

Group or individual counseling comprised the key component in the other five studies,^{22,24,28,30,31} with counseling most frequently being provided by a specialized nurse. The main objective of the counseling was to provide support to patients, educate patients about the ICD and their illness, and to enhance their coping styles.

The duration of the intervention varied from two to five months across studies,^{23–28,30,32} with the average length being three months. In two studies, the duration was not reported.^{22,31} Usual care comprised the control condition for all studies, although the exact constellation of, for example, visits to the cardiologist, ICD nurse, and general practitioner was often not reported.

Effect of Intervention

On Cardiac Outcomes

Shocks

Shocks comprised one of the outcome measures in 5/9 studies.^{23–27} In none of the studies did the intervention lead to a statistically significant reduction in the rate of shocks compared with usual care,^{23–27} although reductions were found.²³

Table I.
Overview of Studies on Psychosocial Interventions in ICD Patients

Authors ^[reference]	Sample Size		Study Design	Intervention	Duration	Comparison Intervention	Endpoint(s) Therapy
	N _{int}	N _{con}					
Badger and Morris (1989) ³⁰	6	6	Comparative study	Support group	2 months	Usual care	QoL
Carlsson et al. (2002) ²²	10	10	RCT	Education	Not reported	Usual care	QoL
Chevalier et al. (2006) ²³	35	35	RCT	CBT	3 months	Usual care	Shocks, HRV, QoL, anxiety, depression, defibrillator tolerance
Dougherty et al. (2004, 2005) ^{24,32}	84	84	RCT	Telephone support	2 months	Usual care	Shocks, QoL, anxiety, depression, health care use, ICD-related knowledge
Fitchet et al. (2003) ²⁵	8	8	RCT	CCR	3 months	Usual care	Ventricular arrhythmias and shocks, exercise test, anxiety, depression
Frizelle et al. (2004) ²⁶	12	10	RCT	CCR	3 months	Usual care	Shocks, ATP episodes, QoL, exercise test, anxiety, depression, ICD-related concerns, perceived health status
Kohn et al. (2000) ²⁷	25	24	RCT	CBT	5 months	Usual care	Shocks, anxiety, depression, psychosocial adjustment
Molchany and Peterson (1994) ³¹	11	5	Comparative study	Support group	Not reported	Usual care	QoL, anxiety
Sneed et al. (1997) ²⁸	17	17	RCT	Telephone support, support counseling, support group	4 months	Usual care	Mood states, psychosocial adjustment

CBT = cognitive behavioral therapy; CCR = comprehensive cardiac rehabilitation; HRV = heart rate variability; N_{int} = number of patients in intervention group; N_{con} = number of patients in control group; RCT = randomized controlled trial; QoL = quality of life.

This null finding may in part be attributed to the relatively short follow-up periods, ranging from 1–12 months. In the study by Dougherty and colleagues evaluating the effect of the intervention on shocks at several time points (i.e. one-, three-, six-, and 12-months postimplantation), there were no statistically significant differences between the intervention and usual care groups at any of the time points.^{24,32} Kohn and colleagues found similar results at nine-months follow-up, although when stratifying by number of shocks using a threshold of ≥ 1 shock, there was a trend for more shocks in the intervention versus usual care group (61% vs 33%, $P = 0.07$).²⁷ A further subgroup analysis revealed, however, that of patients who received ≥ 1 shock, usual care patients ($n = 6$) had significantly higher symptom levels of anxiety and depression compared with patients in the intervention group ($n = 10$). This suggests that the intervention per se had no direct effect on shocks but buffered the effect of shocks on distress.²⁷ In a subgroup analysis of patients without antiarrhythmic drugs, Chevalier and colleagues found a reduced risk of shocks in the CBT group ($n = 19$) versus usual care ($n = 20$) at three months but not at 12 months.²³ It is important to emphasize, however, that the subgroup analyses performed in the latter two studies were based on small numbers with only 16 and 39 patients, respectively.

Heart Rate Variability and Exercise Capacity

Other physiological and cardiac outcome measures used were heart rate variability and exercise capacity. Chevalier and colleagues report an improved sympathovagal balance in patients treated with CBT, with daytime pNN 50 and nocturnal SDNN increasing significantly in the CBT group compared to usual care.²³ The two cardiac rehabilitation trials both found an improvement in exercise capacity in the intervention group. In the study by Fitchet and colleagues, mean exercise time increased with 16% (9 m 55 sec vs 11 m 11 sec, $P = 0.001$) in patients receiving the 12-week rehabilitation program, whereas the mean exercise time did not differ significantly in the usual care group pre- and post-test.²⁵ In the study by Frizelle and colleagues, significant increases were found in the level of difficulty ($P = 0.05$) and the total distance walked ($P = 0.01$) in the rehabilitation group compared to usual care.²⁶ No significant differences were found in heart rate change and patient-rated breathlessness.

On Patient-Centered Outcomes

Quality of Life

Of all studies, six studies focused on QoL as an endpoint.^{22–24,26,30,31,32} Frizelle and colleagues

found an improvement in emotional, physical, social, and global QoL in patients receiving rehabilitation compared with usual care.²⁶ Badger and Morris found a trend toward improvement in role functioning and psychological adjustment in the treatment group, but differences in mean pre- and postscores were not statistically significant.³⁰ Of note, there was a trend in the opposite direction for the usual care group, with these patients experiencing deterioration in adjustment over time. Carlsson and colleagues provide information on change scores within the intervention and usual care group, respectively, but do not compare the effect of the intervention on QoL relative to that in the usual care group.²² None of the other studies found any effect of the intervention on QoL compared with usual care.^{23,24,31,32}

Anxiety

Anxiety was employed as an outcome in the majority of studies (i.e. 7/9), with most^{23–27,32} but not all studies^{28,31} finding that the intervention reduced levels of anxiety. In the study by Chevalier and colleagues, where CBT was the mainstay of treatment, the intervention group experienced significantly less anxiety than usual care at three ($P = 0.04$) and 12 months ($P = 0.03$).²³ Kohn and colleagues, also using CBT as the mainstay of treatment, reported equal levels of state as well as trait anxiety in the intervention and usual care group at baseline, but they found lower levels of trait anxiety in the intervention group compared with usual care ($P = 0.013$) at nine-months follow-up, but no difference on state-anxiety.²⁷ However, this study only compared differences in anxiety between groups cross-sectionally, that is at baseline and at nine-months follow-up, but not the potential impact of the intervention on changes of anxiety over time.²⁷ In fact, when examining changes in anxiety over time both state and trait anxiety were reduced in the intervention group between baseline and follow-up, whereas the usual care group experienced reductions in state anxiety only, but an increase in trait anxiety.

Similarly, cardiac rehabilitation was found to reduce levels of anxiety. Fitchet and colleagues found a significant decrease in anxiety in the rehabilitation group ($P < 0.001$), whereas the usual care group experienced more feelings of anxiety after 12 weeks ($P = 0.028$).²⁵ The second study on cardiac rehabilitation yielded similar results, with significant differences in change of anxiety scores between the rehabilitation and control group ($P = 0.012$).²⁶ The results of Dougherty and colleagues were mixed, with a significant reduction in anxiety over a 12-month period in the intervention group compared with usual care,³² although there were no significant differences between groups at one and three months.²⁴

Dougherty and colleagues also looked at the proportion of patients scoring in the range of severe anxiety, using a cut-off ≥ 40 on the State-Trait Anxiety Inventory.^{24,32} At baseline, 40% of the patients in the intervention group scored within this range, with it being reduced to 20%, 21%, and 18% at three-, six-, and 12-months follow-up. By contrast, fewer patients in the usual care group reported severe anxiety at baseline, namely 29%, with prevalence rates of 27%, 19%, and 23% at three-, six-, and 12-months follow-up. A post-hoc analysis shows that the change in number of cases with severe anxiety in the intervention group was reduced by 55% compared with 21% in the control condition over the 12-month period. Fears and ICD-related concerns, which likely comprise the basis of anxiety in ICD patients, were also reduced in the intervention compared with the usual care group.^{24,26,32}

Depression

Of studies on depression,^{23–28,32} two out of six found a significant reduction in the burden of depression in the intervention group compared with usual care.^{25,26} The choice of intervention used in the two positive studies was comprehensive cardiac rehabilitation. In the study by Fitchet and colleagues, mean depression scores decreased from 9.9 pre- to 6.7 postrehabilitation ($P < 0.001$), whereas mean scores in the control group rose from 7.6 to 9.5 ($P = 0.074$).²⁵ In the study by Frizelle and colleagues, mean depression scores were also reduced between pre- and postrehabilitation from 3.05 ± 3.07 to 1.73 ± 1.90 ($P = 0.003$).²⁶ Although Kohn and colleagues report a lower mean depression score in the CBT compared to the usual care group (6.9 ± 5.9 vs. 15.0 ± 13.0 , $P = 0.037$) at nine-months follow-up, this difference cannot necessarily be attributed to the intervention due to lack of baseline assessment of depression.²⁷ Dougherty and colleagues found no significant differences between groups on depressive symptoms.^{24,32} However, using a cut-off ≥ 16 on the Center for Epidemiologic Studies Depression Scale (CES-D), they found that 26% of patients in the intervention group compared with 19% in the usual care group experienced depressed mood at baseline; at three months, prevalences were similar, with 18% versus 19%. Nevertheless, a post-hoc comparison shows a reduction in the number of patients with depressive symptomatology in the intervention group by 31% versus 0% in the usual care group over the three-months period. Unfortunately, in contrast to anxiety, the authors only report depression prevalence rates for baseline and three months.

Effect Sizes for Changes in Anxiety

Given that the majority of studies were based on relatively small sample sizes and hence at risk

of being underpowered, which limits the chance of finding statistically significant differences if present, we evaluated the clinical significance of the intervention compared with usual care, using Cohen's effect size index.³³ An effect size of 0.20 is considered small, 0.50 moderate, and ≥ 0.80 large. We chose to evaluate the effect of the intervention using anxiety as the outcome measure, since anxiety was the endpoint most frequently used across studies. In addition, in ICD patients symptoms of anxiety are more prevalent than depression,^{6,12} making it an important patient-centered outcome in this distinct patient group.³⁴ Effect sizes were calculated for the difference in anxiety between baseline and the last follow-up reported in the study.

Effect sizes and the measure used with which to assess anxiety are shown in Table II. For three studies, it was not possible to calculate effect sizes for the impact of the intervention on changes in anxiety either because anxiety was not assessed^{22,30} or due to means and standard deviations not being reported for the groups at baseline.²⁸ In the two studies using an RCT with a case-crossover design, means and standard deviations were not reported separately for the groups, but only for the total group (i.e. when all patients had been subjected to the intervention).^{25,26} Generally, the impact of the intervention on reductions in anxiety had a small^{24,26,31,32} to large effect,^{23,25,27} as indicated by Cohen's effect size index, ranging from 0.14 to 1.79.^{31,25} In studies where it was possible to compare the effect size for the intervention versus usual care, the intervention was superior to usual care in terms of reducing anxiety at follow-up in three out of four studies.^{23,27,32} Of note, in the study by Chevalier and colleagues, the usual care group had a large negative effect size, indicating that patients receiving no intervention deteriorated substantially during follow-up.²³

Discussion

Based on the current review, the evidence for a benefit of psychological intervention in ICD patients is most convincing for symptoms of anxiety and exercise capacity, with intervention leading to a significant reduction in anxiety and improvement in exercise capacity. By contrast, there is little evidence to suggest that the interventions studied to date have had a notable impact on depressive symptoms, QoL, heart rate variability, and shocks. These findings, however, should be viewed in the context of the small number of studies, the very small sample sizes, and the variability in their methodological quality.

Generally, there is a paucity of large-scale, well-designed psychological intervention studies in ICD patients. Nevertheless, when calculating effect sizes to indicate the clinical impact of the

Table II.
Effect Sizes for Impact of Intervention Versus Usual Care on Changes in Anxiety

Authors ^[reference]	Follow-up Period	Effect size* Intervention	Effect size* Usual care	Anxiety Measure
Badger and Morris (1989) ³⁰	2 months	–	–	–
Carlsson et al. (2002) ²²	1 month	–	–	–
Chevalier et al. (2006) ²³	12 months	0.72	–0.84	HAM-A
Dougherty et al. (2004, 2005) ^{24, 32}	12 months	0.38	0.15	STAI-S
Fitchet et al. (2003) ²⁵	6 months	1.79	–	HADS
Frizelle et al. (2004) ²⁶	3 months	0.34	–	HADS
Kohn et al. (2000) ²⁷	9 months	0.89	0.30	STAI-S
Molchany and Peterson (1994) ³¹	6 months	0.14	0.20	STAI-S
Sneed et al. (1997) ²⁸	4 months	–	–	POMS

* Based on $\text{mean}_1 - \text{mean}_2 / \text{pooled standard deviation}$.

¹ Pre- and posttreatment scores were not reported separately for the intervention and usual care groups, but only for the total group (i.e. when all patients including the waiting group had undergone the intervention).

HADS = hospital anxiety and depression scale; HAM-A = Hamilton anxiety scale; POMS = profile of mood states; STAI-S = state-trait anxiety inventory (state scale).

intervention on reductions in anxiety, current evidence indicates that this pursuit is worthwhile and that patients may benefit substantially, with large effect sizes found in three trials.^{23,25,27} In turn, reductions in anxiety are likely to have beneficial effects on secondary outcomes, such as avoidance behavior, returning to work, sexual activity, physical activity, and QoL.^{6,8}

In order to expand our knowledge of the most optimal intervention to offer ICD patients, it is paramount that future trials include sufficiently large samples to have adequate power to test the efficacy of a given intervention. This has also been suggested by others.⁶ In addition, it is important to provide an intervention that appeals to patient needs and concerns and is logistically feasible for them to attend, as the response rate was low and the attrition rate high in a number of studies.^{23,25,26} In this regard, a web-based intervention may be worth considering, as it is accessible and can reach large groups of patients as well as safeguard patients' anonymity, in turn providing an interesting alternative to those patients who need help but are less inclined to see a psychologist.³⁵

On the basis of the current review, we would recommend that CBT and exercise training form the mainstays of treatment, as these components were included in those trials showing the largest effect.^{23,25,27} Others have also advocated the inclusion of CBT,⁶ primarily since CBT may be the most effective means by which to deal with ICD-related concerns and fears that are highly prevalent in ICD patients,^{11,26} and which may eventually lead to manifest clinical anxiety, including panic

disorder.⁷ In this regard, education about the ICD in order to avoid misconceptions and minimize ICD-related concerns should form part of any intervention,^{11,26,36} with adjunctive pharmacotherapy being necessary in subgroups of patients to curb emotional distress.⁷ The available evidence also suggests that health policy makers are justified in supporting coverage for psychosocial and exercise interventions for ICD patients to reduce anxiety and improve functioning. However, future trials should evaluate the influence of the intervention on health care utilization and the cost-effectiveness of the intervention in addition to the potential moderating influence of factors, such as ICD indication, cardiac resynchronization therapy, disease etiology, and severity, on the effectiveness of the intervention.

The preferred research design for future studies should be an RCT, which is the most powerful study design to test the efficacy of an intervention.²⁹ We also recommend the inclusion of multiple assessments of the outcome measures under study, spanning both psychological (e.g. anxiety) and physiological markers (e.g. cortisol) whenever possible, in order to evaluate changes overtime and investigate whether the effect of a given intervention will remain stable and not just have short-term effects. The longest follow-up reported in studies included in the current review was 12 months.^{23,24,32} Attention should also be given to the choice of instruments used to evaluate the effect of the intervention. Several instruments routinely used in psychosomatic research are not sensitive to tap treatment-related changes.³⁷ ICD

disease-specific instruments have also been established, including measures of “ICD patient acceptance,” “shock anxiety,” “ICD worries,” and “ICD concerns” that allow for more precise intervention targets.^{11,38–40} Importantly, the instruments used to assess anxiety in the majority of studies in the current review have been shown to be sufficiently sensitive to measure an effect following intervention, if present.

In future interventions, it may also be important to include personality traits, such as type-D personality, given its potential moderating effect on outcome. Type-D is an emerging risk factor in cardiovascular disease⁴¹ that has also been associated with increased anxiety and depressive symptoms in ICD patients, irrespective of shocks.¹² Positive affect comprises another important potentially moderating factor that has been associated with better mental health and social functioning in ICD patients.⁴² Given that patients may not necessarily identify themselves by negative emotions alone, focus on increasing positive emotions rather than only reducing negative emotions may also enhance the compliance and commitment of patients to the intervention.

Finally, when reporting on future RCTs in the context of ICD patients, the CONSORT (Consolidated Standards of Reporting Trials) statement should be adhered to.⁴³ Briefly, the CONSORT statement includes a 22-item checklist and a flow diagram for reporting RCTs. There is preliminary evidence that the quality of the reporting of

RCTs improves with compliance with these guidelines.⁴⁴ In addition, using this statement would enhance the interpretation of RCTs and facilitate the conductance of future meta-analyses.

The results of this review should be interpreted with some caution, given that we only included studies published in English peer-reviewed journals. This could have led to a potential selection bias. In addition, the number of studies was limited, with the review based on only nine studies. The heterogeneity of studies, including the relative small sample sizes, made comparisons across studies difficult. Although we calculated and compared effect sizes for reductions in anxiety in the intervention and usual care group, respectively, with the aim of alleviating the problem of small sample sizes and reduced power, the use of small sample sizes increases the risk of having a selected group of patients.

In conclusion, preliminary evidence from small-scale intervention trials suggests that psychological intervention is worthwhile in ICD patients, in particular with a view to reducing anxiety and concerns about the ICD. Nevertheless, large-scale, well-designed psychological intervention trials are warranted to substantiate these findings, with a multifactorial approach using a cognitive behavioral component and exercise training likely to be the most successful. These intervention trials are necessary in order to provide the most optimal care for the increasing number of patients who receive an ICD now and in the future.¹⁹

References

- Moss AJ, Zareba W, Hall WJ, Klein H, Wilber DJ, Cannom DS, Daubert JP, et al. Multicenter Automatic Defibrillator Implantation Trial II Investigators. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N Engl J Med* 2002; 346:877–883.
- Buxton AE, Lee KL, Fisher JD, Josephson ME, Prystowsky EN, Hafley G. A randomized study of the prevention of sudden death in patients with coronary artery disease. Multicenter Unsustained Tachycardia Trial Investigators. *N Engl J Med* 1999; 341:1882–1890.
- Connolly SJ, Gent M, Roberts RS, Dorian P, Roy D, Sheldon RS, Mitchell LB, et al. Canadian implantable defibrillator study (CIDS): A randomized trial of the implantable cardioverter defibrillator against amiodarone. *Circulation* 2000; 101:1297–1302.
- Kuck KH, Cappato R, Siebels J, Ruppel R. Randomized comparison of antiarrhythmic drug therapy with implantable defibrillators in patients resuscitated from cardiac arrest: The Cardiac Arrest Study Hamburg (CASH). *Circulation* 2000; 102:748–754.
- Ezekowitz JA, Armstrong PW, McAlister FA. Implantable cardioverter defibrillators in primary and secondary prevention: A systematic review of randomized, controlled trials. *Ann Intern Med* 2003; 138:445–452.
- Sears SF Jr, Conti JB. Quality of life and psychological functioning of ICD patients. *Heart* 2002; 87:488–493.
- Kuijpers PMJC, Honig A, Wellens HJJ. Effect of treatment of panic disorder in patients with frequent ICD discharges: A pilot study. *Gen Hosp Psychiatry* 2002; 24:181–184.
- Sears SF Jr, Todaro JF, Lewis TS, Sotile W, Conti JB. Examining the psychosocial impact of implantable cardioverter defibrillators: A literature review. *Clin Cardiol* 1999; 22:481–489.
- Schron EB, Exner DV, Yao Q, Jenkins LS, Steinberg JS, Cook JR, Kutalek SP, et al, and the AVID investigators. Quality of life in the antiarrhythmics versus implantable defibrillators trial: Impact of therapy and influence of adverse symptoms and defibrillator shocks. *Circulation* 2002; 105:589–594.
- Pauli P, Wiedemann G, Dengler W, Blaumann-Benninghoff G, Kühnkamp V. Anxiety in patients with an automatic implantable cardioverter defibrillator: What differentiates them from panic patients? *Psychosom Med* 1999; 61:69–76.
- Pedersen SS, Van Domburg RT, Theuns DAMJ, Jordaens L, Erdman RAM. Concerns about the Implantable Cardioverter Defibrillator: A determinant of anxiety and depressive symptoms independent of shocks. *Am Heart J* 2005; 149:664–669.
- Pedersen SS, Van Domburg RT, Theuns DAMJ, Jordaens L, Erdman RAM. Type D personality is associated with increased anxiety and depressive symptoms in patients with an implantable cardioverter defibrillator and their partners. *Psychosom Med* 2004; 66:714–719.
- Dunbar SB, Kimble LP, Jenkins LS, Hawthorne M, Dudley W, Slemmons M, Langberg JJ. Association of mood disturbance and arrhythmia events in patients after cardioverter defibrillator implantation. *Depress Anxiety* 1999; 9:163–168.
- Whang W, Albert CM, Sears SF, Lampert R, Conti JB, Wang PJ, Singh JP, et al, for the TOVA investigators. Depression as a predictor for appropriate shocks among patients with implantable cardioverter-defibrillators: Results from the Triggers of Ventricular Arrhythmias (TOVA) Study. *J Am Coll Cardiol* 2005; 45:1090–1095.
- Van Melle JP, de Jonge P, Spijkerman TA, Tijssen JFP, Ormel J, van Veldhuisen DJ, Van Den Brink RH, et al. Prognostic association of depression following myocardial infarction with mortality and cardiovascular events: A meta-analysis. *Psychosom Med* 2004; 66:814–822.
- Januzzi JL, Stern TA, Pasternak RC, DeSanctis RW. The influence of anxiety and depression on outcomes of patients with coronary disease. *Arch Intern Med* 2000; 160:1913–1921.

17. Kamphuis HC, de Leeuw JR, Derksen R, Hauer RN, Winnubst JA. Implantable cardioverter defibrillator recipients: Quality of life in recipients with and without ICD shock delivery: A prospective study. *Europace* 2003; 5:381–389.
18. Hegel MT, Griegel LE, Black C, Goulden L, Ozahowski T. Anxiety and depression in patients receiving implanted cardioverter-defibrillators: A longitudinal investigation. *Int J Psychiatry Med* 1997; 27:57–69.
19. Crespo EM, Kim J, Selzman KA. The use of implantable cardioverter defibrillators for the prevention of sudden cardiac death: A review of the evidence and implications. *Am J Med Sci* 2005; 329:238–246.
20. Edelman S, Lemon J, Kidman A. Psychological therapies for recipients of implantable cardioverter defibrillators. *Heart Lung* 2003; 32:234–240.
21. Stroup DF, Berlin JA, Morton SC, Olkin I, Williamson GD, Rennie D, Moher D, et al, for the Meta-analysis Of Observational Studies in Epidemiology (MOOSE) Group. Meta-analysis of observational studies: A proposal for reporting. *JAMA* 2000; 283:2008–2012.
22. Carlsson E, Olsson SB, Hertervig E. The role of the nurse in enhancing quality of life in patients with an implantable cardioverter defibrillator. *J Cardiovasc Nurs* 2002; 17:18–25.
23. Chevalier P, Cottraux J, Mollard E, NanYao S, Brun S, Burri H, Restier L, et al. Prevention of implantable defibrillator shocks by cognitive behavioral therapy: A pilot study. *Am Heart J* 2006; 151:191.e1–e6.
24. Dougherty CM, Pypers GP, Frasz HA. Description of a nursing intervention program after an implantable cardioverter defibrillator. *Heart Lung* 2004; 33:183–190.
25. Fitchet A, Doherty PJ, Bundy C, Bell W, Fitzpatrick AP, Garratt CJ. Comprehensive cardiac rehabilitation programme for implantable cardioverter-defibrillator patients: A randomized controlled trial. *Heart* 2003; 89:155–160.
26. Frizelle DJ, Lewin RJ, Kaye G, Hargreaves C, Hasney K, Beaumont N, Moniz-Cook E. Cognitive-behavioural rehabilitation programme for patients with an implanted cardioverter defibrillator: A pilot study. *Br J Health Psychol* 2004; 9:381–392.
27. Kohn CS, Petrucci RJ, Baessler C, Soto DM, Movsowitz C. The effect of psychological intervention on patients long-term adjustment to the ICD: A prospective study. *Pacing Clin Electrophysiol* 2000; 23:450–456.
28. Sneed NV, Finch NJ, Michel Y. The effect of a psychosocial nursing intervention on the mood state of patients with implantable cardioverter defibrillators and their caregivers. *Prog Cardiovasc Nurs* 1997; 12:4–14.
29. Thacker SB. Meta-analysis. *JAMA* 1988; 259:1685–1689.
30. Badger JM, Morris PL. Observations of a support group for automatic implantable cardioverter-defibrillator recipients and their spouses. *Heart Lung* 1989; 18:238–243.
31. Molchany CA, Peterson KA. The psychosocial effects of support group intervention on AICD recipients and their significant others. *Prog Cardiovasc Nurs* 1994; 9:23–29.
32. Dougherty CM, Thompson EA, Lewis FM. Long-term outcomes of a telephone intervention after an ICD. *Pacing Clin Electrophysiol* 2005; 28:1157–1167.
33. Cohen J. *Statistical power analysis for the behavioral sciences*. Mahwah, NJ: Lawrence Erlbaum Associates Publishers, 1988.
34. Krumholz HM, Peterson ED, Ayanian JZ, Chin MH, DeBusk RF, Goldman L, Kiefe CI, et al. Report of the National Heart, Lung, and Blood Institute Working Group on outcomes research in cardiovascular disease. *Circulation* 2005; 111:3158–3166.
35. Kuhl EA, Sears SF, Conti JB. Using computers to improve the psychosocial care of implantable cardioverter defibrillator recipients. *Pacing Clin Electrophysiol* 2006; 29:1426–1433.
36. Van den Broek KC, Denollet J, Nyklíček I, Van Der Voort PH. Psychological reaction to potential malfunctioning of implantable defibrillators. *Pacing Clin Electrophysiol* 2006; 29:953–956.
37. McGee HM, Hevey D, Horgan JH. Psychosocial outcome assessments for use in cardiac rehabilitation service evaluation: A 10-year systematic review. *Soc Sci Med* 1999; 48:1373–1393.
38. Kuhl EA, Dixit NK, Walker RL, Conti JB, Sears SF. Measurement of patient fears about implantable cardioverter defibrillator shock: An initial evaluation of the Florida Shock Anxiety Scale. *Pacing Clin Electrophysiol* 2006; 29:1–5.
39. DeMaso DR, Lauretti A, Spieth L, Van Der Feen JR, Jay KS, Gauvreau K, Walsh EP, et al. Psychosocial factors and quality of life in children and adolescents with implantable cardioverter-defibrillators. *Am J Cardiol* 2004; 93:582–587.
40. Burns JL, Serber ER, Keim S, Sears SF. Measuring patient acceptance of implantable cardiac device therapy: Initial psychometric investigation of the Florida Patient Acceptance Survey. *J Cardiovasc Electrophysiol* 2005; 16:384–390.
41. Pedersen SS, Denollet J. Is Type D personality here to stay? Emerging evidence across cardiovascular disease patient groups. *Current Cardiology Reviews* 2006; 2:205–213.
42. Sears SF, Serber ER, Lewis TS, Walker RL, Connors N, Lee JT, Curtis AB, et al. Do positive health expectations and optimism relate to quality of life outcomes for the patient with an implantable cardioverter defibrillator? *J Cardiopulm Rehab* 2004; 24:324–331.
43. Moher D, Schulz KF, Altma D, for the CONSORT Group. The CONSORT statement: Revised recommendations for improving the quality of reports of parallel-group randomized trials. *JAMA* 2001; 285:1987–1991.
44. Moher D, Jones A, Lepage L, for the CONSORT Group. Use of the CONSORT statement and quality of reports of randomized trials: A comparative before-and-after evaluation. *JAMA* 2001; 285:1992–1995.