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Web-Based Distress Management for Implantable Cardioverter Defibrillator Patients: A Randomized Controlled Trial

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Objective: Sudden cardiac arrest caused by cardiac arrhythmias is 1 of the leading causes of death worldwide. Implantable cardioverter defibrillators (ICDs) are considered as standard care for patients with increased risk of arrhythmias. However, 1 in 4 ICD patients experiences psychological distress post-ICD implantation. The WEB-based distress management program for ICD patients (WEBCARE) was developed to mitigate anxiety and depression and enhance health-related quality of life in ICD patients. This study investigates the 6- and 12-months outcomes. ***Method:*** A total of 289 consecutive ICD patients from 6 referral hospitals in the Netherlands were randomized to either the WEBCARE ($n = 146$) or usual care ($n = 143$) group. Patients in the WEBCARE group received an online, 12-weeks fixed, 6 lesson behavioral treatment based on problem solving therapy. Patients in the usual care group receive care as usual. ***Results:*** Current findings show no significant difference on anxiety, depression or quality of life between the WEBCARE and Usual Care group at 6- and 12-months postimplantation. ***Conclusions:*** In this clinical trial of a Web-based behavioral intervention for ICD patients, the Web-based treatment was not superior to usual care on the long-term regarding patient reported outcomes. Future studies are warranted to examine the applicability of blended-care models and focus on further personalizing the program in order to increase adherence and improve outcomes.

Keywords: Web-based, distress, implantable cardioverter defibrillators, quality of life, anxiety

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The implantable cardioverter defibrillator (ICD) is the treatment of choice for the prevention of sudden cardiac death (Zipes et al., 2006). The ICD is indicated for patients who have experienced a sudden cardiac arrest (secondary prevention) and for patients who have an increased risk to experience one in the future (primary prevention) (Ezekowitz et al., 2007). The ICD monitors the heart rate and is able to give an electric shock (up to 840 V) to the heart muscle in case of life-threatening arrhythmias (Mirowski et al., 1980). The experience of an electric shock has been described by patients as "getting kicked in the chest by a big horse from the inside out" (Adams, 2011). Despite its unpredictable nature, the ICD is generally well accepted by the majority of patients (Pedersen, Hoogwegt, Jordaens, & Theuns, 2013); however, one in four patients experiences psychological distress postimplantation (Magyar-Russell et al., 2011). Not only device-related concerns (e.g., shock anxiety) and decreased quality of life (Morken et al., 2012; Pedersen, van Domburg, Theuns, Jordaens, & Erdman, 2005), but also anxiety, depression, and posttraumatic stress have been reported within the ICD population (Habibović, van den Broek, Alings, Van der Voort, & Denollet, 2012; Magyar-Russell et al., 2011; Rosman et al., 2015). In addition, an increasing number of studies have demonstrated an association between psychological distress and risk of tachyarrhythmia's and mortality despite state-of-the-art treatment with the ICD (Habibović, Pedersen, et al., 2013; Ladwig et al., 2008; Pedersen, Brouwers, & Versteeg, 2012). Hence, it is of utmost importance to address distress in these patients to provide the maximum benefits of the ICD in terms of quality of life and survival.

In the last decades, intervention studies targeting anxiety and depression in ICD patients have shown promising results (Dunbar et al., 2012; Habibović, Burg, & Pedersen, 2013; Russell et al., 2015). Especially the use of cognitive–behavioral therapy seems to be effective in reducing anxiety and depression in ICD patients (Habibović, Burg, et al., 2013). However, because of methodological shortcomings of these studies (e.g., small sample sizes; high drop-out; Salmoirago-Blotcher & Ockene, 2009), well-designed studies with sufficient power are still warranted.

To reach a larger proportion of the ICD population and to reduce the time and travel burden to patients (as compared to traditional face-to-face treatment), we designed the WEB-based distress management program for implantable CARdioverter dEfibrillator patients (WEBCARE) with the objective of reducing distress (e.g., anxiety and depression) and improving quality of life (Pedersen et al., 2009). The program was adapted from the existing Everything Under Control (*Alles Onder Controle*) program developed to reduce distress in physically healthy patients by means of problem-solving therapy (van Straten, Cuijpers, & Smits, 2008; Warmerdam, van Straten, Twisk, Riper, & Cuijpers, 2008). Patients were encouraged to assess their problems and actively start working on these using the problem-solving framework provided in the online program. We have previously reported on the short-term effects of the study, which showed no significant difference between the WEBCARE and usual care group on psychological outcomes (Habibović, Denollet, et al., 2014). The WEBCARE intervention was set up as a preventive intervention to reduce the number of patients experiencing distress on the long-term. Hence, in the current study, we will evaluate the long-term effects of WEBCARE, focusing on (a) psychological disease-specific and generic outcome measures, and (b) which patients benefit the most based on subgroup analyses stratified by baseline distress, Type D personality, age, gender, number of lessons completed, and comorbidities.

Method

Participants

Consecutive ICD patients hospitalized between April 2010 and February 2013 were recruited from six Dutch referral hospitals (Amphia, Breda; Canisius-Wilhelmina, Nijmegen, Catharina, Eindhoven; Erasmus Medical Center, Rotterdam; Onze Lieve Vrouwe Gasthuis, Amsterdam; Vlietland, Schiedam). All patients with a first-time ICD implant and aged between 18 and 75 years were screened for study eligibility. Exclusion criteria were significant cognitive impairments (e.g., dementia), history of psychiatric illness other than affective/anxiety disorders, life-threatening comorbidities (e.g., cancer), life expectancy <1 year, being on the waiting list for heart transplantation, lack of Internet/computer skills, and insufficient knowledge of the Dutch language.

Study Design

The WEBCARE study was a randomized controlled trial comprised of two study arms (intervention vs. usual care). Patients' psychological functioning was assessed at four separate time points (i.e., at baseline, 3-, 6-, and 12 months postimplantation) using standardized and validated questionnaires. At baseline, patients' medical records were screened to capture information on clinical data. Based on a sample size calculation with a power of .80 (two-tailed test), an alpha of .05, and an effect size of .30, 350 participants were required (175 in each condition) to demonstrate an effect on the primary endpoint (symptoms of anxiety). A detailed description of the trial design has been published elsewhere (Pedersen et al., 2009).

Procedure

Prior to or briefly after ICD implantation, patients were approached for study participation by an ICD nurse or technician at the implanting center. If they fulfilled all of the inclusion criteria and none of the exclusion criteria, they were informed orally and in writing about the study. Patients who were eligible and willing to participate were requested to sign the informed consent and were asked to complete a set of standardized questionnaires within 10 days postimplantation and return them in a prestamped envelope to Tilburg University, which served as the core-lab for the trial. If the questionnaires were not returned within 2 weeks, patients received up to 3 reminder phone calls. For follow-up assessment, the questionnaires were sent by mail to all patients with the request to return the questionnaires within 7 days. If the questionnaires were not returned within this timeframe, patients received up to three reminder phone calls. The study was conducted in accordance with the Helsinki declaration and approved by the Medical Ethics Committees of the participating centers. WEBCARE was registered on www.clinicaltrials.gov (NCT00895700). Study results are presented as advocated by the Consolidated Standards of Reporting Trials guideline (Campbell, Piaggio, Elbourne, Altman, & the CONSORT Group, 2012).

Randomization

Patients were randomized on a 1:1 basis upon receipt of the baseline questionnaires. Block randomization by computer was used to randomize sets of 20 patients per hospital. The randomization list was generated by an independent, blinded statistician and sealed by a research assistant. Prior to opening the envelope containing the questionnaires, a sealed envelope containing the condition (WEBCARE vs. Usual Care) was drawn for each patient. The health care providers were blinded to which condition patients were assigned. Blinding participants and coaches was not possible given the nature of the study.

Intervention

A detailed description of the intervention has been published elsewhere (Habibović, Denollet, et al., 2014). In brief, patients randomized to the WEBCARE condition received a 12-week fixed six lesson online problem-solving training in addition to usual care. The program was adapted from the Everything Under Control treatment, which has previously been developed and evaluated within a physically healthy population for treatment of depression and anxiety (van Straten et al., 2008; Warmerdam et al., 2008). The program consisted of six preprogrammed lessons starting with psycho-education (Lesson 1) related to living with an ICD. In Lessons 2 to 6, patients were required to make homework assignments for which they received written personalized feedback via the website from their coach. In Lesson 2, patients were required to list the problems that they were experiencing at the moment and to label them as either (a) important problems that can be solved, (b) unimportant problems that can be solved, and (c) problems that cannot be solved. In Lesson 3, patients were asked to choose one of the important problems that can be solved and start working on this problem using problem-solving skills (provided in the program). In Lesson 4, "unimportant problems that can be solved" were addressed and in Lesson 5 dealing with "problems that cannot be solved" was discussed. Finally, in Lesson 6, patients were asked to make a plan on how they plan to reach future goals. Feedback was provided by master course students enrolled in a 2-year Medical Psychology degree program. As part of the degree program, students were doing a clinical internship at a Dutch hospital. Students received a specific standardized training about providing online feedback. The program was amended to fit the needs of ICD patients, providing them additional information about living with an ICD, how to deal with shock anxiety (e.g., making a shock plan), and describing normal psychological problems associated with having an ICD. The WEBCARE group also received a CD with relaxation exercises and was encouraged to use it throughout the study. The control condition was care as usual.

Measures

Information on demographic variables were obtained by patient self-report. Information on clinical data was captured from patients' medical records. Patients' psychological functioning was assessed using standardized and validated questionnaires, both generic and disease-specific.

Generic Outcome Measures

Anxiety. Anxiety was assessed using the seven-item General Anxiety Disorder (GAD-7) Scale (Spitzer, Kroenke, Williams, & Lowe, 2006). Items (e.g., "Feeling nervous, anxious, or on edge") were rated on a 4-point Likert scale ranging from 0 (*not at all*) to 3 (*almost every day*), with a total score range of 0–21. A cut-off score of $\geq$10 was used to indicate probable clinical levels of anxiety. The GAD-7 has a good internal consistency, as indicated by Cronbach's alpha of 0.92 (Spitzer et al., 2006) and has previously been used within the ICD population to assess anxiety (Qintar et al., 2015).

Depression. Depression was assessed using the nine-item Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001). Items were (e.g., "Feeling down, depressed, or hopeless") evaluated on a 4-point Likert scale ranging from 0 (*not at all*) to 3 (*almost every day*), with a total score range of 0–21. A cut-off score of $\geq$10 was used to indicate the presence of depressive symptomatology. The PHQ-9 has a good validity (Kroenke et al., 2001) and reliability, with a Cronbach's alpha of .91(Dum, Pickren, Sobell, & Sobell, 2008). The PHQ-9 has been validated within the cardiac population showing a Cronbach's alpha of .83 (Hammash et al., 2013).

Quality of life. The Dutch version of the Short-Form Health Survey 12 (SF-12) was administered to assess patients' quality of life (Ware, Kosinski, & Keller, 1996). The 12-item scale consists of two components: Physical Component Summary (PCS) and Mental Component Summary (MCS). The total score (on both subscales) ranges between 0 and 100, with a higher score indicating better quality of life (Ware et al., 1996). The SF-12 has shown to be a valid and reliable instrument within Dutch cardiac populations (Mols, Pelle, & Kupper, 2009).

Personality. Type D (distressed) personality was assessed using the 14-item DS14 Scale (Denollet, 2005). The DS14 consists of two seven-item subscales: negative affectivity (e.g., "I often feel unhappy") and social inhibition (e.g., "I am a closed kind of person"). Items were answered on a 5-point Likert scale ranging from 0 (*false*) to 4 (*true*), with a total score for each scale of 0–28 (Denollet, 2005). A cut-off score of $\geq$10 on both subscales indicates a Type D personality. Both scales are internally consistent with a Cronbach's alpha of 0.88 for negative affectivity and 0.86 for social inhibition (Denollet, 2005).

Psychological Disease-Specific Outcome Measures

ICD related concerns. The Dutch version of the eight-item ICD Patient Concerns (ICDC) Questionnaire was administered to assess ICD related concerns (Pedersen et al., 2005). The ICDC taps into fears about getting an ICD shock (e.g., "I am worried that my ICD will fire"), with items rated on a 5-point Likert scale ranging from 0 (*not at all*) to 4 (*very much*; Frizelle, Lewin, Kaye, & Moniz-Cook, 2006). The total score range is 0–32, with a higher score indicating higher levels of concerns. The ICDC is an internally consistent scale with a Cronbach's alpha of 0.91 (Pedersen et al., 2005).

Shock anxiety. Shock anxiety was assessed using the 10-item Florida Shock Anxiety Survey (FSAS; e.g., "I worry about the ICD firing and creating a scene"; Kuhl, Dixit, Walker, Conti, & Sears, 2006). Items were rated on a 5-point Likert scale ranging from 1 (*never*) and 5 (*always*), with a higher score indicating higher levels

of shock anxiety. The FSAS is a reliable measure of ICD shock anxiety, with a Cronbach's alpha of 0.89 (Ford et al., 2012).

Device acceptance. The Florida Patient Acceptance Survey (FPAS) was administered to assess device acceptance (Burns, Serber, Keim, & Sears, 2005). Device acceptance has been described as "psychological accommodation and the understanding of the advantages and disadvantages of the device, the recommendation of the device to others, and the derivation of benefits in terms of biomedical, psychological, and social functioning" (Burns et al., 2005). The 12-item (e.g., "I have returned to a full life") short version of the FPAS was used with items being answered on a 5-point Likert scale ranging from 0 (*strongly disagree*) to 4 (*strongly agree*; Pedersen, Spindler, Johansen, Mortensen, & Sears, 2008; Versteeg et al., 2012). The total score ranges between 0 and 100, with a higher score indicating higher acceptance. The FPAS has shown to be internally consistent with a Cronbach's alpha of 0.85 for the Dutch ICD population (Versteeg et al., 2012).

Statistical Analyses

Continuous variables were compared using the Student's *t*-test for independent samples and are presented as mean values and standard deviations. Discrete variables were compared using the χ^2 test and are presented as numbers and percentages. Analyses were performed according to the intention-to-treat principle, with mean imputation for missing item scores (if <80% of the items was missing). In addition, multiple imputation with 20 iterations was carried out for total score missings using the default option for multiple imputation in SPSS 22.0.

To evaluate the treatment effectiveness over time, the linear mixed models (LMM) procedure was performed. The LMM procedure is similar to linear regression analyses except that in LMM the dependent variable is measured at multiple time points. These analyses were all adjusted for baseline distress levels. If the interaction effects were not significant, the main effects only were entered in the final model.

To examine whether the WEBCARE intervention had a differential impact on particular subgroups of patients, the LMM procedure was adapted evaluating the interaction effects between the treatment condition and the subgroup variables of interest (baseline distress score, Type D personality, age, gender, number of lessons completed, and comorbidity burden as measured by Charlson's Comorbidity Index). For these analyses, the Bonferroni correction was applied, dividing alpha with the number of tests conducted, with a statistically significant difference indicated at a p value of $0.05/6 = 0.008$ or lower.

All analyses were conducted with IBM SPSS Statistics for Windows 22.0. For main analyses, a p value of $<.05$ (two-tailed test) was used to indicate statistical significance.

Results

Sample

Figure 1 shows a flowchart of the patient recruitment, including patients lost to follow-up. A total of 1,024 patients were approached for participation, of which 492 (48%) did not meet the inclusion criteria (lack of Internet, 53%; age >75, 30%; language barrier, 6%). Of the remaining 532 patients, a total of 192 (36%) refused to participate, and 51 (10%) did not return the baseline questionnaire, leaving 289 patients that were randomized to WEBCARE ($n = 146$) versus usual care ($n = 143$) group. A total of 41 (28%) patients were lost to follow-up in the WEBCARE group and 31 (22%) in the usual care group at 12 months follow-up.

Of the 146 patients randomized to the WEBCARE condition, 34 (23%) completed all six lessons of the online treatment. The remaining 112 patients prematurely terminated the treatment due to technical problems, time constraints, or lack of psychological distress. No significant baseline differences were observed between treatment completers and drop-outs, a detailed description of treatment adherence in WEBCARE has been published elsewhere (Habibović, Cuijpers, et al., 2014).

Patients who did not return the baseline questionnaire ($n = 51$) did not differ significantly on demographic variables from patients who were randomized. However, significant differences on clinical variables were observed, with patients who were not randomized being more likely to have more severe heart failure, as indicated by a higher New York Heart Association functional class ($p = .045$) and peripheral artery disease ($p = <.001$) and more likely to use psychotropic mediation ($p = <.001$).

Baseline Characteristics

A detailed overview of patients' baseline characteristics has been published elsewhere (Habibović, Denollet, et al., 2014). In Table 1 an overview is provided of the sample characteristics. The mean age of the sample was 58.5 ± 9.9, with the majority of patients being male (81%). Approximately half of the patients were employed (49%) and 85% had a partner. Baseline differences between the WEBCARE and usual care groups were observed with respect to the proportion of patients having undergone a percutaneous coronary intervention (usual care: 36% vs. WEBCARE: 21%; $p = .003$) and using ACE-inhibitors (usual care: 69% vs. WEBCARE: 56%; $p = .03$). No other systematic baseline differences were observed between groups on psychological measures (Habibović, Denollet, et al., 2014).

Intervention Effects on Generic Outcome Measures

As displayed in Figure 2, no significant differences between the WEBCARE and usual care group were observed on anxiety ($\beta = -.374$; $p = .23$) and depression ($\beta = .085$; $p = .80$). For quality of life, two different patterns were observed. On the MCS of the SF-12, no significant differences were observed ($\beta = .367$; $p = .69$), however, on the PCS a significant interaction effect for Time × Condition was observed. This indicates that the PCS scores tended to have a different pattern over time for the WEBCARE versus usual care groups. Focusing on simple effects, no significant differences between groups were observed at any measurement point (T_1: $\beta = -.623$; $p = .57$; T_2: $\beta = -.384$; $p = .74$; T_3: $\beta = 1.647$; $p = .15$) on the PCS.

Intervention Effects on Psychological Disease Specific Outcome Measures

On psychological disease specific outcomes no differences were observed regarding ICD related concerns ($\beta = -.302$; $p = .47$),

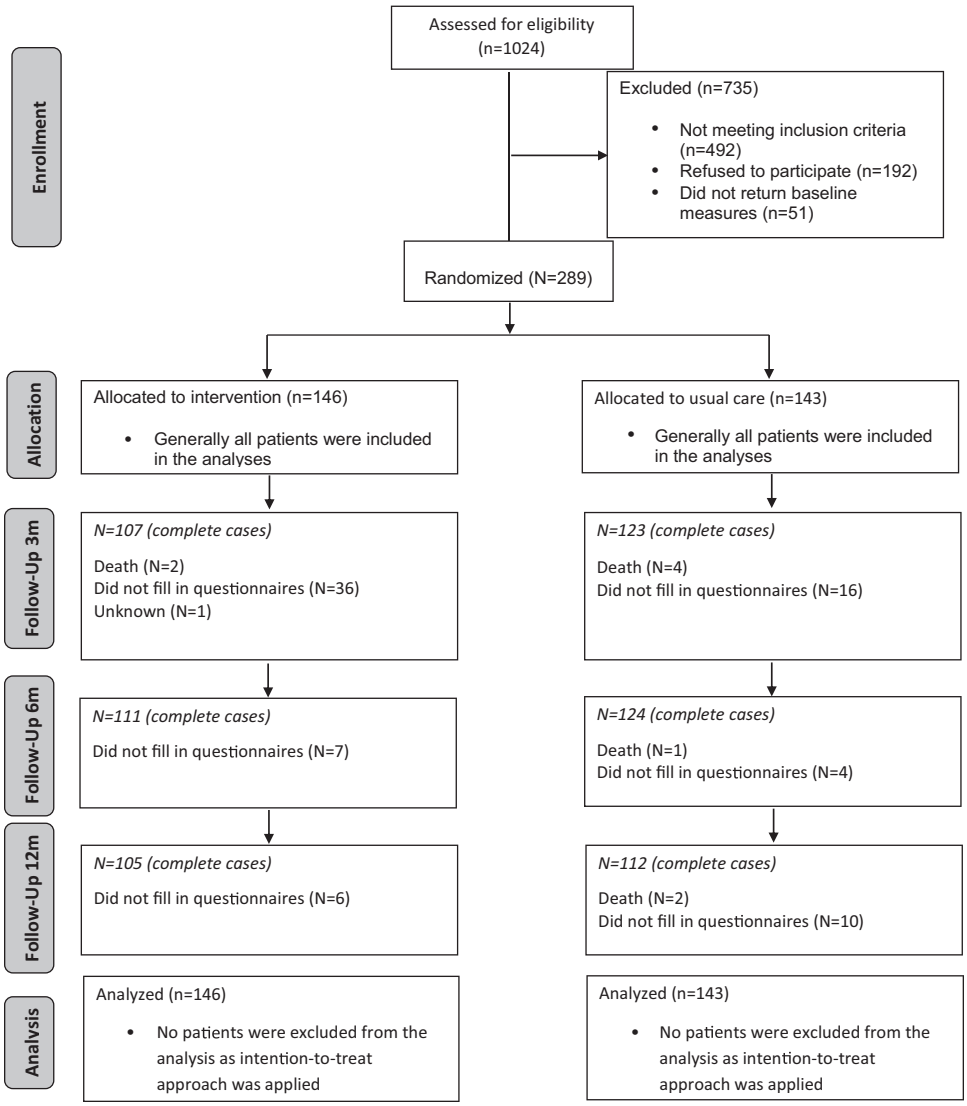

Figure 1. Flowchart patient recruitment.

shock anxiety ($\beta = .177$; $p = .90$) or device acceptance ($\beta = -.024$; $p = .955$) over time (Figure 3). These results indicate that the WEBCARE treatment was not superior to usual care with respect to decreasing device-related distress and increasing device acceptance.

Subgroup Analyses

Subgroup analyses stratified by baseline distress, Type D personality, age, gender, and number of lessons completed showed no significant treatment effects (results not shown) on any of the outcome measures (neither generic nor disease specific). Patients with a higher comorbidity burden as indicated by Charlson's Comorbidity Index reported increased scores on shock anxiety ($\beta = 0.847$; $p = .038$) however, after Bonferroni correction, this was no longer significant.

Discussion

This is the first study to evaluate the long-term effectiveness of a fully Web-based behavioral treatment for ICD patients. Our findings showed that the Web-based intervention was not superior in reducing distress (generic and psychological disease-specific) or increasing quality of life as compared to usual care. Generally, a comparable decline in distress and increase in quality of life was observed in both conditions over time. Subgroup analyses indicated that patients with a higher comorbidity burden in the treatment condition had somewhat increased shock anxiety, however, this was not statistically significant.

Our findings are not in line with previously published results on the effectiveness of the Everything Under Control intervention, which the WEBCARE intervention was adapted from (van Straten et al., 2008; Warmerdam et al., 2008). It is important to emphasize, however, that our study included ICD patients while the previously

Table 1
Baseline Patient Characteristics for the Total Group and Stratified by Intervention

Patient characteristic	Total (N = 289)	WEBCARE (n = 146)	Usual care (n = 143)	p
Demographics				
Age	58.5 ± 9.9	58.2 ± 9.9	58.6 ± 10.2	.73
Gender (male)	235 (81.3)	120 (82.2)	115 (80.4)	.70
Education (high[a]; n = 285)	208 (73.0)	106 (73.1)	102 (72.9)	.96
Working (yes; n = 288)	141 (49.0)	68 (46.6)	73 (51.4)	.41
Clinical				
Secondary indication	90 (31.1)	39 (26.7)	51 (35.7)	.10
Previous PCI	82 (28.4)	30 (20.5)	52 (36.4)	.003
QRS > 120 (n = 287)	128 (44.6)	59 (41.0)	69 (48.3)	.22
Heart failure	157 (54.3)	78 (53.4)	79 (55.2)	.76
NYHA III/IV (n = 232)	45 (19.4)	20 (17.4)	25 (21.4)	.44
LVEF ≤ 35	184 (63.7)	87 (59.6)	97 (67.8)	.15
Comorbidity				
Diabetes	42 (14.5)	18 (12.3)	24 (16.8)	.28
Hypertension	64 (22.1)	35 (24.0)	29 (20.3)	.45
CCI	1.7 ± 1.0	1.6 ± 1.1	1.8 ± 1.0	.15
Medication				
Beta-blocker	237 (82.0)	117 (80.1)	120 (83.9)	.40
ACE-inhibitor	180 (62.3)	82 (56.2)	98 (68.5)	.03
Statins	182 (63.0)	92 (63.0)	90 (62.9)	.99
Psychotropics	20 (6.9)	13 (8.9)	7 (4.9)	.18
Psychological				
Anxiety (n = 288)	4.30 ± 4.54	4.57 ± 5.02	4.03 ± 3.98	.31
Depression	5.65 ± 4.83	5.93 ± 5.11	5.37 ± 4.53	.32
Quality of life				
PCS	40.57 ± 10.44	40.19 ± 10.55	40.96 ± 10.35	.53
MCS	44.29 ± 11.08	43.83 ± 11.28	44.76 ± 10.89	.48

Note. PCI = percutaneous coronary intervention; QRS = QRS-Complex; NYHA = New York Heart Association functional class; LVEF = left ventricular ejection fraction; CCI = Charlson Comorbidity Index; PCS = Physical Component Summary (PCS); MCS = Mental Component Summary.
[a] ≥10 years of education.

mentioned studies focused on a physically healthy population. Despite the adaptations made to Everything Under Control to fit patients with an ICD, it is possible that the intervention did not succeed to meet the specific needs of these patients and should have been more patient tailored. In addition, the current study enrolled all patients regardless of their distress level at baseline, as WEBCARE was designed as a prevention trial. Hence, a large proportion of the patients did not experience any or low levels of distress, leaving little room for improvement. Consequently, the subgroup of patients with increased distress was perhaps too small to detect any significant differences as compared to the nondistressed patients, if present. Finally, in the current study patients were approached for participation at the hospital, while in the trial that evaluated the efficacy of the Everything Under Control intervention, patients were recruited by means of self-selection (van Straten et al., 2008; Warmerdam et al., 2008). The latter might have resulted in a highly motivated sample of patients with severe psychological distress who are willing to work on it (Kroenke, 2014).

As compared to other chronic patient populations engaged in online treatment described in a previous study by Paul et al., the current findings are in line with some, but not all studies (Paul, Carey, Sanson-Fisher, Houlcroft, & Turon, 2013). Generally, Web-based behavioral treatments for the chronically ill are promising with respect to improvements in psychological functioning (Paul et al., 2013). A recent meta-analysis showed that the effects of Web-based treatments in patients with somatic disease are comparable to the effects of face-to-face treatment (Andersson, Cuijpers, Carlbring, Riper, & Hedman, 2014). Hence, despite the negative results of WEBCARE, it is important to continue to develop and fine-tune Web-based treatment for the chronically ill, as this might be a time- and money-saving approach to behavioral treatment that is also patient-friendly in terms of patients accessing treatment at a time that is suitable to them.

To advance the field of Web-based psychological interventions for the chronically ill, there are several knowledge gaps that need to be filled. Because of more intensive therapist involvement in face-to-face treatment, associated costs are higher (McCrone et al., 2004). There might also be a difference in drop-out rates in face-to-face versus Web-based interventions. Drop-out rate in face-to-face behavioral interventions in cardiac patients is mostly related to time and travel burden (Habibović, Burg, et al., 2013), whereas drop-out in the Web-based treatments tends primarily to be related to technical problems (Habibović, Cuijpers, et al., 2014). Introducing a treatment that combines personal contact (e.g., face-to-face encounters and feedback) with Internet-based therapy (e.g., patient access in their own home at a time of their own convenience)—blended care—might be a way forward to high-quality and sustainable care (Wilhelmsen et al., 2013). However, it should be noted that the subsequent costs associated with such an approach might be significantly higher due to an active involvement of a coach/clinician. Another viable approach for future studies

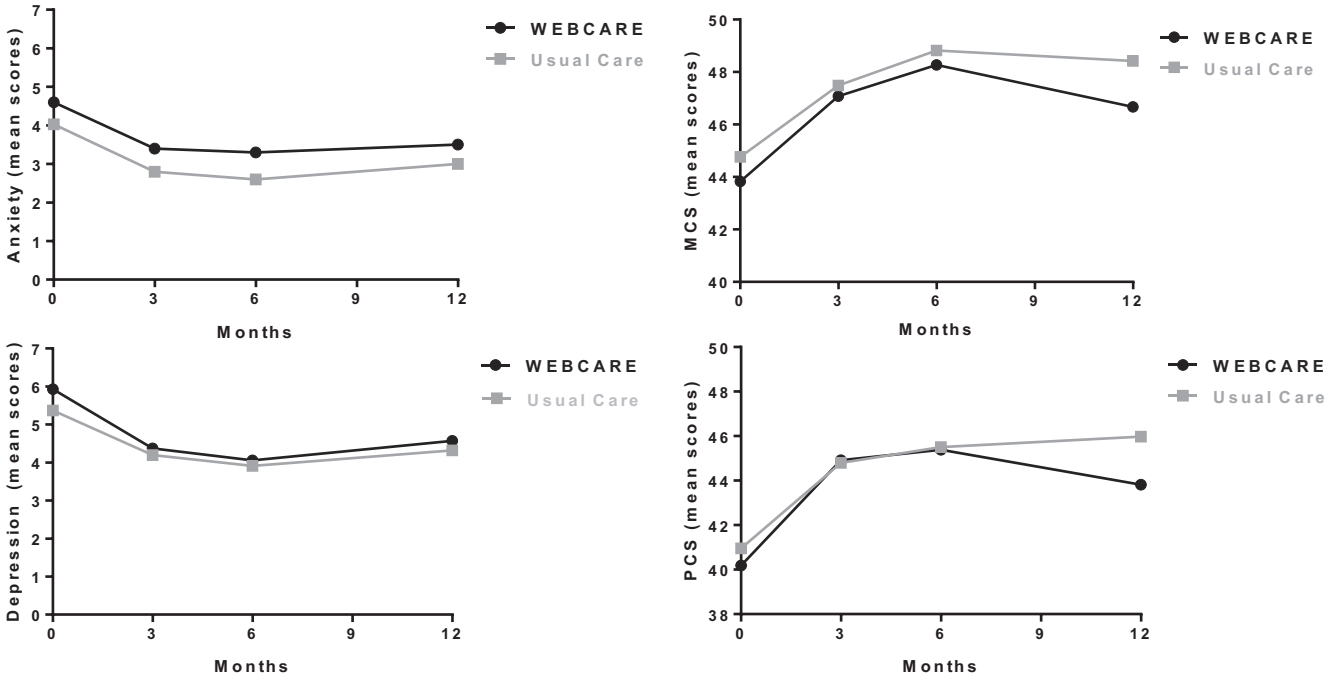

Figure 2. Mean scores on generic measures at baseline, 3-, 6-, and 12 months.

would be to focus on the improvement of the technical and design features of fully automated interventions. Improving these aspects might contribute to higher adherence and could keep the associated treatment costs to a minimum. Involving patients in the development of the trial—also referred to as a *user-centered design*—or having patients as a part of the treatment team, such that they are actively involved during the intervention to support/guide the patients who are participating in the treatment—might also enhance the success of the intervention (Yu et al., 2014). Treatment should be tailored to the individual patient's needs and preferences, as the "one-size fits all approach" is unlikely to work (Habibović, Burg, et al., 2013). Furthermore, the appropriate timing and length of the treatment is still to be examined. Offering a too-demanding treatment, too soon will most likely result in high drop-out rates, influencing potential effects negatively (Habibović, Burg, et al., 2013; Kroenke, 2014).

A number of study limitations must be acknowledged. First, the intervention was offered within 2 weeks postimplantation. This might have been too soon, as ICD patients are faced with several challenges postimplant that include getting used to a life with a device that can provide uncontrollable shocks, driving restrictions, and concerns about how much they can and dare do with the ICD. In addition, generally distress levels within the ICD population decline within the first 3 months postimplant, representing adaption to living with a device (Pedersen et al., 2013). Hence, it might have been better if patients were monitored for distress the first 3 months and, if prevalent, offered the intervention. Second, we assessed distress using validated and standardized self-report questionnaires rather than a clinical diagnostic interview. However, some of the chosen measures (e.g., the ICDC and the HADS) have been shown to predict mortality independent of traditional risk factors in ICD patients, despite state-of-the-art treatment with the ICD, and also to be sensitive to demonstrate treatment-related effects (Mastenbroek, Versteeg, Jordaens, Theuns, & Pedersen, 2014; Pedersen, van den Broek, Erdman, Jordaens, & Theuns, 2010; Vazquez, Conti, & Sears, 2010). Third, we observed a relatively high attrition and nonadherence rate during the intervention and the study, although these rates are to some extent comparable to those found in other studies (van Straten et al., 2008; Warmerdam et al., 2008) this might have negatively affected the power of the study making it difficult to detect differences between the groups.

In the current sample three main reasons for drop-out, as given by patients, were technical problems with the computer, time constraints, and "feeling fine" not having any problems to work on (Habibović, Cuijpers, et al., 2014). In addition, patients who refused to participate in the study but provided baseline medical information appeared to have a higher disease severity burden than patients who were enrolled in the study. Hence, this might have contributed to the null findings as the patients who were enrolled were relatively healthy and perhaps not in need of additional care. These limitations might have reduced the ability of the current trial to demonstrate significant treatment effects. Furthermore, as the intervention was designed as a "one size fits all" prevention approach, personalizing it to patients' needs was not possible.

An important strength of the study is that the current sample reflects the real-life uptake of a (preventive) Web-based intervention, as it would be upon implementation in the health care system. Patients were approached and included based on the relatively broad inclusion criteria in a naturalistic setting. Hence, this reflects the uptake of the intervention among the general ICD population. The high attrition rates observed in the current study may thus actually be a realistic representation of the intervention uptake upon implementation.

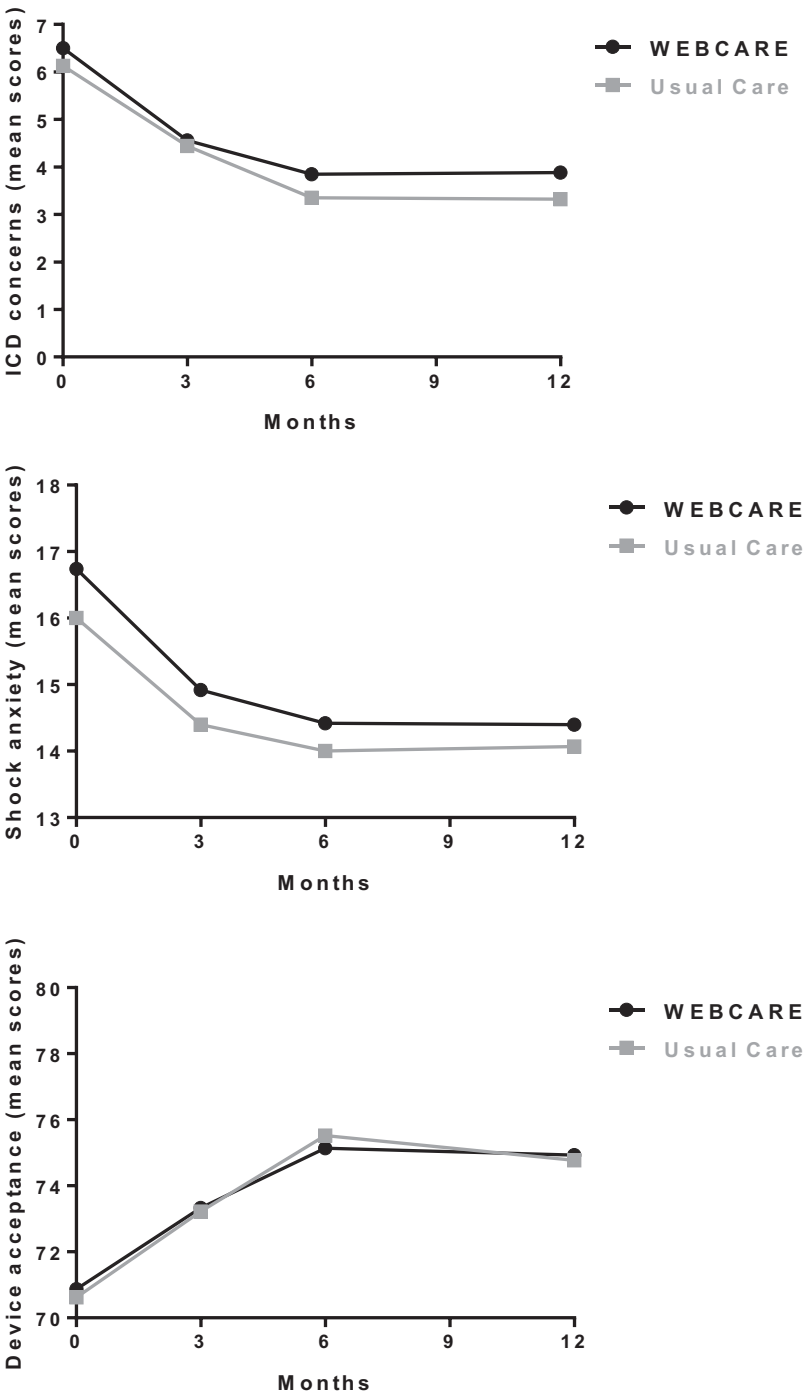

Figure 3. Mean scores on disease specific measures at baseline, 3-, 6-, and 12 months.

In conclusion, we found no main treatment effect of WEBCARE in ICD patients on generic and psychological disease-specific measures of distress and quality of life 12 months' postimplant nor in subgroup analyses. Despite the negative results of WEBCARE, and associated possible limitations of e-health interventions (e.g., high drop-out rates), it is advocated to focus on e-health solutions as a viable options in ICD patients in particular and in patients with cardiovascular disease in general as this might be a time- and cost-effective approach. Further research is warranted to examine which factors might contribute to treatment adherence (e.g., technical features/design of the intervention; human involvement). E-Health solutions have many advantages, in particular that patients can do it in their own time and in their own home, thus avoiding the stigma of seeing a mental health professional that is

still present in the 21st century. Targeting distress in ICD patients remains important due to the association of distress with premature mortality in ICD patients despite state-of-the-art treatment with ICD therapy.

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