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E-Health to Manage Distress in Patients With an Implantable Cardioverter-Defibrillator: Primary Results of the WEBCARE Trial

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Objective: The Web-based distress management program for patients with an implantable cardioverter-defibrillator (ICD; WEBCARE) was developed to mitigate distress and enhance health-related quality of life in ICD patients. This study investigated the treatment effectiveness at 3-month follow-up for generic and disease-specific outcome measures. **Methods:** Consecutive patients implanted with a first-time ICD from six hospitals in the Netherlands were randomized to either the "WEBCARE" or the "usual care" group. Patients in the WEBCARE group received a 12-week fixed, six-lesson behavioral treatment based on the problem-solving principles of cognitive behavioral therapy. **Results:** Two hundred eighty-nine patients (85% response rate) were randomized. The prevalence of anxiety and depression ranged between 11% and 30% and 13% and 21%, respectively. No significant intervention effects were observed for anxiety ($\beta = 0.35$; $p = .32$), depression ($\beta = -0.01$; $p = .98$) or health-related quality of life (Mental Component Scale: $\beta = 0.19$; $p = .86$; Physical Component Scale: $\beta = 0.58$; $p = .60$) at 3 months, with effect sizes (Cohen *d*) being small (range, 0.06-0.13). There were also no significant group differences as measured with the disease-specific measures device acceptance ($\beta = -0.37$; $p = .82$), shock anxiety ($\beta = 0.21$; $p = .70$), and ICD-related concerns ($\beta = -0.08$; $p = .90$). No differences between treatment completers and noncompleters were observed on any of the measures. **Conclusions:** In this Web-based intervention trial, no significant intervention effects on anxiety, depression, health-related quality of life, device acceptance, shock anxiety, or ICD-related concerns were observed. A more patient tailored approach targeting the needs of different subsets of ICD patients may be warranted. **Trial registration:** clinicaltrials.gov. Identifier: NCT00895700. **Key words:** implantable cardioverter-defibrillator, anxiety, depression, quality of life, Web-based behavioral treatment.

CBT = cognitive behavioral therapy; **FSAS** = Florida Shock Anxiety Scale; **GAD-7** = General Anxiety Disorder scale; **ICD** = implantable cardioverter-defibrillator; **ICDC** = ICD Patient Concerns; **MCS** = Mental Component Scale; **NYHA** = New York Heart Association functional class; **PCS** = Physical Component Scale.

INTRODUCTION

The implantable cardioverter-defibrillator (ICD) is the treatment of choice for the primary and secondary prevention of life-threatening ventricular tachyarrhythmias (1–4). In Europe, 800,000 patients live with a cardiovascular implantable electronic device, such as the ICD (5). Since emotional distress in ICD patients has been linked to risk for ventricular tachyarrhythmias and mortality (6,7), there is increasing interest in the well-being of ICD patients (8).

Previous trials have shown that cognitive behavioral therapy (CBT) reduces anxiety and depression in ICD patients (9,10). However, these trials are characterized by relatively small sample sizes, large dropout rates, and potential selection bias (9). To make behavioral treatment accessible to a large group of ICD patients, we developed the Web-based Distress Management Program for Implantable Cardioverter Defibrillator (WEBCARE) patients (11). A Web-based approach requires no extra hospital visits, as patients are able to access treatment in their own time and at a place that is convenient to them. The use of the Web-based approach for treatment of psychological distress has shown promising results in both healthy and chronically ill patients (12). The WEBCARE intervention is a 12-week fixed, six-lesson behavioral treatment based on the problem-solving principles of CBT.

The aims of the current study were to investigate (1) the short-term effectiveness of the WEBCARE intervention on symptoms of anxiety, depression, health-related quality of life, device acceptance, shock anxiety, and ICD-related concerns 3 months postimplant, and (2) the sample characteristics of patients who elected to participate in the WEBCARE trial.

METHODS

Study Design

Within the first year after trial inclusion, patients were asked to complete a set of standardized and validated questionnaires at four time points (i.e., baseline and 3, 6, and 12 months). For the current study, only the baseline and 3-month follow-up data were used, as the short-term effectiveness of the intervention was assessed. Patients' clinical characteristics were assessed at the time of implantation, whereas data on ICD therapy, captured from the information saved by the ICD, were available throughout the follow-up period. A detailed description of the trial design has been published previously (11). The trial was designed to "treat" existing distress but also to prevent the onset of distress. The sample size was calculated based on the expected difference in anxiety (the primary study outcome). Based on a power of 0.80 (two-tailed test) and an α of .05, we needed 175 participants in each condition to show an effect size of 0.30, requiring a total sample of 350 patients. The study protocol was approved by the medical ethics committees of the participating hospitals, and the trial was registered on http://www.ClinicalTrials.gov (NCT00895700).

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Participants

The study cohort comprised consecutive patients from six Dutch referral hospitals (Amphia Hospital, Breda; Canisius-Wilhelmina Hospital, Nijmegen; Catharina Hospital, Eindhoven; Erasmus Medical Center, Rotterdam; Onze Lieve Vrouwe Gasthuis Hospital, Amsterdam; Vlietland Hospital, Schiedam) who were admitted for a first-time ICD implant between April 2010 and February 2013. Inclusion criteria were first-time ICD implant and age between 18 and 75 years. 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 less than 1 year, being on the waiting list for heart transplantation, lack of Internet/computer skills, and insufficient knowledge of the Dutch language. Patients were included regardless of their psychological distress levels (e.g., anxiety and depression), as WEBCARE was designed as a (primarily anxiety) prevention and reduction trial. For this reason, distress was not an eligibility criterion for trial participation.

Procedure

Patients were approached by the ICD nurse or technician before or briefly after ICD implantation. The inclusion criteria were checked by reviewing patients' medical records and by checking them in person with the patient (e.g., availability and use of the Internet). Patients were informed about the study both orally and in writing. If patients met the inclusion criteria and none of the exclusion criteria and were willing to participate, they signed the informed consent form and were provided with the first set of questionnaires (baseline). After completing the questionnaires, patients returned them in a preaddressed, stamped envelope to Tilburg University, which served as core laboratory for the trial. If the questionnaires were not returned within 2 weeks, patients received up to three reminder telephone calls. For follow-up assessment, patients received per mail the second set of questionnaires and were asked to return these to Tilburg University within 1 week. If patients did not return the questionnaire within the first week, they received up to three reminder telephone calls.

Randomization

Upon returning the baseline questionnaires and before opening the envelope, patients were randomized on a 1:1 basis (by drawing a sealed envelope for each patient containing the condition) to either the WEBCARE or the usual care group. Block randomization by computer was used, randomizing 20 patients per hospital, at each time point. The randomization list was generated by an independent, blinded, statistician and sealed by a research assistant. The health care providers were blinded to assignment to WEBCARE versus usual care. Blinding of participants and coaches (master-level psychologists who were trained according to a standardized protocol to provide online feedback to patients) was not possible given the nature of the study.

Intervention

Patients in the WEBCARE group received a 12-week fixed, online course consisting of six lessons, based on problem-solving therapy, in addition to usual care. The problem-solving approach was based on the self-examination therapy of Bowman et al. (13) in combination with cognitive behavioral components. The intervention was based on the course "Everything under control" (Alles Onder Controle) (14). The online course has been evaluated within a physically healthy, depressed population and has shown to be effective in reducing psychological distress (14,15). For the current study, the online course was modified for ICD patients (in collaboration with the Dutch ICD patient organization *STIN*) to take into account issues pertinent to this specific target group. The major modifications included the addition of a lesson on psychoeducation with respect to living with an ICD and adaptation of the cases that are presented in relation to the homework assignments for patients to ICD-specific cases to enhance patient identification and adherence. A detailed description of the course has previously been published (14,16). Briefly, the *first lesson* was educational (psychological problems experienced by ICD patients), with no additional homework assignments. As of *Lesson 2*, a more active problem-solving approach was introduced. Patients were asked to list what they considered important in their lives and which problems they were experiencing at this time and to label the problems as either a) important problems that can be solved, b) unimportant problems that can be solved, or c) problems that cannot be solved. In *Lesson 3*, patients were asked to choose one problem that they labeled as an "important problem that can be solved" and actively work on this problem using problem-solving techniques. In *Lesson 4*, patients were asked to choose a problem from the "unimportant problems that can be solved" and actively work on these using techniques like engaging in positive thinking, stop ruminating, and so on. In *Lesson 5*, patients worked with problems that cannot be solved (here was mostly mentioned "not being able to drive within the two months post ICD implantation"). Patients were taught how to deal with these problems but not how to solve them. In *Lesson 6*, the last lesson, patients were asked to make a future plan of which goals they wanted to achieve in the future and how they would go about this. All patients also received a CD with relaxation training exercises. In addition, with every lesson, patients were able to read about the experiences of other ICD patients and how they manage their lives and problems.

Patients were allowed to complete the six lessons in their own time and pace. Patients could only proceed to the next lesson if they had finished the former and sent the homework assignment to their coach (who provided feedback online). Patients received automatic reminder e-mails every 2 weeks if they did not submit their homework; their account was closed after 12 weeks.

Patients in the control group received standard care from the hospital, equivalent to patients not enrolled in the study. No restrictions were applied to care as usual.

Measures

Information on demographic and clinical variables (Table 1) was obtained via self-report or patients' medical records. The Charlson Comorbidity Index (17) was calculated based on self-report data and information from patients' medical records. All baseline questionnaires were filled in postimplantation (mean = 9.9 days postimplant). To explore whether the prevalence of anxiety and depression may vary depending on the instrument used, we administered multiple questionnaires to assess anxiety and depression.

Generic Outcome Measures

Anxiety

The seven-item General Anxiety Disorder scale (GAD-7) was used to assess symptoms of anxiety. The GAD-7 consists of seven items (e.g., "Feeling nervous, anxious, or on edge") that are rated on a 4-point Likert scale ranging from 0 (not at all) to 3 (almost every day) (18). The total score ranges from 0 to 21, with a higher score indicating higher anxiety levels. A cutoff score of at least 10 is used as an indication of probable clinical levels of anxiety. The internal consistency of the GAD-7 is good with a Cronbach α of .92 (18).

The State version of the State-Trait Anxiety Inventory was also administered to assess anxiety (19). It consists of two 10-item subscales measuring the presence (e.g., "I am worried") and absence of anxiety (e.g., "I feel calm"). Items are answered on a 4-point Likert scale ranging from 0 (not at all) to 4 (very much so). The total score ranges between 20 and 80, with a higher score indicating higher anxiety levels and 40 or higher indicating probable clinical anxiety levels (19).

All patients also completed the seven-item anxiety subscale (e.g., "I feel tense or wound up") from the Hospital Anxiety and Depression Scale (20,21). Items are answered on a 4-point Likert scale from 0 to 3 (score range of 0–21), with a higher score indicating more symptoms of anxiety and 8 or higher indicating the presence of probable clinical levels of anxiety (20).

Depression

The Patient Health Questionnaire (22) is a self-administered version of the PRIME-MD comprising nine items that are evaluated on a 4-point Likert scale (e.g., "Little interest or pleasure in doing things") (score range, 0–27). A higher score indicates higher depression symptom severity and 10 or higher indicates the presence of likely depressive symptoms (22). The scale taps into the nine diagnostic criteria for DSM-IV depressive disorders. The Patient Health Questionnaire-9 has excellent reliability with a Cronbach α of .91 (23) and good validity (22),

All patients also completed the seven-item depression subscale (e.g., "I feel as if I am slowed down") from the Hospital Anxiety and Depression Scale

TABLE 1. Baseline Demographic and Clinical Variables for the Total Sample and Stratified by Treatment Condition

	Total (n = 289)	WEBCARE (n = 146)	Usual Care (n = 143)	*p*
Demographics				
Age, means (SD), y	58.52 (9.89)	58.23 (9.87)	58.63 (10.19)	.73
Sex (male)	235 (81.3)	120 (82.2)	115 (80.4)	.70
Partner (yes), *n* = 288	244 (84.7)	124 (84.9)	120 (84.5)	.92
Education (high), *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
Smoking (yes), *n* = 288)	40 (13.9)	21 (14.4)	19 (13.4)	.81
BMI, *n* = 287, means (SD), kg/m^2	28.09 (10.74)	27.76 (11.00)	28.43 (10.46)	.60
Children (yes), *n* = 287	237 (82.6)	125 (85.6)	112 (82.6)	.17
Hospital				.93
Amphia	64 (22.1)	34 (23.3)	30 (21.0)	
Canisius	22 (7.6)	10 (6.8)	12 (8.4)	
Catharina	119 (41.2)	60 (41.1)	59 (41.3)	
Erasmus	47 (16.3)	22 (15.1)	25 (17.5)	
OLVG	24 (8.3)	14 (9.6)	10 (7.0)	
Vlietland	13 (4.5)	6 (4.1)	7 (4.9)	
Clinical				
Secondary indication	90 (31.1)	39 (26.7)	51 (35.7)	.10
PMI	148 (51.2)	73 (50.0)	75 (52.4)	.68
PPCI	82 (28.4)	30 (20.5)	52 (36.4)	.003
CABG	51 (17.6)	23 (15.8)	28 (19.6)	.39
Structural heart disease[a]	12 (4.2)	6 (4.1)	6 (4.2)	.97
History of arrhythmia	66 (22.8)	37 (25.3)	29 (20.3)	.31
Heart rate, *n* = 284, means (SD)	71.71 (16.15)	71.76 (16.84)	71.66 (15.48)	.96
QRS >120, *n* = 287	128 (44.6)	59 (41.0)	69 (48.3)	.22
BBB, *n* = 287	109 (38.0)	52 (36.1)	57 (39.9)	.51
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				
Anemia	16 (5.5)	7 (4.8)	9 (6.3)	.58
CVA	11 (3.8)	6 (4.1)	5 (3.5)	.79
TIA	14 (4.8)	8 (5.5)	6 (4.2)	.61
COPD	23 (8.0)	13 (8.9)	10 (7.0)	.55
Diabetes	42 (14.5)	18 (12.3)	24 (16.8)	.28
Dysplipidemia	62 (21.5)	30 (20.5)	32 (22.4)	.71
Hypertension	64 (22.1)	35 (24.0)	29 (20.3)	.45
Malignancy	11 (3.8)	6 (4.1)	5 (3.5)	.79
PAD	12 (4.2)	9 (6.2)	3 (2.1)	.08
Creatinine, *n* = 254, means (SD)	94.97 (37.73)	94.74 (29.11)	95.25 (45.84)	.92
CCI, means (SD)	1.69 (1.04)	1.60 (1.06)	1.78 (1.02)	.15
Cardiac medication				
Amiodarone	26 (9.0)	12 (8.2)	14 (9.8)	.64
β-Blocker	237 (82.0)	117 (80.1)	120 (83.9)	.40
Aspirin	139 (48.1)	70 (47.9)	69 (48.3)	.96
Class I agents	5 (1.7)	1 (0.7)	4 (2.8)	.17
Sotalol	9 (3.1)	4 (2.7)	5 (3.5)	.71
Nitrates	36 (12.5)	21 (14.4)	15 (10.5)	.32
Calcium antagonist	19 (6.6)	10 (6.8)	9 (6.3)	.85
Digoxin	16 (5.5)	11 (7.5)	5 (3.5)	.13

(Continued on next page)

TABLE 1. *(Continued)*

	Total (n = 289)	WEBCARE (n = 146)	Usual Care (n = 143)	*p*
ACE inhibitor	180 (62.3)	82 (56.2)	98 (68.5)	.03
ARB	46 (15.9)	29 (19.9)	17 (11.9)	.06
Spironolactone	70 (24.2)	34 (23.3)	36 (25.2)	.71
Diuretics	147 (50.9)	72 (49.3)	75 (52.4)	.59
Statins	182 (63.0)	92 (63.0)	90 (62.9)	.99
Anticoagulants	127 (43.9)	58 (39.7)	69 (48.3)	.14
Thyrax	5 (1.7)	4 (2.7)	1 (0.7)	.18
Psychotropics	20 (6.9)	13 (8.9)	7 (4.9)	.18
Antidepressants	7 (2.4)	3 (2.1)	4 (2.8)	.68
Anxiolytics	17 (5.9)	11 (7.5)	6 (4.2)	.23
Hypnotics	10 (3.5)	6 (4.1)	4 (2.8)	.54

WEBCARE = Web-based Distress Management Program for Implantable Cardioverter Defibrillator; M = mean; SD = standard deviation; BMI = body mass index; OLVG = Onze Lieve Vrouwe Gasthuis; PMI = previous myocardial infarction; PPCI = previous percutaneous coronary intervention; CABG = coronary artery bypass grafting; BBB = bundle branch block; NYHA = New York Heart Association functional class; LVEF = left ventricular ejection fraction; CVA = cerebrovascular accident; TIA = transient ischemic attack; COPD = chronic obstructive pulmonary disease; PAD = peripheral artery disease; CCI = Charlson Comorbidity Index. Results are presented as total number (%); continuous variables are presented as means (SD).
[a]Dilated cardiomyopathy, hypertrophic cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy, congenital heart disease.

(20,21). Items are answered on a 4-point Likert scale from 0 to 3, with a score range of 0 to 21, and the reliability/validity of this measure has been demonstrated in cardiac patients (24). A predefined cutoff score of 8 or higher indicates probable clinical levels of depressive symptoms (20).

Health-Related Quality of Life

The Dutch version of the Short-Form Health Survey 12 was administered to assess health-related quality of life (25). The 12 items contribute to physical and mental health status that are summed into a Physical Component Scale (PCS) and Mental Component Scale (MCS) score (score range, 0–100), with a higher score indicating better functioning. The Short-Form Health Survey 12 has previously been used in the ICD population (26) and has shown to be a valid and reliable instrument (27).

Disease-Specific Outcome Measures

Device Acceptance

Device acceptance was assessed with the Florida Patient Acceptance Survey (28). The abbreviated 12-item version was used, which has been validated in Dutch (29) and Danish (30) ICD patients (e.g., "I have returned to a full life"). Items are rated on a 5-point Likert scale ranging from 0 (strongly disagree) to 4 (strongly agree), with a total score of 0 to 100, with a higher score indicating higher acceptance. The Florida Patient Acceptance Survey has shown to be internally consistent with Cronbach α of .82 and .85 for Dutch (29) and Danish (30) ICD populations.

Shock Anxiety

The Florida Shock Anxiety Scale (FSAS) was used to assess shock anxiety (31). The FSAS is a 10-item disease-specific questionnaire with items (e.g., "I worry about the ICD firing and creating a scene") rated on a 5-point Likert scale ranging from 1 (never) to 5 (always), with higher scores indicating a higher level of shock anxiety (32). A total scale score was used in the current study. The FSAS has proven to be a reliable measure with a Cronbach α of .89 (31).

Patient Concerns About the ICD

To measure patients' concerns about the ICD, the Dutch version of the ICD Patient Concerns (ICDC) questionnaire was used (33). The ICDC consists of eight items (e.g., "I'm worried that my ICD will fire") that are rated on a 5-point Likert scale ranging from 0 (not at all) to 4 (very much), with a score range of 0 to 32, with a higher score indicating higher levels of concerns. The ICDC is an internally consistent scale with a Cronbach α of .91 (33)

Statistical Analyses

Baseline

Discrete variables were compared using the χ^2 test and are presented as percentages. Continuous variables were compared using the Student's *t* test for independent samples and are presented as mean values and standard deviations. The number of missing data (for randomized patients) was relatively small, ranging between 0 and 2% for demographic and psychological variables and between 0 and 20% for clinical measures, with most patients missing information on New York Heart Association (NYHA) functional class, which is a measure of the severity of heart failure. If a questionnaire had less than 80% missing data, data were imputed using the mean score of the patient on the completed items.

Follow-Up

To perform the analysis according to the intention-to-treat principle, mean imputation was performed for missing item scores (<80% of items missing), while multiple imputation was carried out, with 20 iterations, for total missing scores using the default option for multiple imputation in SPSS. To analyze intervention effects, linear regression was performed, adjusting for baseline distress. To compare intervention effects for treatment completers versus noncompleters, univariable and multivariable linear regressions were performed adjusting for age, sex, education level, left ventricular ejection fraction, QRS width, Charlson Comorbidity Index, (17), and ICD indication (primary versus secondary). Cohen *d* was calculated to indicate the magnitude of the intervention effect (0.20 = small; 0.50 = medium; 0.80 = large) (34).

A $p < .05$ indicated statistical significance; all tests were two tailed. All data were analyzed using SPSS Statistics 19.0 for Windows.

RESULTS

Sample Characteristics

A total of 1024 consecutive patients implanted between April 2010 and February 2013 were screened for study participation (Fig. 1), of which 492 (48%) were excluded because they did

not meet the inclusion criteria (i.e., lack of Internet [53%], age >75 years [30%], language barrier [6%]). Of the remaining 532 patients, 192 (36%) refused to participate (due to time constraints, having to deal with a lot of issues, not needing psychological help, not interested in participating in clinical studies, too much work/too sick) and 51 (10%) patients did not return the baseline measures, leaving 289 (54%) patients for randomization to the WEBCARE (n = 146) versus usual care group (n = 143). Of the 146 patients who were randomized to the WEBCARE group, 34 (23%) completed the full six lessons of the intervention (see Fig. 1 for a detailed description). Reasons for dropout most often given by patients were as follows: technical problems with the computer (21%), time constraints (15%), feeling fine, and not needing additional support (11%). A detailed description of attrition and adherence in the WEBCARE cohort is provided elsewhere (35).

Nonparticipants

Patients who did not return the baseline questionnaires (n = 51) or were excluded (not randomized) from current analyses did not differ systematically on demographic variables. However, patients who were not randomized were more likely to have NYHA class III/IV (p = .045) and peripheral artery disease (p = .022), and more likely to use psychotropic medication (p <. 001; anxiolytics [p = .004] and hypnotics [p = .010]). Of the 192 patients who fulfilled the inclusion criteria but refused to participate, 60 signed consent and gave permission for medical record screening at the time of implantation. These patients were older (60.26 ± 1.80 versus 58.16 ± 10.30; p = .042) and were more likely to have NYHA class III/IV (39.0% versus 21.3%; p = .013), previous myocardial infarction (76.6% versus 50.1%; p = .001), coronary artery bypass grafting (34.0% versus 19.2%; p = .019), peripheral artery disease (13.6% versus 5.3%; p = .018), or an ICD with cardiac resynchronization therapy (57.9% versus 25.9%; p < .001) as compared with patients who signed informed consent form for study participation (n = 340).

Baseline Characteristics

The mean (standard deviation) age of the total sample was 58.5 (9.9) years, and 81% of the sample were men (Table 1). The WEBCARE and usual care groups did not differ on demographic characteristics, but the usual care group was more likely to have been treated with percutaneous coronary intervention (36.4% versus 20.5%; p = .003) and angiotensin-converting enzyme inhibitors (68.5% versus 56.2%; p = .031) as compared with the WEBCARE group. No other systematic differences between groups were observed (Table 1).

There were no systematic differences on any of the psychological measures between both groups at baseline (Table 2). The prevalence ranged between 11% and 30% for anxiety and

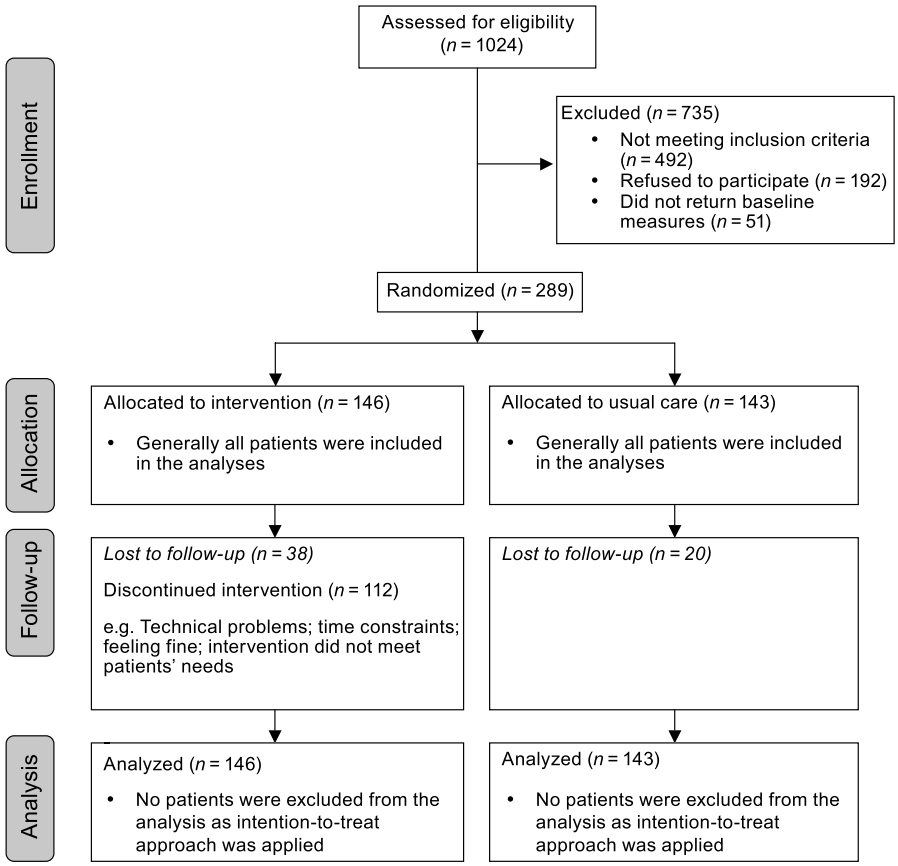


Figure 1. Flowchart patient recruitment.

TABLE 2. Psychological Profile and Health-Related Quality of Life for the Total Sample and Stratified by Treatment Condition at Baseline

	Total (n = 289)	WEBCARE (n = 146)	Usual Care (n = 143)	p
Generic measures				
Anxiety				
GAD-7, n = 288	4.30 (4.54)	4.57 (5.02)	4.03 (3.98)	.31
HADS-A, n = 288	4.59 (3.26)	4.91 (3.39)	4.27 (3.09)	.09
STAI-S, n = 288	35.24 (10.32)	35.57 (10.65)	34.90 (9.99)	.59
Depression				
PHQ-9	5.65 (4.83)	5.93 (5.11)	5.37 (4.53)	.32
HADS-D, n = 288	3.52 (3.01)	3.55 (3.02)	3.49 (3.02)	.89
Health-related quality of life				
SF-12				
MCS	44.29 (11.08)	43.83 (11.28)	44.76 (10.89)	.48
PCS	40.57 (10.44)	40.19 (10.55)	40.96 (10.35)	.53
Disease-specific measures				
FPAS, n = 288	66.53 (11.19)	66.36 (11.99)	66.71 (10.35)	.79
FSAS, n = 287	16.37 (5.74)	16.73 (6.13)	16.00 (5.32)	.28
ICDC, n = 287	6.33 (6.48)	6.53 (6.68)	6.12 (6.28)	.59

WEBCARE = Web-based Distress Management Program for Implantable Cardioverter Defibrillator; GAD-7 = General Anxiety Disorder scale; HADS (A-D): Hospital Anxiety and Depression Scale; STAI-S = State-Trait Anxiety Inventory Scale–State Version; PHQ-9 = Patient Health Questionnaire; SF-12 = Short-Form Health Survey 12; MCS = Mental Component Scale; PCS = Physical Component Scale; FPAS = Florida Patient Acceptance Scale; FSAS = Florida Shock Anxiety Scale; ICDC = ICD Patient Concerns.
Results are presented as mean (standard deviation).

between 13% and 21% for depression, indicating great variability depending on the instrument used. Given that no standardized cutoffs are available for the disease-specific measures, we could not present prevalence rates for these measures.

Effects of the Intervention on General Distress and Health-Related Quality of Life

No significant differences between the WEBCARE and usual care groups were observed at 3-month follow-up on anxiety ($\beta = 0.35$; $p = .32$), depression ($\beta = -0.01$; $p = .98$), or health-related quality of life (MCS: $\beta = 0.19$; $p = .86$; PCS: $\beta = 0.58$; $p = .60$). A similar decrease in anxiety and depression was observed in both groups, as was an increase in both mental and physical health-related quality of life (Fig. 2). The effect sizes for these measures were 0.13, 0.003, 0.02, and 0.06, indicating a negligible effect. Comparing treatment completers versus noncompleters also revealed no differences in anxiety ($\beta = 0.52$; $p = .50$), depression ($\beta = -0.12$; $p = .88$), and health-related quality of life (MCS: $\beta = 0.22$; $p = .91$; PCS: $\beta = 0.54$; $p = .80$) between groups. Subgroup analyses were performed for patients with increased distress at baseline, but no significant effects were observed (data not shown).

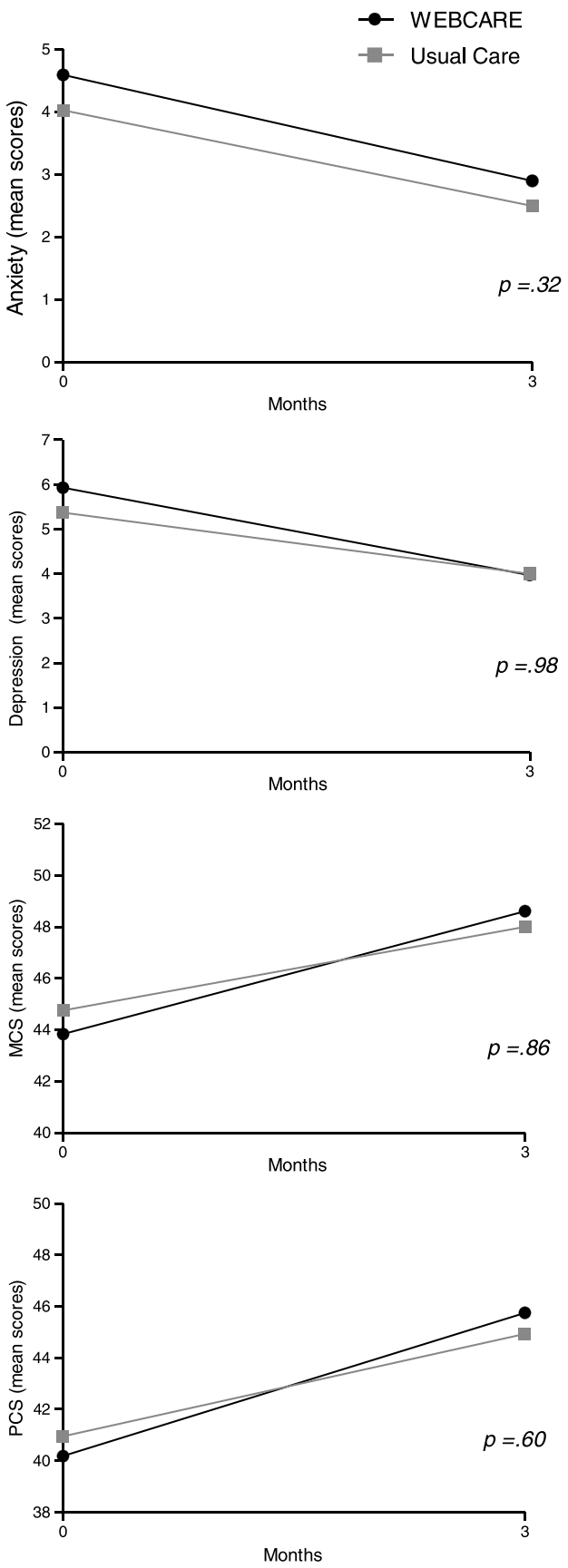
Effects of the Intervention on Device-Related Concerns

No significant differences between the WEBCARE and usual care groups were observed at 3 months on any of the disease-specific measures: device acceptance ($\beta = -0.37$; $p = .82$), shock anxiety ($\beta = 0.21$; $p = .70$), and ICD-related concerns ($\beta = -0.08$; $p = .90$). The effect sizes for the three outcome measures were 0.03, 0.05, and 0.02, respectively, indicating a negligible effect. No significant differences were observed between completers and noncompleters on any of the above-mentioned measures: device acceptance ($\beta = 2.69$; $p = .39$), shock anxiety ($\beta = 26$; $p = .81$), and ICD-related concerns ($\beta = -0.21$; $p = .86$). Subgroup analyses of patients with increased concerns at baseline showed no significant effects of the intervention (data not shown; Fig. 3).

DISCUSSION

To our knowledge, this is the largest e-health trial targeting emotional distress in cardiac patients in general and in ICD patients in particular. Patients in the WEBCARE group did not report better outcomes 3 months postimplant as compared with patients in the usual care group, indicating no effect of the intervention on the short term. Patients who completed the full six lessons of the treatment as compared with patients who did not initiate or failed to complete the six lessons did not differ significantly on any of the generic or disease-specific, patient-reported outcomes.

Patients included in the WEBCARE trial were predominantly male, with a higher educational level and a partner. In addition, mean scores on psychological measures (e.g., anxiety and depression) were relatively low at the time of implant. These findings suggest that we may not have been successful in reaching those patients who might have benefited the most (e.g., female patients and patients with high distress levels). Previously female-specific interventions have been suggested by others (36). Although in the current study, no significant intervention



effects were observed in patients with increased distress at baseline, other studies did demonstrate some effects of CBT in this subgroup (9).

The observed discrepancy between prevalence rates of anxiety and depression depending on the self-report measure used has, to date, not been addressed in ICD patients. The prevalence rates of anxiety and depression ranged between 11% and 30% and 13% and 21%, respectively, depending on which instrument was used. This finding underlines that anxiety and depression measures cannot necessarily be used interchangeably and that the choice of instrument may have implications for the screening of and treatment for patients in clinical practice. Further research is warranted to critically evaluate and compare current instruments to provide recommendations with respect to which instrument might be preferred and for which purpose (i.e., as a screening tool or an outcome measure) (37).

Generally, behavioral interventions in ICD patients have shown promising results in terms of reducing distress (9,10). Although WEBCARE does not confirm these findings, previous trials were based on face-to-face treatment rather than a Web-based approach, and included only patients with increased distress levels at baseline. Because patients were included in the WEBCARE trial regardless of their distress level at baseline, this may have influenced both the effect of the intervention and treatment adherence. A low distressed population may not feel the need to complete the full six-lesson course. Moreover, Web-based approach may likely only appeal to a subgroup of patients who feel comfortable with such an approach and are willing to work on their problems via the computer. Despite the well-known benefits of a Web-based approach (high accessibility, ability to reach underserved groups, etc), the issue of reaching only particular subgroups of patients who are interested in using Internet for health care purpose has been described by others (38,39). Time constrains, competing interests, perception of limited worth of the intervention, and anxiety about spending time on the computer were previously described as factors that contributed to an increased attrition in an online treatment for older adults with comorbid cardiac disease (40). To a degree, this is in line with the reasons provided by WEBCARE patients for prematurely terminating the treatment. In addition, the design of the WEBCARE trial and the intervention might have been inadequate to promote adherence (e.g., too soon, too long, and too complicated), and the high attrition rate might have influenced the effect sizes related to the intervention. A detailed description of attrition and adherence in the WEBCARE trial is provided elsewhere (35).

To increase adherence and likely treatment effects, future research should focus on understanding the reasons for nonadherence

Figure 2. Mean scores on generic measures at baseline and 3 months stratified by group. Scores on the anxiety scale can range between 0 and 21; scores on the depression scale can range between 0 and 27; scores on the PCS and MCS scales can range between 0 and 100. SDs for baseline means are presented in Table 2; SDs at follow up are for the WEBCARE and usual care groups, respectively: 4.0 and 3.6 (anxiety), 4.3 and 3.9 (depression), 10.17 and 10.39 (MCS), and 10.72 and 11.29 (PCS). PCS = Physical Component Scale; MCS = Mental Component Scale, SD = standard deviation; WEBCARE = WEB-Based Distress Management Program for Implantable Cardioverter Defibrillator.

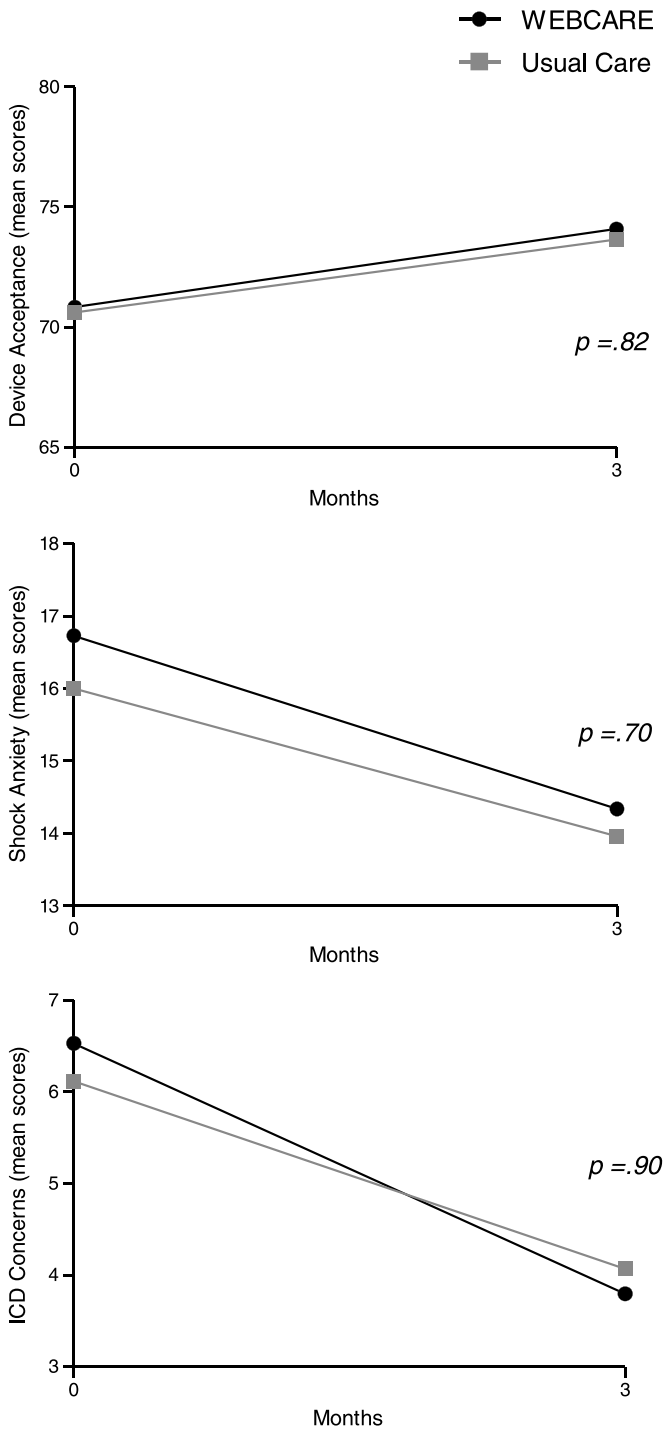


Figure 3. Mean scores on disease-specific measures at baseline and 3 months stratified by group. Scores on device acceptance scale can range between 0 and 100; scores on shock anxiety scale can range between 10 and 50; scores on ICD concerns scale can range between 0 and 32. SDs for baseline means are presented in Table 2; SDs at follow-up are for the WEBCARE and usual care groups, respectively: 15.27 and 14.44 (device acceptance), 5.95 and 5.07 (shock anxiety), and 6.2 and 6.0 (ICD concerns). ICD = implantable cardioverter-defibrillator; SD = standard deviation; WEBCARE = Web-based Distress Management Program for Implantable Cardioverter Defibrillator.

and developing more patient tailored Web-based approaches that will better meet patients' needs. As with previous trials in cardiac patients, WEBCARE confirms that also a Web-based intervention is unlikely to be a "one size fits all" approach, as participants were predominantly highly educated men. Furthermore, the timing of the intervention might be essential, with WEBCARE being offered already within the first 2 weeks postimplant. This might have been too soon, as patients are preoccupied with practical issues (e.g., driving restrictions, physical impairments, etc) and might not be ready to start working on their psychological problems. One way of circumventing premature intervention in patients who do not really need it would be to include a "watchful waiting period," as has been done in some of the collaborative care trials in patients with acute coronary syndrome, such as the COPES (41) and CODIACS trial (42).

Limitations and Strengths

Most participants were highly educated men who might have been more motivated to participate, leading to a potential selection bias. A significant number of patients were excluded due to not meeting the inclusion criteria or refusing to participate, jeopardizing generalizability, as results showed systematic differences on demographic and clinical characteristics between these groups and patients who participated. This may suggest a selection bias toward more healthy patients. The follow-up period of 3 months was relatively short, and thus, we are not able to make any conclusions about potential long-term effects.

However, this is the first trial targeting distress in ICD population using a Web-based approach. In addition, we included a broad range of outcome measures and, thus, were able to tap into disease-specific distress and clinical change postintervention. This approach has recently been advocated by others (43), as it remains unclear whether generic measures are sensitive enough to detect changes in psychological distress posttreatment. Our results did not differ dependent on the outcome measure used (i.e., disease-specific versus generic). However, our findings demonstrate that the notion of "one size fits all" does not apply to a Web-based approach targeting distress in ICD patients, but may only be appropriate for a particular subset of patients.

Clinical and Research Implications

The findings of the current study are informative for designing future psychological and behavioral intervention trials in ICD patients, as we have gained a better understanding of the demographic, psychological, and clinical profile of patients who are (less) willing to participate in online behavioral interventions. Future research is warranted to look into patients' specific needs and evaluate the appropriate timing of the intervention. A collaborative, stepped-care approach that includes a watchful waiting period before the intervention is offered, with serial evaluations to monitor distress over time with potential to intervene when needed, and that is targeted to patients' needs and preferences, may be one of the ways forward (9). Blended-care treatments where face-to-face and Web-based approaches are integrated may comprise another avenue to pursue. With this

knowledge, we will be able to further "customize" treatment to patients' needs and perhaps increase treatment adherence and improve patients' outcomes.

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