

Efficacy of a web-based intervention for improving psychosocial well-being in patients with implantable cardioverter-defibrillators: the randomized controlled ICD-FORUM trial

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Aims

Anxiety, depression, and reduced quality of life (QoL) are common in patients with implantable cardioverter-defibrillators (ICDs). Treatment options are limited and insufficiently defined. We evaluated the efficacy of a web-based intervention (WBI) vs. usual care (UC) for improving psychosocial well-being in ICD patients with elevated psychosocial distress.

Methods and results

This multicentre, randomized controlled trial (RCT) enrolled 118 ICD patients with increased anxiety or depression [≥ 6 points on either subscale of the Hospital Anxiety and Depression Scale (HADS)] or reduced QoL [≤ 16 points on the Satisfaction with Life Scale (SWLS)] from seven German sites (mean age 58.8 ± 11.3 years, 22% women). The primary outcome was a composite assessing change in heart-focused fear, depression, and mental QoL 6 weeks after randomization to WBI or UC, stratified for age, gender, and indication for ICD placement. Web-based intervention consisted of 6 weeks' access to a structured interactive web-based programme (group format) including self-help interventions based on cognitive behaviour therapy, a virtual self-help group, and on-demand support from a trained psychologist. Linear mixed-effects models analyses showed that the primary outcome was similar between groups ($\eta_p^2 = 0.001$). Web-based intervention was superior to UC in change from pre-intervention to 6 weeks (overprotective support; $P = 0.004$, $\eta_p^2 = 0.036$), pre-intervention to 1 year (depression, $P = 0.004$, $\eta_p^2 = 0.032$; self-management, $P = 0.03$, $\eta_p^2 = 0.015$; overprotective support; $P = 0.02$, $\eta_p^2 = 0.031$), and 6 weeks to 1 year (depression, $P = 0.02$, $\eta_p^2 = 0.026$; anxiety, $P = 0.03$, $\eta_p^2 = 0.022$; mobilization of social support, $P = 0.047$, $\eta_p^2 = 0.018$).

Conclusion

Although the primary outcome was neutral, this is the first RCT showing that WBI can improve psychosocial well-being in ICD patients.

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Keywords

Implantable cardioverter-defibrillator • Web-based intervention • Anxiety • Depression • Randomized controlled trial • Efficacy

Introduction

Implantable cardioverter-defibrillators (ICDs) are considered the most effective treatment to prevent sudden cardiac death in patients at risk for potentially lethal ventricular arrhythmias.¹ Despite this medical success, psychosocial issues are highly prevalent in ICD patients, including anxiety (reported prevalence 13–38%) and depression (13–33%), and can be linked to hard endpoints such as hospitalization and mortality.²

Research supports a bidirectional link between heart disease and psychosocial distress.² In addition to the burden associated with arrhythmias or heart failure themselves, frequency of ICD shocks has been shown to predict anxiety,³ but results are controversial.² More recently, concerns about ICD shock were found to mediate the association between shock frequency and anxiety.⁴ One study reported that anxiety remained stable over 2.5 years after ICD placement, despite significantly reduced avoidance behaviour, which is a critical factor for the perseveration of anxiety.⁵ Information compromising patients' trust in device safety (e.g. lead recalls) and lack of information are also major sources of anxiety,⁶ feeding into avoidance and depression.⁷

Current guidelines recommend assessment and treatment of psychosocial distress in ICD patients.¹ Traditional concepts such as self-help groups, individual face-to-face, and group therapy have proven efficacious in ICD patients.^{8,9} However, screening is rarely performed in clinical practice and treatment options including psychotherapy and psychotropic drugs are inaccessible to patients with limited mobility¹⁰ or of limited value.^{11–13} A webcast system¹⁴ and individual telephone counselling¹⁵ successfully resolved these issues, but only patients aged <65 years benefitted from the latter approach.

Time- and location-independent accessibility and low cost recommend web-based interventions (WBIs) as a promising solution.¹⁶ More than 80% of Germans are already using the internet, almost half of those aged ≥65, and growth rates are particularly high in individuals aged ≥50.¹⁷ Web-based intervention can be as effective as face-to-face therapy,¹⁸ but evidence for efficacy in ICD patients is restricted to small pilot studies.^{9,16,19}

We, therefore, examined the efficacy of a WBI integrated into routine care for improving heart-focused fear, depression, and mental quality of life (QoL) in ICD patients with increased psychosocial distress. Additionally, we expected positive effects of WBI on variables known to buffer psychosocial distress such as self-management, coping, and social support.

Methods**Design**

This multidisciplinary, multicentre, two-arm, open-label, randomized, controlled trial (NCT01589913) evaluated the efficacy of 6 weeks' WBI

on psychosocial well-being compared with usual care (UC) in patients with an ICD. Written informed consent was obtained from all subjects. The study protocol was approved by all responsible ethics committees and complied with the Declaration of Helsinki.

Setting and participants

Patients were screened and recruited at seven centres in Germany (Supplementary material online) by trained psychology students, study nurses, and the responsible physician at routine medical control appointments or after referral from private practice cardiologists or while in-hospital after ICD implantation.

Inclusion criteria were age 18–75 years (only a minority of patients above 75 years of age has internet-access¹⁷), ICD implantation for primary or secondary prevention, and at least mildly increased psychosocial distress (≥6 points on the anxiety or depression subscale of the HADS²⁰ or ≤16 points on the SWLS²¹). Exclusion criteria were medical or technical reasons preventing participation in the WBI, current suicidal ideation, severe cognitive deficit (based on clinical impression at the time of recruitment), insufficient command of German language, or current psychiatric diagnosis (ICD-10 codes F1x, F2x, F30, F32).

Intervention

The WBI consisted of 6 weeks' access to a password-protected structured interactive internet programme scheduled for groups of 7–14 patients. Login to the WBI via the public homepage (www.ICD-Forum.de) with any standard browser was available time- and location-independent. R.Z. and S.M.S. provided technical support via phone when needed.

The WBI included information on medical, technical, and psychosocial issues associated with having an ICD (e.g. aetiological and treatment models of anxiety and depression), self-help interventions based on cognitive behaviour therapy with interactive elements (e.g. two column-technique for challenging/modifying potentially irrational assumptions, tools for planning positive activities and resource-oriented problem-solving), a virtual self-help group, and on-demand support by a trained clinical psychologist (S.M.S.) via an open discussion board or asynchronous peer-to-peer communication. The system automatically unlocked additional content each week. The user interface is shown in Figure 1.

Patients could enter feedback regarding usability and helpfulness of particular contents via ratings and text entries. Based on this input, patients received automatic feedback (e.g. recommendation to discuss poorly understood content with other users or the psychologist). S.M.S. also initiated and moderated group discussions for each topic.

The WBI was hosted on a Linux OS and apache web-server with full 1024-bit SSL-encryption utilizing a JAVA-based open source WIKI system (d3web.KnowWE) plus custom extensions developed in cooperation with the Chair of Computer Science VI, University of Würzburg.

Study flow and randomization

After psychosocial distress was confirmed and informed consent obtained, participants were randomized 1:1 to WBI or UC using Pocock's minimization algorithm.²² Strata were age, gender, and indication for ICD implantation (primary vs. secondary prevention). Patients

The screenshot shows the ICD-Forum web interface. On the left is a vertical menu with 'ICD-Forum' at the top, followed by 'Help', 'How to use ICD-Forum?!', and a list of weekly topics from Week 1 to Week 6. The main content area is titled 'Content focus of weekly units:' and lists the following:

- Week 1:** interactive tutorial explaining all features of the system, introduction of the virtual self-help group, testing communication with other patients and the trained psychologist
- Week 2:** closing knowledge gaps regarding technical and medical aspects of wearing an ICD (e.g., safety issues, sports or traveling with an ICD)
- Week 3:** dealing with depressive symptoms, improving physical activity, social support, partner communication and intimacy
- Week 4:** improving understanding of and coping with anxiety related to the ICD, heart failure and end of life
- Week 5:** tools for coping with psychosocial distress including anxiety exposure training, goal-setting, stress-management, information on support options beyond self-help (e.g., face-to-face therapy)
- Week 6:** individualized goal-setting and tips for enhancing transfer of WBI content into everyday life

Figure 1 Weekly content superimposed on the user interface of the web-based intervention (originally in German). Left pane: menu to access weekly topics. Upper middle pane: trained psychologist contact and patient discussion board. Upper right pane: individual settings, including printable individualized emergency plan. Main pane: content as hypertext and interactive elements.

randomized to WBI were mailed information on starting date, login credentials, and a user manual. Patients randomized to UC were also contacted by mail, including information that they could participate in the WBI after the end of the study. All patients received usual standard after-care. Repeat assessments of psychosocial status were completed via mailings pre-intervention, 6 weeks later (post-intervention), and at 1-year follow-up. Reminder phone calls (≤ 3) were made if patients did not return questionnaires within 2 weeks.

Data collection and measurements

The baseline assessment included demographic and clinical data (physical status, laboratory testing, electrocardiography, echocardiography, ICD log-file analysis, physical examination, and medical record review).

Standardized self-report questionnaires were used for psychometric assessments: HADS subscales for anxiety and depression assessment; Cardiac Anxiety Questionnaire (CAQ) subscales for heart-focused fear, avoidance, and attention; mental and physical health component summaries of RAND Short Form 36 (SF-36) for generic QoL; Berlin Social Support Scales (BSSS) subscales (perceived available social support, actual received support, need for support, mobilization of support, and protective buffering); subscales of the Perceived Family Support and Communication Questionnaire (PFUK) (mobilization to be proactive, overprotective support) for assessing social support; and the Resources and Self-Management Skills Questionnaire (FERUS; Fragebogen zur Erfassung von Ressourcen und Selbstmanagementfähigkeiten) subscales (motivation to change, self-monitoring, active and passive coping, self-efficacy, self-verbalization, hope and social support) and an overall self-management score for assessing health-related resources, coping, and

self-management skills. All questionnaires were presented in German and have well-documented validity and reliability (full details and references in Supplementary online material).

Data were managed by S.M.S. and R.Z. utilizing an electronic query database implemented and monitored by the Centre for Clinical Studies Leipzig.

Outcomes

Outcomes were specified at trial registration. The composite primary outcome was change of psychosocial well-being 6 weeks after randomization, calculated from equally weighted z-scores derived from crude scores of the CAQ heart-focused fear subscale, the HADS depression subscale, and the SF-36 mental health component summary. Measures specifically addressed by the WBI, such as social support (BSSS), family communication and support (PFUK), and coping and self-management strategies (FERUS), were secondary outcomes. The frequency of hospitalization between pre-intervention and 1 year was defined as a preliminary estimate of cost-effectiveness. Participants in the WBI group were asked to rate the programme on a scale from 0 = not helpful to 4 = very helpful, the helpfulness of specific elements on a scale from 0 = absolutely not true for me to 4 = completely true for me, and the helpfulness of topics on a scale from 0 = not helpful to 3 = very helpful.

Sample size

Sample size calculations took into account that previous studies on WBI for ICD patients reported small effect sizes for psychosocial

outcomes.^{9,16,19,23} The original protocol aimed to enrol 200 patients. Low recruitment rates led to refined power calculations following an established algorithm that accounts for effects of the *a priori* defined covariates by adjusting the expected effect size.²⁴ With power = 0.80, $\alpha = 0.05$ (two-tailed) and adjusted $f \geq 0.26$, the required sample size was $N = 119$ to detect a meaningful difference in the efficacy of WBI vs. UC over time (Supplementary material online).

Statistical analyses

Data analysis was conducted with SPSS 20 and R (v3.4.0). Mean, standard deviation, and 95% confidence intervals (CIs) were calculated for continuous variables, which were compared using Student's *t*-tests. For skewed data, median (Mdn) and interquartile range (IQR) are reported and Mann–Whitney *U* tests (exact sig.) were applied. For discrete variables, frequencies, percentages, and χ^2 tests or Cramer's *V* were used, and relative risk values for WBI vs. UC were calculated.

Missing data were missing completely at random (Little's test; $\chi^2_{24798} = 12066.2$, $P > 0.999$) and treated with state-of-the-art procedures.²⁵ Variables with >30% missing data were discarded. For the remaining variables, mean \pm standard deviation (SD) proportion of missing data was 13.6 ± 11.1 for demographics, and 19.4 ± 7.3 and 7.7 ± 7.8 for psychosocial and clinical measures, respectively; multiple imputation was applied to estimate missing information including data for patients who dropped out ($n = 28$, 23.7%) (Supplementary material online).

The efficacy of WBI was evaluated in an intent-to-treat manner by computing linear mixed-effects models (LMEM) for each of $n = 100$ multiple imputation datasets. Results were pooled according to Rubin's rules and Akaike's information criterion was used for model selection (Supplementary material online). For LMEM, computation of effect sizes is the subject of debate,²⁶ therefore, partial eta squared (η_p^2) has been supplemented from pooled results of repeated measures analysis of covariance.

The final model compared change in outcomes over time (pre-intervention, 6 weeks, and 1 year) between UC and WBI. Covariates controlled for baseline scores of the outcome variable, stratification criteria (age, gender, and indication for ICD implantation), New York Heart Association functional class as a global indicator of physical limitation and a random effects term accounting for the fact that WBI was presented in group format. *P*-values <0.05 (two-tailed) were considered statistically significant.

For analysis of multiple secondary outcomes and sensitivity analysis, equivalent models were computed and both uncorrected (minimizing Type II error) and Bonferroni-corrected (14 tests, $\alpha = 0.004$, minimizing Type I error) test statistics are reported as upper and lower boundaries of the true effect (Supplementary material online). Finally, we examined whether the effects of WBI were clinically significant by assessing the reliable change index²⁷ (Supplementary material online).

Results

Patient characteristics

Between May 2012 and July 2015, 118 eligible ICD patients were identified (years since implantation: Mdn = 1.39, IQR = 0.51–4.01), provided informed consent and randomized to the WBI or UC group, out of 1204 ICD patients screened for increased psychosocial distress (see Figure 2, listing all known reasons for non-participation); 1-year follow-up was completed in August 2016.

There were only negligible statistically significant differences between patients in the UC ($n = 59$) and WBI ($n = 59$) groups at baseline (Table 1 and Supplementary material online, Table S2). The WBI vs. UC group had higher rates of coronary revascularization ($P = 0.01$), and lower rates of stroke ($P = 0.03$) and amiodarone prescription ($P = 0.05$); all other ($P > 0.05$). Levels suggesting clinically significant psychopathology (≥ 8 points on HADS subscales²⁸) were well-balanced; using these criteria, 38% of the total sample had comorbid anxiety, 33% had comorbid depression, and in 24% both conditions were present. Low QoL (SWLS scores ≤ 16) was documented in 23% of patients. Comorbidity for all three criteria was found in 12% of patients.

Patients included in the study had higher anxiety and depression and worse QoL compared with screened patients who did not meet inclusion criteria for increased psychosocial distress ($n = 625$; all $P < 0.001$). A total of 175 eligible patients (15%) refused consent. They had similar characteristics to included patients, specifically regarding anxiety, depression, and QoL, but cardiac health and functional status appeared slightly worse, and time since ICD placement was 2 years longer (all $P < 0.03$; Supplementary material online, Table S3).

The dropout rate was higher in the WBI group ($n = 18$, 30.5%) than in the UC group ($n = 10$, 16.9%). Descriptively, dropout in the WBI group was associated with higher relative risk for the presence of medical comorbidity, having children, and being employed. Psychosocial status of completers was very similar to that of patients who dropped out (Supplementary material online, Table S4).

Primary outcome

Changes from baseline in the composite primary outcome were similar in the WBI and UC groups, both at 6 weeks [parameter estimate (EST) -0.12, standard error (SE) 0.18, 95% CI -0.23 to 0.47; $P = 0.50$; $\eta_p^2 = 0.001$] and 1 year (EST -0.19, SE 0.18, 95% CI -0.55 to 0.17; $P = 0.29$; $\eta_p^2 = 0.003$) (Take home figure and Supplementary material online, Tables S5 and S6, Figure S1).

Secondary outcomes

WBI vs. UC differences emerged in the HADS depression component of the primary outcome. An EST of -2.98 points (SE 1.03, 95% CI -5.00 to -0.96; $P = 0.004$; $\eta_p^2 = 0.032$) results from a mean \pm SD decrease from 8.1 ± 3.8 to 5.9 ± 3.8 points in the WBI group and an increase from 7.2 ± 3.8 to 8.0 ± 3.8 points in the UC group from pre-intervention to 1 year (note that EST reflects change in units of each respective measure; Supplementary material online, Table S6). The majority of this difference emerged between 6 weeks and 1 year (EST -2.43, SE 1.00, 95% CI -4.40 to -0.47; $P = 0.02$; $\eta_p^2 = 0.026$) (Take home figure). The HADS anxiety subscale score decreased from 6.8 ± 4.6 to 6.5 ± 4.6 points in the WBI group and increased from 6.1 ± 4.6 to 7.7 ± 4.6 points in the UC group from 6 weeks to 1 year (EST -2.33, SE 1.07, 95% CI -4.44 to -0.23; $P = 0.03$; $\eta_p^2 = 0.022$) (Take home figure and Supplementary material online, Table S6). All other components of the primary outcome showed no statistically significant differences between the WBI and UC groups, but some differences were clinically interesting. Numerically, the greatest improvements in the WBI group compared with UC were seen from 6 weeks to 1 year on the CAQ subscale heart focused fear ($P = 0.06$;

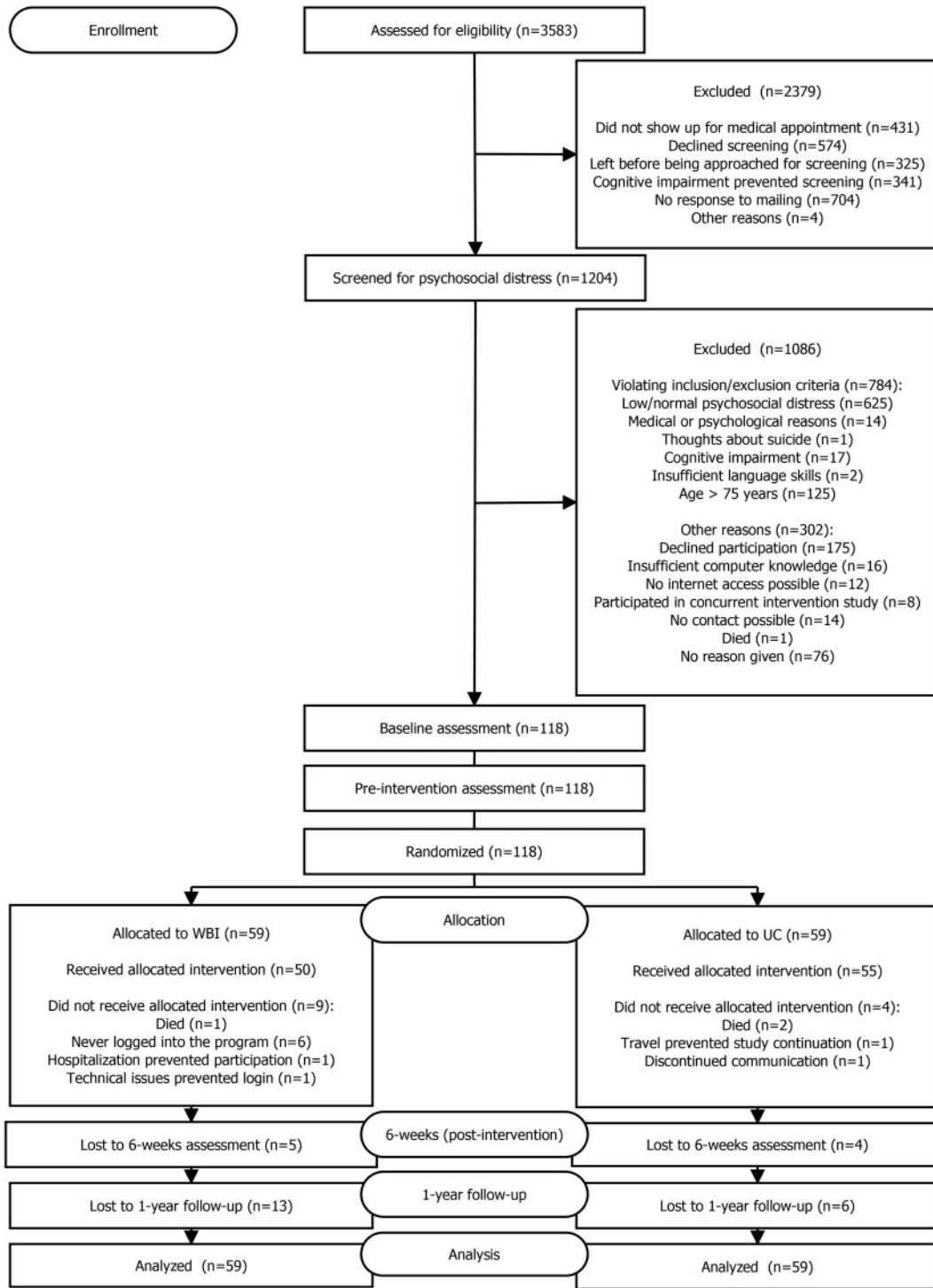


Figure 2 Participant flow through the study. UC, usual care; WBI, web-based intervention.

$\eta_p^2 = 0.010$), and from pre-intervention to 1 year in the SF-36 mental health component summary ($P = 0.07$; $\eta_p^2 = 0.015$) (Supplementary material online, Table S6).

Further positive effects of WBI vs. UC were seen for increased availability of overprotective support by family members from pre-

intervention to 6 weeks ($P = 0.004$; $\eta_p^2 = 0.036$), mobilization of support ($P = 0.047$; $\eta_p^2 = 0.011$), self-management ($P = 0.03$; $\eta_p^2 = 0.015$), and increased availability of overprotective support ($P = 0.02$; $\eta_p^2 = 0.031$) from pre-intervention to 1 year (Supplementary material online, Table S6).

Table 1 Sample characteristics at baseline

	Total (n = 118)	UC (n = 59)	WBI (n = 59)
Sociodemographic variables			
Age (years) (n = 118)	58.8 ± 11.9	59.9 ± 10.8	57.6 ± 11.5
Female (n = 118)	26 (22)	15 (24.5)	11 (18.6)
Married (n = 118)	84 (71.2)	43 (72.9)	41 (69.5)
Working (n = 118)	50 (42.4)	28 (47.5)	22 (37.3)
Current smoker (n = 117)	12 (10.2)	6 (10.3)	6 (10.2)
Body mass index (kg/m ²) (n = 112)	27.2 (24.4–31.2)	27.6 (23.9–30.9)	27.6 (24.8–31.9)
Children (n = 118)	23 (19.5)	9 (15.3)	14 (23.7)
Hospital (n = 118)			
Würzburg	79 (66.9)	40 (67.8)	39 (66.1)
Bad Neustadt/S.	15 (12.7)	6 (10.2)	9 (15.3)
Aschaffenburg	2 (1.7)	1 (1.7)	1 (1.7)
Rothenburg o.d.T.	10 (8.5)	5 (8.5)	5 (8.5)
Bad Wörishofen	2 (1.7)	2 (3.4)	0 (0)
Associated cardiologists	10 (11.8)	5 (8.5)	5 (8.5)
Clinical variables			
Secondary indication (n = 118)	39 (33.1)	23 (39)	16 (27.1)
Previous myocardial infarction, (n = 116)	33 (28.5)	12 (20.7)	21 (36.2)
QRS >120 ms (n = 100)	44 (44)	21 (40.4)	23 (47.9)
Bundle-branch block (n = 118)	15 (12.7)	7 (11.9)	8 (13.6)
Systolic blood pressure, mmHg (n = 109)	131.6 ± 17.7	133.8 ± 17.6	129.4 ± 17.1
NYHA functional class ≥III (n = 101)	20 (19.8)	12 (23.1)	8 (16.3)
Pacemaker-dependent (n = 80)	25 (31.3)	14 (32.6)	11 (29.7)
Resuscitation (n = 114)	25 (21.9)	13 (23.2)	12 (20.7)
ICD-related information			
Device therapy after implantation (n = 118)			
≥1 appropriate shock	9 (7.6)	4 (6.8)	5 (8.5)
≥1 inappropriate shock	3 (2.5)	2 (3.4)	1 (1.7)
Complications during implantation (n = 113)			
Complications following implantation (n = 113)	2 (1.8)	1 (1.8)	1 (1.8)
Complications following implantation (n = 113)	6 (5.3)	3 (5.4)	3 (5.3)
Device replacement (n = 98)	19 (19.4)	11 (22)	8 (16.7)
Lead revision (n = 98)	11 (11.2)	6 (12)	5 (10.4)
Time since implantation (years) (n=117)	1.39 (0.51–4.01)	1.09 (0.49–4.63)	1.48 (0.50–3.52)
Comorbidities			
Anaemia (n = 107)	9 (8.4)	4 (7.6)	5 (9.3)
Chronic obstructive pulmonary disease (n = 116)	5 (4.3)	3 (5.2)	2 (3.4)
Exertional dyspnoea (n = 93)	65 (69.9)	31 (66)	34 (73.9)
Sleep apnoea (n = 111)	13 (11.7)	3 (5.5)	10 (17.9)
Diabetes mellitus (n = 116)	25 (21.6)	12 (20.7)	13 (22.4)
Hyperlipidaemia (n = 116)	48 (41.4)	21 (36.2)	27 (46.6)
Hypertension (n = 116)	82 (70.7)	38 (65.5)	44 (75.9)
Malignancy (n = 116)	13 (11.2)	6 (10.3)	7 (12.1)
Peripheral artery disease (n = 116)	5 (4.3)	4 (6.9)	1 (1.7)
Renal insufficiency (n = 112)	16 (14.3)	9 (16.4)	7 (12.3)
Hyperuricaemia (n = 116)	18 (15.5)	9 (15.5)	9 (15.5)
Stroke (n = 116)	6 (5.2)	6 (10.3)	0 (0)
Major depression (n = 112)	14 (12.5)	4 (7.3)	10 (17.5)
Psychotropic medication			
Antidepressant (n = 116)	14 (12.1)	7 (12.1)	7 (12.1)
Psychometric variables			
HADS anxiety at screening (n = 105)	6.8 ± 3.8	6.6 ± 3.8	6.9 ± 3.9
HADS depression at screening (n = 105)	6 ± 3.7	6 ± 3.9	6 ± 3.5

Continued

Table 1 Continued

	Total (n = 118)	UC (n = 59)	WBI (n = 59)
SWLS QoL at screening (n = 96)	21.9 ± 6	22.7 ± 5.4	21.2 ± 6.6
CAQ heart-focused fear (n = 109)	1.6 ± 0.7	1.6 ± 0.7	1.6 ± 0.7
CAQ avoidance (n = 109)	1.6 ± 1	1.7 ± 1	1.5 ± 1
CAQ attention (n = 109)	1.4 ± 0.7	1.4 ± 0.8	1.5 ± 0.6
SF-36 physical health component summary (n = 103)	39.9 ± 10.3	41.1 ± 9.7	38.6 ± 10.8
SF-36 mental health component summary (n = 103)	46.7 ± 10.9	46 ± 11.6	47.4 ± 10.2
FERUS self-management summary (n = 83)	47.9 ± 10.2	49.1 ± 10.9	46.6 ± 9.4

Values are mean ± standard deviation, number of patients (%), or median (interquartile range).

CAQ, Cardiac Anxiety Questionnaire; FERUS, questionnaire for assessment of resources and self-management skills; HADS, Hospital Anxiety and Depression Scale; ICD, implantable cardioverter-defibrillator; n, available data; NYHA, New York Heart Association; SF-36, 36-Item Short Form Survey; SWLS, Satisfaction with Life Scale; UC, usual care; WBI, web-based intervention.

Exploratory analyses

Questionnaire subscales

Exploratory analysis of FERUS subscales showed significant effects of WBI compared with UC from pre-intervention to 6 weeks for active and passive coping ($P = 0.01$; $\eta_p^2 = 0.018$) and from 6 weeks to 1 year for social support ($P = 0.048$; $\eta_p^2 = 0.014$). Similar non-significant trends emerged for hope ($P = 0.08$; $\eta_p^2 = 0.011$) and social support ($P = 0.07$; $\eta_p^2 = 0.011$) from pre-intervention to 1 year ([Supplementary material online, Tables S4 and S5](#)).

Evaluation of clinical significance

Reliable change index analysis showed that WBI vs. UC was associated with clinically significantly improved mental QoL in five patients (8.5%) from pre-intervention to 1 year. In contrast, UC vs. WBI was associated with clinically significantly deterioration of mental QoL in three patients (4.7%).

Web-based intervention was also associated with clinically insignificant improvements from pre-intervention to 6 weeks [SF-36 mental QoL: $n = 4$ (6.1%), HADS anxiety: $n = 1$ (1.2%), HADS depression; $n = 2$ (4.8%)] and from pre-intervention to 1 year [SF-36 mental QoL: $n = 5$ (8.5%), HADS anxiety: $n = 13$ (21.7%), HADS depression $n = 4$ (6.4%)]. Additionally, at 1 year, UC vs. WBI was associated with insignificant deterioration of mental QoL and depression in 6 (9.9%) and 2 (5.2%) patients, respectively.

There was no significant difference in hospitalization frequency between the WBI and UC groups. The trained clinical psychologist spent 1.5 ± 0.42 h/week online for support and moderating group discussions.

Evaluation of web-based intervention content

Ratings from 36 patients randomized to WBI indicate that the programme was quite helpful (mean ± SD 3.1 ± 0.9) and usability was high (3.1 ± 0.9). Support provided by the trained psychologist and reading contributions to the discussion board were considered particularly helpful ([Supplementary material online, Table S8](#)). The WBI was considered a trustworthy and supportive place where patients could learn coping strategies, were inspired to try new things, and

learned how to manage their illness ([Supplementary material online, Table S8](#)).

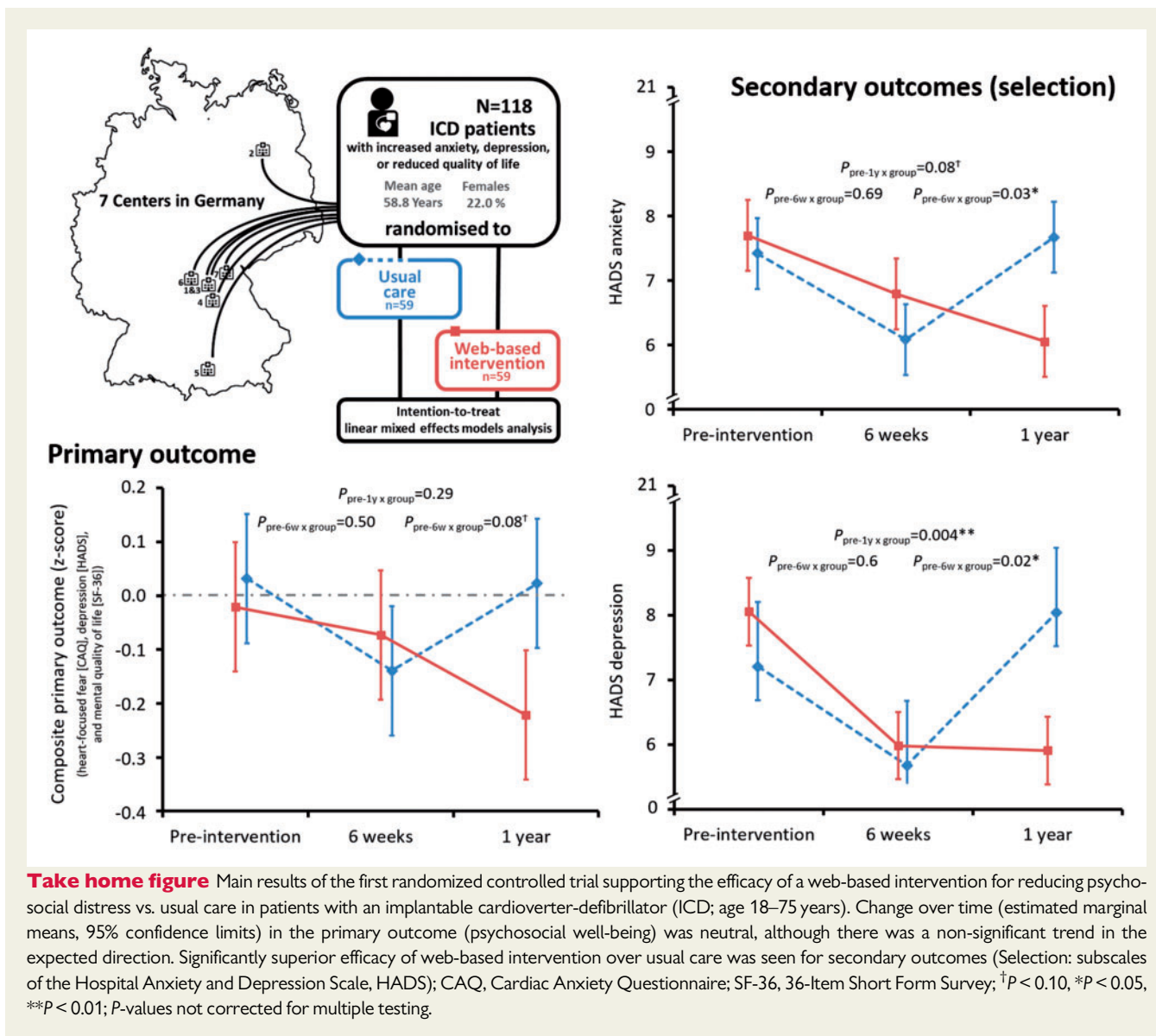
Topics rated as most helpful (score ≥ 2.5) were medical background information, information on what (not) to avoid with an ICD, understanding ICD shock therapy, psychological models regarding factors that contribute to development and persistence of anxiety, the two column-technique for dealing with cognitive error, and guidance for developing a resource-oriented problem-solving style ([Supplementary material online, Table S9](#)).

Discussion

This randomized controlled trial (RCT) was neutral for the pre-defined composite primary endpoint incorporating measures of heart-focused fear, depression, and mental QoL, finding no statistically significant difference between the WBI and UC group. Nonetheless, there was a non-significant trend in the expected direction. Additionally, this is the first RCT to demonstrate that WBI can improve important dimensions of psychosocial well-being in ICD patients including anxiety, depression and several aspects of social support and improved self-management/coping. To the best of our knowledge, this is also the first study to report comorbidity rates for anxiety, depression, and reduced QoL for ICD patients.

Benefits of the WBI were most pronounced at 1 year. Significant short-term (6 weeks) effects of WBI, such as increased availability of overprotective support by family members, may have contributed to the longer-term effects in the current trial. Concurrent improvements of self-management, active and passive coping, mobilization of support, and social support from pre-intervention to 1 year are also well known for supporting improvement of depression.²⁹ Furthermore, the effects of WBI may have become evident only when later events necessitated (successful) application of skills learnt in the intervention.³⁰ This is one potential explanation for why the efficacy of WBI increased from 6 weeks to 1 year.

The current findings are in line with pilot studies suggesting positive effects of WBI in ICD patients.^{9,16,19} Compared with the current trial,



larger effects have been reported at post-intervention for internet-based interventions in other target groups.¹⁸ One other RCT investigating the efficacy of a WBI for ICD patients reported a neutral effect.²³ This WBI included similar elements to ours, but patients were unselected, and were followed up for the 3-month intervention only. As was seen in the current RCT, positive effects may have developed thereafter. In addition, patients in the current trial had at least mildly increased psychosocial distress at baseline. This may have increased their motivation and supported a positive learning experience when they realized that the WBI met their needs.

Clinically significant change was found in a small number of patients. Average improvements in anxiety and depression (HADS) with WBI ranged from values above the cut-off considered to indicate likely clinical significance²⁸ to those considered mild to negligible. Therefore, effects of WBI vs. UC were likely to be clinically relevant for at least a subgroup of participants, and subclinical benefits of WBI were present for a considerably larger proportion of patients. In

contrast, UC was associated with an overall deterioration of psychosocial well-being over time supporting a previous hypothesis²³ that WBI also acts preventively.

Participant ratings indicated that the WBI was well-received and met patients' needs and expectations. As in previous reports,³¹ participants rated the availability of the trained psychologist and reading discussion board contributions in this WBI as particularly helpful. Together with other components seen as very useful by WBI participants, these variables may have mediated the efficacy of the intervention.

Although our preliminary hospitalization-related cost analysis showed no difference between WBI and UC, the fact that the WBI required only 1.5 h/week for the trained clinical psychologist, was well-integrated into routine care, and would be easily scalable to higher patient volumes, indicate that cost-effectiveness could be favourable; additional research is needed in this area.

A limitation of our study is its moderate sample size. Although sufficiently powered for assessment of the primary outcome, the number of

subjects was too small for multiple testing. Nevertheless, effects of the WBI on HADS depression and availability of support by family members were statistically significant both with and without Bonferroni correction. Inclusion of a larger sample may also change perspectives regarding the non-significant trends found for components of the primary outcome (CAQ heart-focused fear, SF-36 mental health component summary). Once psychosocial screening is integrated in routine medical care as recommended,¹ three times as many patients may consider using WBI. Implantable cardioverter-defibrillators patients share many issues with chronic heart failure patients, a much larger population in need of psychosocial support.³² The current WBI could be adapted to provide useful support also for these patients.

The rate of missing data, particularly due to dropout, may also be considered a limitation. Bias can occur due to systematic dropout, missing data and associated imputation. However, in this study, we did not see a systematic pattern for missing data, the psychosocial status of completers was very similar to patients who dropped out, and we applied an intention-to-treat approach, which is considered a primary measure for reducing or eliminating bias in RCTs. In addition, sensitivity analyses confirmed the validity of our findings across methodological variations (Supplementary material online) such as analysis with data imputed by multiple imputation vs. 'last observation carried forward' vs. available data. We also compared multiple imputation with vs. without variables that distinguished completers from patients who dropped out. Based on these analyses, we consider that bias due to missing data should not have an important impact on the validity of the current findings.

A final limitation is that the current findings may not generalize to younger patients or those aged above 75 years or those with low/negligible psychosocial distress. Furthermore, the considerable number of patients who declined participation due to unknown reason represents an important target for further research to increase generalizability of the current findings.

Consequently, our findings appear to be generalizable to ICD patients with at least mildly increased psychosocial distress who are capable and motivated to take part in WBI. HADS scores ≥ 6 points on either subscale appeared well-suited for efficiently identifying these patients, but we cannot exclude the possibility that patients with lower scores may also benefit from WBI. Reducing the number of questionnaires and additional visits compared with the current RCT may make the WBI more accessible to a wider range of patients when it is applied in routine settings. Although we found no indication of selection bias, this would further enhance generalizability.

Future improvement of WBI could include content-tailoring and an interactive modular design, or time- and location-independent coordination of transdisciplinary medical and psychosocial support. Rather than being considered competitive to traditional support models, WBI may be valuable as part of a stepped care approach, motivating patients to take advantage of complementary care including face-to-face psychotherapy when indicated.

Conclusion

Although the primary outcome was neutral, the results of this RCT suggest that WBI can improve important psychosocial well-being

dimensions in ICD patients. It can easily be scaled up at moderate cost. Further research is warranted to optimize the WBI intervention and evaluate its effects in larger trials.

Supplementary material

Supplementary material is available at *European Heart Journal* online.

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