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EFFECT OF A PSYCHOEDUCATIONAL INTERVENTION ON DEPRESSION, ANXIETY, and HEALTH RESOURCE USE IN ICD PATIENTS

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Abstract

Background—Psychological responses have been reported for some patients after insertion of an implantable cardioverter defibrillator (ICD). This study tested the effects of a psychoeducational intervention on anxiety, depressive symptoms, functional status and health resource use during the first year after ICD implantation.

Methods—ICD patients (n=246) were randomized to usual care (UC), group (GRP), or telephone counseling (TC) intervention that included education, symptom management, and coping skill training. Participants were 58 ± 11 years, 73% men, and 23% minorities. Anxiety (STAI), depressive symptoms (BDI-II), and functional status (DASI) were measured at baseline and after 1, 3, 6 & 12 months. Health resource use and disability days were tracked. Analyses were repeated-measures ANCOVA to assess Group X Time effects, Chi-square for percentage with clinically significant anxiety and depression at each time point, and logistic regression.

Results—All groups experienced decreased anxiety and depressive symptoms over the 12 months; GRP intervention had lower STAI (p=.03) than UC at 3 months. Logistic regression revealed group differences for predicted probability of having depressive symptoms at 12 months (UC=.31, GRP=.17, TC=.13, p=.03). UC had greater calls to providers at 1 and 6 months (p<.05) and more sick/disability days at 12 months (p=.01) than intervention groups.

Conclusions—A psychoeducational intervention reduced anxiety and depressive symptoms early after ICD, lowered probability of depressive symptoms at one year, and decreased disability days/calls to providers. These findings support further study and clinical use of both group and telephone interventions to yield better psychological outcomes after ICD implant.

Keywords

VT; Defibrillation - ICD; Quality of Life

Background & Purpose

The implantable cardioverter defibrillator (ICD) is more effective than antiarrhythmic drugs for preventing arrhythmic death, and it is now the treatment of choice in high risk patient populations. Randomized trials have documented the survival benefit in patients with life threatening ventricular arrhythmias who have left ventricular dysfunction due to ischemia,^{1, 2} as well as nonischemic cardiomyopathy^{3 4 5} and in the setting of primary prevention.⁶ Although highly effective in preventing arrhythmic death, the person receiving an ICD may experience psychological consequences including anxiety, depressive symptoms, fear, post-traumatic stress, and reduced quality of life.⁷⁻¹⁰ Adverse psychological outcomes have been associated with certain demographic and clinical characteristics including younger age,^{11 12-14} female gender,^{15- 16} particularly younger women,¹⁷ and multiple comorbidities.^{7- 18} Additionally, low social support,^{7- 19} use of avoidant coping and greater threat appraisals,^{18- 20} the experience of shocks,²¹⁻²³ and less acceptance as well as greater overall symptoms and concerns about the device²⁴⁻²⁶ have been associated with greater anxiety, depression and mood disturbances. The experience of inappropriate as well as appropriate shocks is implicated in adverse patient outcomes.⁹ Further, increased anxiety, depressive symptoms and shocks, in turn, may lead to greater arrhythmia potential^{27-29 30} and contribute to high health care resource use in this population.^{31- 32}

Several studies that have tested psychological and counseling interventions suggest that a proactive approach may be effective in preparing patients for the experiences in living with an ICD.³³⁻³⁵ The patient characteristics of ICD behavioral intervention studies to date have varied in terms of age, gender and minority representation, etiology of arrhythmia risk, and indication for the ICD, and the behavioral intervention approach that was tested has also varied.³⁶ Thus, there is not a generally accepted method to reduce adverse psychological outcomes. Therefore, the purpose of this study was to develop and test a nurse-managed psychoeducational intervention to reduce psychological consequences attributed to the ICD through provision of education, counseling, symptom management and coping skill training. Based on stress and coping theory,³⁷ the intervention focused on the modifiable factors associated with reduced outcomes – coping, illness appraisal, shock preparation and ICD symptoms and concerns. The randomized design was developed to test the hypothesis that the intervention would result in lower symptoms of anxiety and depression, improved functional status, and less health care resource use at 12 months when compared with usual care.

Methods

Design

A longitudinal, randomized intervention trial was designed to test the effects of the psychoeducational intervention with ICD implantations between March, 2001 and August, 2004. The project was titled “Psychoeducational Intervention for ICD Patients” and referred to as the PEACE Trial. Study time points were baseline (BL; during hospitalization) and 1, 3, 6 and 12 months after implantation. ICD patients (n=246) meeting the inclusion criteria were randomized to one of three groups to receive usual care (UC), telephone counseling (TC) or group (GRP) intervention. Randomization occurred in blocks of 6 to allow for creation of the GRP intervention groups and included a minimization procedure to maintain equivalency of the groups by race and gender. The intervention, provided in acute care and

2-3 months after implant by trained cardiovascular and mental health nurses, included education, symptom management training (SMT), and cognitive techniques to teach coping skills and improve illness appraisal. The SMT component was delivered in the acute care setting prior to hospital discharge followed by the coping skills training at 2-3 months after implantation. A booster session was provided between 4-5 months in the same randomized format, i.e. group or telephone. The UC group received routine education and support by their providers and unstructured follow up phone calls by the research staff at the same time of the intervention and booster sessions.

The intervention content of the telephone and group formats was identical to allow for testing of the effects of the intervention content as well as to contrast the GRP and TC formats. The formats to be tested were selected for several reasons. Although numerous anecdotal reports suggested that support groups were beneficial to some ICD patients,³⁸⁻⁴¹ no reported studies had used structured coping skill training and reappraisal as the content for group sessions. Additionally, in many cases, ICD recipients live geographically distant from the enrolling center and have difficulties attending groups, thus a cost-effective telephone counseling format was selected due to its potential to reach more ICD recipients and its effectiveness in reducing distress and improving outcomes in ICD and other chronically ill patients.^{34, 42, 43} Without strong evidence for the advantage of one approach over the other, we did not hypothesize which would be superior. Outcomes were measured at one month to determine the response to the acute care intervention, and the other time frames were selected to examine effects immediately after the GRP or TC intervention (3 months), booster sessions (6 months), and a sustained time frame (12 months).

All procedures were reviewed and approved by the Institutional Review Board of the enrolling hospitals and the academic setting. Participants were recruited from 5 participating hospitals in the greater Atlanta area. All participants signed written informed consents.

Patient Population

The intent was to select a broad sample of ICD patients who did not have conditions that would interfere with their ability to comprehend or participate in the study activities. Participants were selected if they were recipients of their first ICD (i.e. not scheduled for a replacement or battery/lead change) and could be receiving the ICD for either primary or secondary prevention. Additional inclusion criteria were: 23-75 years of age, English fluency, non-thoracotomy insertion, living within 100 miles of the enrolling center, and accessible by phone. Patients were excluded if they were being evaluated for heart transplant, had congenital heart disease, genetic arrhythmia etiology, psychiatric disorder, a progressively debilitating musculoskeletal comorbidity such as multiple sclerosis, cognitive problems represented by ≥ 3 incorrect responses on the Short Portable Mental Status Inventory,⁴⁴ or hospital discharge to another facility versus home.

Intervention

The intervention had three major components: education and information about the device, SMT, and CBT to teach cognitive techniques to improve coping skills and illness appraisal. The education and SMT were provided to both intervention groups on the day of hospital discharge. Structured information was provided by the research nurse using a standard script to guide a 20-30 minute session, and participants were provided with an audiotape to take home for later reference. Concrete objective information was used to provide evidenced-based preparation for expected symptoms and sensations in early recovery, and the SMT component included strategies for identifying and managing symptoms, sensations and experiences associated with incisional and device site pain, sleep disturbances, ICD shocks, and progressive return to activities. These topics were selected based on previous work

identifying high priority concerns for ICD recipients.^{18, 21, 26, 45-48} A short telephone call was provided one week after discharge to reinforce the information and encourage the use of the symptom management techniques. Usual care participants received standard discharge teaching from their providers, and an audiotape with the same information as found in the standard ICD teaching booklets⁴⁹ and those provided by industry at the time.

The reappraisal and coping skills intervention was initiated 1-2 months after ICD, and was designed to provide ICD-specific information and to teach active coping strategies. Starting the outpatient component of the intervention 1-2 months after implant allowed some time both for recovery and experience living with the ICD. A standardized script and written materials were used to guide the intervention which was provided in four group (2 hour each) or four telephone (approximately 60 minutes each) sessions held one week apart. Approximately 4 participants attended each group. Family members were welcome to attend but were not enrolled as participants of the study. Educational material was presented in an active learning and discussion format, with opportunities for questions from the participants and homework activities. Educational content included maintaining a normal lifestyle, reinforcement of SMT provided in the acute care setting, dealing with fear and anxiety, dealing with electromagnetic interference issues, traveling with an ICD, and recognizing and responding to emotional responses. Coping skills training was also designed to teach relaxation techniques, proactive coping such as developing a shock plan and activity goals, recognition of and strategies to reduce negative thoughts about arrhythmic conditions and the device, strategies for managing depressive symptoms, and how to reach out to family members and friends for social support. An audiotape with relaxation exercises was provided to GRP and TC participants, and was demonstrated at the end of one of the group sessions. For telephone participants, instructions on use of the tape was discussed in one session with encouragement to use the tape/technique and report back in the next session. The group sessions were co-led by a cardiovascular research nurse and mental health clinical nurse specialist who were specifically trained to deliver the outpatient interventions. The telephone sessions were delivered by a different cardiovascular research nurse who had also received specific training for the intervention.

Measures

Demographic and Clinical Data—Demographic and clinical data including cardiovascular history, arrhythmia information, and comorbidities (Charlson comorbidity score)⁵⁰ were obtained from the participants and their medical records during hospitalization. In addition, the following outcome variables were assessed by patient completion of self report questionnaires as follows:

Anxiety: The state component of the State-Trait Anxiety Inventory (STAI)⁵¹ consists of 20 statements to which the participant rates how they feel at the moment about that item on a 4 point scale with higher scores indicating higher levels of anxiety. The scale is considered a sensitive indicator of changes in transitory anxiety within individuals compared to the trait anxiety scale which measures anxiety proneness.⁵¹ STAI scores ≥ 40 , indicate severe and clinically significant anxiety.⁵¹ The state component of the STAI has been used in ICD patient populations ^{34, 52, 53} with reliability reported as .94. ⁵³ Internal reliability consistency measured by Cronbach's alpha (.95) was acceptable in this study.

Depressive Symptoms: The Beck Depression Inventory II (BDI-II)⁵⁴ was used to measure depressive symptoms, which are characterized by feelings, thoughts, and behaviors that reflect sadness, loss of interest in life, and negative perceptions of self or future. The BDI-II is a self-report instrument consisting of 21 groups of 4 statements rated on a 0 to 3 scale indicating how they felt over the past 2 weeks, and higher scores represent greater

acknowledgement of depressive symptoms. Cronbach's alpha was .90 in this sample. BDI-II scores >13 is the level indicating at least mild depressive symptoms.⁵⁴

Physical Function: Defined as the patient's perception of physical ability in relationship to their cardiac illness, physical function was measured by the Duke Activity Status Inventory (DASI).⁵⁵ The DASI has 12 items that reflect common daily activities, and participants rate the amount of difficulty they experience in performing these activities on a 1 to 4 scale which are then summed. Higher scores indicate better perceived physical function. The DASI has been used with multiple types of cardiac patients, including ICD recipients, and has demonstrated a correlation of .80 with peak oxygen uptake measured by exercise testing.^{9, 55-57} The obtained Cronbach's alpha was .86.

Health Resource Use: The number of hospital admissions for ICD or arrhythmia related conditions, emergency room visits for ICD related events, number of calls to providers, and number of sick/disability days were obtained from health resource use diaries maintained by participants over the 12 months. Diaries were collected at study follow up times and reviewed by the research nurses who prompted for memory of events and data verification. Validation of selected health resource use occurred through chart audits.

Data Analysis

Baseline demographic and clinical variables were compared across the three groups using one-way ANOVA and F-tests for continuous variables, and through χ^2 tests for proportions. Intention to treat analysis was used. Analysis of the outcome variables was conducted in several steps. First, change over time in each of the outcome variables (STAI, DASI, BDI-II, health resource use) was analyzed using repeated measures analysis of covariance variance (ANCOVA) implemented using the SAS Proc Mixed software, version 9.1. This procedure provides for flexible modeling that is capable of handling the various issues that typically arise with repeated measures data such as missing data. With SAS, parameter estimation is carried out using the restricted maximum likelihood (REML) method, which has the advantage of including patients with partially missing outcome data. Each model included the between-participants variable (Group) with three levels, the within-participants variable (Time) with five levels (baseline, 1, 3, 6 and 12 months), and the Group*Time interaction, which if significant, would indicate that the pattern of change in the three groups was different. When a significant effect was observed groups were contrasted using the planned post hoc analysis. Baseline demographic and clinical variables with potential theoretically-based relationships to the specific outcome variables were tested for relationships with the STAI, BDI-II, and DASI scores for possible inclusion in the model as covariates to reduce the influence of the variable and to allow for more accurate assessment of the effect of randomization group. Covariates were included if they met assumptions of significant relationships with the outcome variable at the $p \leq .20$ level. Significant covariates in the models ($p \leq .05$) for STAI scores were age, education, and BDI-II scores; significant covariates for the BDI-II scores were DASI and STAI scores, and finally, significant covariates for the DASI were gender, LVEF, history of SCA, comorbidities, and BDI-II scores. Second, categorical variables were constructed using standard scoring criteria for clinically significant anxiety and depression, and the percentages in each group were contrasted using Chi-square. The two intervention groups were compared, and when no differences were found, they were combined and contrasted with the UC group. Finally, although the repeated measures ANCOVA analyses did not result in a significant group by time effect, we noted a pattern of decline in mean depression for the 2 treatment groups but not for the UC group. Since the BDI has recognized cut scores that could be applicable to clinical practice, we used this categorization as a way of further investigating any potential

effects on depression via logistic regression while controlling for gender, and baseline depressive symptoms, and use of antidepressant or anti-anxiety medications.

Results

Over the period of the study, 940 patients were assessed for eligibility and 694 (73%) were excluded due to not meeting the rigorous inclusion criteria, refusal to participate, or physician preferences that the patient not be enrolled. Of the 474 approached to participate, a total of 246 (51.9% of those eligible) participants consented and were randomized to the three groups. Comparison of the 228 (32%) who declined participation revealed no differences based on the screening data of age, gender, NYHA class, and EF. The most frequent reasons provided for refusal were “feeling overwhelmed” due to illness or other ongoing studies, and concerns about their current and future health. Over the 12 month period, 10 deaths occurred, and an additional 55 participants (22.3%) were lost to follow up (relocation, disconnection of phone) or withdrew due to declining health (i.e. increased severity of heart problem, stroke, trauma, cardiac transplant) or loss of interest in the study (Figure 1). No significant differences in attrition rates were found by group, and there were no differences in baseline information on any study variable between those who were lost to follow-up and those who completed the study. No differences were found at baseline or over time by enrolling center. Intention to treat analysis was used, and in tracking the adherence to the intervention, 100% of those randomized to intervention received the acute care component, and approximately 85% and 82% randomized to group and telephone intervention respectively, received the full outpatient intervention. The reasons for not receiving the randomized outpatient intervention were related to perceived health and not feeling well enough to participate, transportation issues, travel or other personal obligations at the time of scheduled intervention.

Demographic and clinical variables are presented in Table 1 for the total sample and the three randomized study groups. The mean age of the sample was 58 ± 12 years, 75% were male, the majority were married, and 46% had greater than high school education with some college or trade school training, and 23% were minorities, primarily African Americans. Approximately 32% were NYHA class III & IV, and the mean LVEF was $26 \pm 12\%$ reflecting significant compromised cardiac function. During the course of the study, new technology and indications emerged, and approximately 20% of the sample had resynchronization with biventricular devices. At baseline, 16% were on antidepressant or anti-anxiety medications. After ICD implant, only 5.6% participated in any type of support group, and cardiac rehabilitation participation was low at 7.2%. There were no differences by group on any of these variables. No statistically significant differences by study group were found on baseline measures of the STAI, BDI-II or DASI. The study results related to the outcome variables including descriptive statistics results of the repeated measures ANCOVAs and Chi Square analyses, and effect sizes are presented in Table 2, and the outcomes variables are discussed below.

Anxiety

At baseline, the overall percentage of participants with STAI scores ≥ 40 , indicating severe and clinically significant anxiety, was 36.6%. Over the 12 months of the study, the STAI scores of the UC group reflected little change, whereas the STAI scores of the intervention groups showed a small but progressive decline. At 3 months, anxiety scores were lower in the intervention groups than UC ($p=.03$), and GRP primarily accounted for this change, and chi square analysis revealed that significantly fewer participants in the combined GRP and TC intervention groups (26%) compared with UC (41%) had clinically significant anxiety as reflected by the STAI scores. However, while the trends for lower levels of clinical

significant anxiety in the intervention groups persisted over time, statistically significant differences were not retained, and no group differences were present at 6 or 12 months.

Depressive Symptoms

At baseline, 23.4% of the sample had BDI-II scores >13 which is the level indicating at least mild depressive symptoms.⁵⁴ Examining the group by time patterns, the UC group showed little change in BDI-II scores and reflected the highest scores, whereas the intervention groups showed a small decline in BDI-II scores over time. At 3 months, 26% of the UC group versus around 16% of the combined intervention groups had depressive symptoms. This pattern was maintained with 33% of the UC group versus 18% of the combined intervention group exhibiting depressive symptoms at 12 months ($p=.01$). When controlling for baseline level of BDI-II score and antidepressant/antianxiety medications, gender, and randomized intervention group, logistic regression revealed a significant model (see Table 4). Baseline BDI-II score ($p=.001$), baseline use of antidepressant or antianxiety medications ($p=.01$), and randomized intervention group ($p=.03$) were significant predictors of probability of having depressive symptoms at 12 months. The different predicted probabilities obtained from the logistic regression analysis (UC =.31, GRP=.17, TC =.13, $p=.03$) suggest the chance of having depressive symptoms at 12 months was lower for the intervention groups (17% for support group and 13% for telephone) compared with the control group (31%).

Physical Function

Participants of this study exhibited fairly low DASI scores at baseline reflecting low perceived physical function. Overall, DASI scores reflected little change over time, and no statistically significant differences in change were observed by group.

Health Resource Use (Table 3)

Over the course of the study, participants incurred 95 emergency department (ED) visits, and 128 hospitalizations for cardiac reasons. ICD shocks ($n=273$) occurred in 39 participants with several experiencing multiple shocks (“electrical storm”). No group differences in the percent experiencing shocks for any reason or storms were observed, and although STAI scores were slightly higher in those receiving any type of shock over those who did not receive ICD shocks, the scores were not significantly different. ICD shocks were not significant independent predictors in any of the ANCOVA models testing for differences in group outcomes of STAI, BDI-II or DASI scores. Additionally, no differences by randomized group in the DASI, STAI, or BDI-II were found in this small subgroup of participants who received shocks. There were no statistically significant differences in either adjusted (NYHA class, age) or unadjusted analysis between groups in physician visits, tests and procedures, ED visits, hospitalizations or number of shocks. However the UC group had more calls to their providers at 1 ($p=.01$) and 6 months ($p<.05$) than the intervention groups. Participant-initiated calls to the study research nurse did not differ by group or increase at any point. Of the 57 participants employed at enrollment in the study, 13 (22%) left the workforce during the study due to retirement or disability. At 12 months the UC group had more disability days ($p=.02$) with a larger percent missing work for any reason than the two combined intervention groups. Adjusting for NYHA class, participants receiving shocks consumed more tests and procedures ($p=.05$) at one month than patients not receiving shocks regardless of study group. As might be expected, persons with heart failure were noted in all groups to seek more health care as evidenced by increased MD visits ($p=.03$) and consume more tests and procedures ($p=.02$) regardless of study group assignment, but did not receive more shocks than persons without HF.

Use of the audiotape given at hospital discharge was tracked during the first week and this “dose” was obtained as self report at the one week phone call. Participants reported listening to the tape 0-5 times (median 1.0) after hospital discharge, and the frequency did not differ by group. A greater number of GRP and TC participants evaluated the audiotapes as very helpful (72%) over UC (60.8%) (Chi square = 10.3, $p=.03$), and number of times listening was related to the perceived usefulness ($r=.30$, $p<.01$). However, the one month scores for the STAI, BDI-II and DASI, and health resource variables did not vary by number of times the tape was heard or perceived usefulness.

Discussion and Conclusions

Approximately 37% of the participants had clinically relevant levels of anxiety at baseline. Anxiety was reduced in the two intervention groups at 3 months after ICD. In contrast, the UC group showed no decline in anxiety over time. Baseline anxiety measures in this study are similar to the STAI scores reported in other studies of ICD patient populations.^{34-35, 53-58} The psychoeducational intervention was effective in significantly reducing anxiety early in recovery as exhibited by the greatest decrease in scores occurring at 3 months, the time most proximal to the outpatient coping skill training intervention. The reduction in STAI scores at 3 months was primarily observed in the study group receiving the intervention by group format, and the mean reduction was similar to that observed by other psychological interventions delivered in group³³ or telephone format.³⁴ Although overall effect sizes in this study were small (.20) as defined by Cohen⁵⁹, the largest effect size for STAI was found in the comparison of GRP with UC (.37) at 3 months which would be considered to be midrange between small (.20) and moderate (.50). The reduction in the percent with clinically significant anxiety was similar to that reported by Lewin⁶⁰ who implemented a post-ICD intervention consisting of three brief counseling telephone calls. Additionally, 12 month STAI mean scores were lower than baseline in the GRP and combined intervention groups, however even with booster sessions, statistically significant differences in anxiety between intervention and usual care groups results were not sustained. This suggests the need for a stronger, more protracted, repeated, and/or readily available intervention as ICD patients encounter new experiences in living with an ICD over time. Several other studies of brief or unstructured support group interventions also were not effective in significantly reducing anxiety in ICD patients.^{53-61, 62} Dougherty et al³⁵ reported a sustained effect of telephone counseling on anxiety, and the difference between studies may be explained by the greater duration of intervention (i.e. 8 versus 4 sessions) and the lower severity of illness compared to this sample.

Depressive symptoms were observed in 24% of the overall sample at baseline with mean scores and percentages similar to those reported by some,⁵⁷⁻⁵⁸ although post-ICD depression reported in other studies tends to be higher (between 22-66%).⁶³⁻⁶⁴ The percent of the groups experiencing depressive symptoms dropped after 3 months in the intervention groups and were consistently lower compared with UC for the duration of the study. A remarkable 33% of the UC group exhibited depressive symptoms at 12 months, which was 60% greater than the percent in the two intervention groups. Based on the predicted probabilities obtained in the logistic regression model, the chance of having depressive symptoms at 12 months for the intervention groups was almost half that of the control group, and the corresponding effect size of .31 would be considered midrange between small and moderate.⁵⁹ The significant effect of the intervention on depressive symptoms was observed at 12 months when controlling for baseline depressive symptoms and whether participants were taking antidepressant or anti-anxiety medications at baseline (indicative of prior psychological problems). Since a component of the intervention, labeled “handling the blues,” specifically dealt with recognizing and responding to depressive symptoms, it is likely that participants in the intervention groups were more adept in using the behavioral

coping strategies taught in the session. The change in depression scores and percent with depressive symptoms is similar to the intervention response reported by Lewin and colleagues,⁶⁰ and Kohn et al.⁶⁵ This study highlights the need for assessing depressive symptoms at the time of implant which could help target those who are at greater risk for post ICD depression and in need of different or early support. The study also demonstrates that depression after ICD may be prevented with structured psychoeducational intervention.

No significant changes were observed over time or by group in the DASI scores. The mean DASI scores obtained from participants in this study were slightly lower than reported by other studies of ICD patient populations.⁹ Although the intervention encouraged return to usual activities and assisted participants to set activity goals, this was not sufficient to promote increased physical function. Additionally, few participants attended cardiac rehabilitation. To improve physical function in a population with this level of cardiac compromise, a more structured physical activity intervention might be more successful.^{66, 67} Pederson and colleagues recently reviewed published ICD intervention studies and suggested a combination of psychological and exercise interventions may be the most optimal.³⁶

The intervention did not significantly reduce health resource use in terms of hospitalizations or emergency department visits. This differs from the results of Lewin and colleagues, who found a behavioral intervention resulted in reducing unplanned hospital admissions by 50%, and the intervention was deemed 67% more cost effective than usual care.⁶⁰ Cost-effectiveness analysis was not conducted in our study. However there were effects noted in disability days and calls to physicians. Importantly, the calls to providers were not replaced by calls to the study RNs at the 1 and 6 month time frames when effects were observed, thus we do not believe a substitution effect occurred. Because only a small percent of participants were employed at baseline, tracking change in work days was limited to this small subsample; nevertheless, those in the intervention group were less likely to miss work for any reason at 12 months, which coincides with the time frame of reduced probability for depressive symptoms. Closer tracking of a broader array of health resource outcomes such as disability days may be enlightening for future studies of this population.

The study was limited to those receiving their first ICD, and participation at the time of implant in the acute care setting was required, limiting the overall generalizability of the study results. Another limitation of the study was the attrition due to severity of illness and loss to follow up reflecting the inherent difficulties in implementing a behavioral intervention with a seriously ill patient population. Finally, it is important to acknowledge that all self-report inventories are subject to some degree of response bias, and individual endorsement or denial of symptoms may affect the depression and anxiety scores. The absence of group differences at baseline and in longitudinal analyses argues against the influence of this problem on study outcomes. Finally, except for the DASI which is specific for cardiac populations, the measures represented a generic versus ICD-specific assessment of outcomes and may not have tapped improved responses to the ICD specific intervention. The measures were selected for their well established use in behavioral outcome studies and the lack of ICD specific outcome instruments at the initiation of the study.

There were no significant differences between GRP and TC on outcome variables over time, thus the content of the intervention was deemed a key factor versus the format. The changes in anxiety and depression between baseline values obtained in the acute care setting and the 1 month scores were negligible, suggesting the acute care intervention should be reconsidered. The time in the acute care setting tends to be very short, and delivery of in-depth information is difficult with poor retention, yet ICD patients need to be well prepared for what they will experience between the time of hospital discharge and first routine follow

up clinical visit. Telephone counseling and follow-up may provide a cost effective and clinically feasible approach to bridge the gap between acute and outpatient care and may help improve outcomes for those distant to a center and unable to attend groups. Agreement to participate was not obtained in 49% of those invited, most frequently due to perceived burden of illness, other studies, and expressed uncertainty about their future ability to participate. ICD patients, while in the acute care setting, may need further reassurance about the recovery process and the potential benefits of participating in such a study or interventions. Implementation of the intervention will likely depend on the resources of an institution and the patient/provider preferences. Future studies should focus on developing methods to sustain the desired psychosocial effects (i.e. reduced anxiety) and create biobehavioral approaches to improve both physical and psychosocial outcomes in ICD patients. The importance of this study is found in its evidence that a nurse-led intervention combining education, symptom management training and cognitive behavioral approaches to teach coping and reframe illness appraisal was well received and reduced adverse psychosocial outcomes in first-time ICD recipients.

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Figure 1.
PEACE Trial Consort Flowchart

Table 1

Demographic and Clinical Characteristics of the Sample by Group

Variable	Randomized Study Groups			
	Total N=246	Usual Care N=78	Group Intervention (GRP) n=85	Telephone Counseling (TC) n=83
AGE (yrs) (mean $\pm$ SD)	58.5 $\pm$ 11.1	58.4 $\pm$ 12.0	59.0 $\pm$ 10.6	58.0 $\pm$ 10.9
Gender (n/%)				
Male	180 (75%)	54 (70.1%)	68 (82.9%)	58 (71.6%)
Female	60 (25%)	23 (29.9%)	14 (17.1%)	23 (28.4%)
MARRIED (n/%)				
single/divorced/widowed	61 (25.4%)	23 (29.9%)	18 (21.9%)	20 (24.7%)
married/domestic partner	179 (74.6%)	54 (70.1%)	64 (78.1%)	61 (75.3%)
EDUCATION (n/%)				
$\leq$ High school	128 (53.6)	35(45.4%)	46 (56.1%)	47 (58.7%)
> High school	111 (46.4)	42 (54.5%)	36 (43.9%)	33 (41.3%)
RACE (n/%)				
White	188 (76.5)	63 (81)	59 (69)	64 (78)
African American	50 (20.3)	12 (15)	23 (27)	17 (20)
Other minorities	8 (3.2)	3 (2)	3 (3)	2 (2)
TYPE OF DEVICE (n/%)				
ICD only	190 (79.5)	60 (77.9)	68 (83.9)	62 (76.5)
Bi-ventricular pacemaker with ICD	49 (20.5)	17 (22.1)	13 (16.1)	19 (23.5)
NYHA Class (n/%)				
I & II	162 (67.2)	54 (70.1)	54 (65.9)	54 (66.7)
III & IV	78 (32.5)	23 (29.9)	28 (34.1)	27 (33.3)
LVEF (%) (mean $\pm$ SD)	26.3 $\pm$ 11.8	25.7 $\pm$ 10.7	26.4 $\pm$ 12.1	26.8 $\pm$ 12.5
History of CAD (n/%)	133 (54)	41 (52.5)	43 (50.5)	49 (59)
History of SCA (n/%)				
No	122 (49.6)	37 (47.4)	44 (51.8)	41 (49.4)
Yes	124 (50.4)	41 (52.6)	41 (48.2)	42 (50.6)
Charlson comorbidity score (mean $\pm$ SD)	2.17 $\pm$ 1.49	2.12 $\pm$ 1.54	2.11 $\pm$ 1.52	2.27 $\pm$ 1.41
Antidepressant/antianxiety meds at BL (n/%)	40 (16.5)	8(10.3)	14(35)	18(45)
Participated in Another Support Group n/(%)	11 (5.6)	0	5 (7.6)	6 (9.1)
Attended Cardiac Rehabilitation n/(%)	14 (7.2)	5 (8.1)	3 (4.5)	6 (9.1)
Received ICD shock within the 12 months n/(%)	39 (15.8)	11 (14.1)	17 (20)	11 (13.2)

Legend: LVEF = left ventricular ejection fraction; CAD = coronary artery disease; SCA = sudden cardiac arrest;

Table 2

Study Outcomes by Time and Results of the Repeated Measures ANOVA

Variable	Study Time ^a					Repeated Measures ANOVA results		
	Baseline	1 month	3 month	6 months	12 months	Group	Time	Group X Time
Anxiety (STAI)^d								
Mean ± SD								
UC	36.4 ± 11.8 n=78	37.9 ± 14.0 n=74	36.7 ± 14.0 [*] n=69	36.5 ± 12.7 n=63	35.0 ± 11.8 n=56			
GRP	36.0 ± 12.9 n=85	36.0 ± 12.7 n=75	32.0 ± 11.2 n=69	33.3 ± 11.1 n=66	33.2 ± 11.4 n=63			
TC	33.7 ± 11.9 n=83	34.0 ± 12.7 n=70	33.2 ± 12.9 n=64	32.6 ± 13.2 n=64	33.9 ± 13.4 n=62	p=.44	p=.02	p=.29
Effect Size ^d	.03, .23, .18	.14, .29, .16	.37, .26, -.10	.27, .30, .06	.15, .09, -.06			
Anxiety (STAI)								
% scoring ≥40								
UC	41% n=32	50% n=37	42% ^{**} n=29	40% n=25	33% n=18			
GRP	37.6% n=32	40% n=30	26.1% n=18	24% n=16	30% n=19			
TC	32.5 % n=27	32% n=24	26.7% n=17	27% n=17	29% n=18			
Depressive Symptoms (BDI-II)^b								
Mean ± SD								
UC	9.6 ± 7.4 n=78	9.4 ± 7.9 n=74	9.9 ± 8.0 n=69	9.5 ± 7.7 n=63	9.4 ± 6.7 n=56	p=.46	p=.43	p=.49
GRP	9.0 ± 8.2 n=85	8.6 ± 6.7 n=75	7.1 ± 5.8 n=69	7.9 ± 6.3 n=66	7.5 ± 5.4 n=63			
TC	8.6 ± 6.8 n=83	8.6 ± 7.4 n=70	8.0 ± 8.7 n=64	7.8 ± 7.6 n=64	7.1 ± 6.2 n=62			
Effect Size	-.08, -.14, .05	-.11, -.10, .00	-.40, -.23, -.12	-.23, -.22, .01	-.31, -.36, .07			
Depressive Symptoms (BDI-II)								
% scoring >13								
UC	26% n=20	29.7% n=22	26.2% n=18	25% n=9	33% ^{**} n=18			
GRP	21.2% n=18	24% n=18	17.4% n=12	17% n=11	19% n=12			
TC	22.8% n=19	15.7% n=11	15.6% n=10	17% n=11	16% n=10			
Physical Function (DASI)^c								

Variable	Study Time [^]					Repeated Measures ANOVA results		
	Baseline	1 month	3 month	6 months	12 months	Group	Time	Group X Time
Mean ± SD								
UC	17.8 ± 14.6 n=78	16.8 ± 11.7 n=74	17.8 ± 14.7 n=69	18.9 ± 15.8 n=63	18.2 ± 14.5 n=56	p =.20	p= .18	p = .15
GRP	21.6 ± 17.7 n=85	18.9 ± 15.7 n=75	21.0 ± 15.3 n=69	19.0 ± 15.3 n=66	17.5 ± 14.4 n=63			
TC	19.8 ± 16.6 n=83	19.0 ± 13.8 n=70	22.7 ± 16.9 n=64	22.9 ± 16.3 n=64	23.9 ± 18.3 n=62			
Effect Size	.23, .13, .10	.15, .17, -.01	.21, .31, -.11	.01, .25, -.25	-.05, .34, -.39			

KEY: UC = usual care; GRP = support group intervention; TC = telephone counseling

[^] unadjusted means are presented;

* p =.03 when comparing UC with GRP;

** p<.05 when comparing UC with combined GRP and TC;

Significant Covariates (p<.05):

^a p values reflect adjusting for age, education, BDI-II;

^b p values reflect adjusting for DASI, STAI;

^c p values reflect adjusting for gender, LVEF, SCA, comorbidities, BDI-II;

^d Effect size d for each comparison, GRP vs UC, TC vs UC, and GRP vs TC, respectively.

Table 3

Logistic Regression Results for Depressive Symptoms at 12 Months

Outcome	Predictors	B	SE	p	Odds ratio	95% Confidence Interval	
Mild to severe depression at 12 months (BDI-II >13)						Upper	Lower
	Baseline BDI-II score	1.92	.44	<.001	6.79	2.84	16.20
	Gender	6.8	.45	.13	1.97	.81	4.75
	Antidepressant or antianxiety med at BL	1.09	.45	.01	2.98	12.3	7.22
	Intervention Group	-9.2	.44	.03	.40	.17	.93
	Constant	-.35	.25	.16	.70		

Model $X^2(4)=34.4$, $p=.001$; predicted probabilities: UC =.31, GRP=.17, TC =.13, $p=.03$

Table 4

Health Resource Use by Study Groups

Variable	Study Time				
	Baseline	1 month	3 month	6 months	12 months
Hospitalizations					
Mean + SD (n)					
UC		.13 ± .38 (67)	.09 ± .38 (64)	.18 ± .46 (62)	.42 ± .81 (55)
GRP		.19 ± .55 (70)	.11 ± .45 (61)	.15 ± .44 (61)	.25 ± .89 (63)
TC		.16 ± .53 (67)	.14 ± .35 (57)	.16 ± .42 (55)	.22 ± .53 (59)
ED Visits					
Mean + SD (n)					
UC		.11 ± .31 (66)	.18 ± .53 (61)	.14 ± .43 (63)	.22 ± .49 (55)
GRP		.13 ± .33 (71)	.11 ± .37 (63)	.06 ± .24 (65)	.30 ± 1.1 (63)
TC		.08 ± .27 (66)	.12 ± .57 (57)	.10 ± .36 (58)	.14 ± .68 (59)
Calls to Providers					
Mean + SD (n)					
UC		1.1 ± 1.27* (68)	.98 ± 1.6 (64)	.95 ± 1.3** (64)	1.3 ± 1.6 (55)
GRP		.65 ± .84 (71)	.83 ± 1.5 (65)	.71 ± 1.1 (65)	1.6 ± 2.7 (62)
TC		.58 ± .92 (67)	.95 ± 1.4 (59)	.44 ± .95 (59)	1.3 ± 2.1 (58)
Missed work for any reason⁺ (% of group)					
UC		63%	43%	31%	56%***
SG		59%	45%	42%	7.6%
TC		50%	50%	50%	46%

⁺ reported only for those employed; UC, n=19; GRP n=22; TC n=16

* ANOVA results: F = 4.57, df=2, p=.01

ANOVA results: $F = 4.03$, $df = 2$, $p = .05$

Chi Square = 7.5, $p = .02$