The Effectiveness of an Online behavioural Intervention (WEBCARE) on Disease-Specific Outcomes in Patients with an Implantable Cardioverter Defibrillator: A Randomized Controlled Trial.

by

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Abstract

Background: The number of patients living with an implantable cardioverter defibrillator (ICD) has increased exponentially in many countries for the last few years. Unfortunately, the implantation of an ICD and shock delivery itself has been associated with a lower quality of life (QOL) and 20 to 30% of the patients keep experiencing chronic levels of distress post implant. Online interventions trials to reduce distress have been studied before in other populations than ICD patients and the results were positive. For this reason, this study examines the effectiveness of the WEBbased distress management program for implantable CARdioverter dEfibrillator patients (WEBCARE) on disease-specific patient reported outcomes.

Methods: Participants were recruited in six Dutch referral hospitals and randomized to the WEBCARE condition or usual care condition. Patients assigned to the WEBCARE condition received a 12-week fixed, six-lesson behavioral treatment, which was based on cognitive behavioral therapy.

Results: After controlling for age, gender, education, and distress (anxiety and depression) at baseline the effect of the WEBCARE treatment on the outcome measures were non-significant: FPAS, $F(1, 215) = 0.113$, $p = .737$, $\eta_p^2 = 0.001$; ICDC, $F(1, 215) = 0.759$, $p = .385$, $\eta_p^2 = 0.004$; FSAS, $F(1, 215) < 0.001$, $p = .993$, $\eta_p^2 < 0.001$.

Conclusions: The findings of this study show that there is no effect of WEBCARE on distress in ICD patients compared with usual care that is given nowadays. However, the emergence of web-based interventions is still in its early stages and further research needs to be done to examine ways this new medium might help us.

Introduction

The number of patients living with an implantable cardioverter defibrillator (ICD) has increased exponentially in many countries for the last few years (Mond & Proclemer, 2011). At first, ICDs were only used for patients who were successfully resuscitated from ventricular fibrillation or ventricular tachycardia (secondary prevention) (Alsheikh-Ali et al., 2013). Nowadays the device is also used as primary prevention for people who have an increased risk to experience life-threatening arrhythmias (Crespo, Kim & Selzman, 2005). Studies have showed that ICDs reduce the risk of all-cause mortality by 24% and the risk of sudden cardiac deaths by 50% as compared to medication alone (Crespo et al., 2005; Sears et al., 2007). Hence it has become the treatment of choice for patients with a left ventricular ejection fraction of 35% or less due to either ischaemic or nonischaemic cardiomyopathy (Gigli et al., 2014; Gelder, Smit, Nieuwland, & Veldhuizen, 2006).

Unfortunately, the life-saving ICD can have some negative consequences regarding psychological well-being. The implantation of an ICD and shock delivery itself has been associated with a lower quality of life (QOL) (Heatherly, et al., 2011; Kuhl, Sears, & Conti, 2006). Although psychological stress can decrease in the first year following implantation, 20 to 30% of the patients keep experiencing chronic levels of distress post implant (Pedersen et al., 2011; Tavenaux et al., 2011). A possible cause for this distress is that patients do not know when the device will go off, which can be frightening (Sears et al., 2007). Alerts or recall warnings that some ICD devices could be malfunctioning are also reasons for worry in patients, including cases where ICDs have actually given inappropriate shocks (Anderson, Gillberg, Torrey & Koneru, 2012; Davis et al., 2009; Fisher, 2009; Heatherly, Simmons, Fitzgerald, & Mitchell, 2011; Rasania, Mountantonakis & Patel, 2012). Studies have shown that around one fifth of the patients suffer from depression too, which is associated with

mortality in both a healthy population as in these patients (Broek et al., 2013; Schulz et al., 2000; Tzeis et al., 2011).

It is important to treat distress in ICD patients, because this distress is associated with mortality and an increase of vulnerability to arrhythmic events (Broek et al., 2013; Kohn, Petrucci, Baessler, Soto, & Movsowitz, 2000). So far, various psychological interventions have been described to reduce anxiety and depression in ICD patients (Kohn et al, 2000). However, interventions like cognitive behavioral therapy are associated with large dropout rates and generally small sample sizes (Kohn et al., 2000; Salmoirago-Blotcher & Ockene, 2009). Online interventions can be a solution to these shortcomings, because they have a number of advantages, like portability, timeliness, efficiency, mobility, accessibility, plus it is less stigmatising (Archer, Keshavjee, Demers, & Lee, 2014; Robinson et al., 2014). Since the prevalence of chronic diseases is growing, online interventions are a good option to save money for the health-care system too (Archer et al., 2014; Ruwaard, 2009). Online interventions trials have been studied before in other populations than ICD patients and the results were positive (Archer et al., 2014; Robinson et al., 2014; Ruwaard, 2009). Kuhl et al. (2006) argue that there could be a future for online interventions with ICD patients too, but that there is a need for randomized controlled trials to evaluate the effect of such interventions. The current study follows that advice and examines the effectiveness of the WEBbased distress management program for implantable CARdioverter dEfibrillator patients (WEBCARE) on disease-specific patient reported outcomes.

The focus of the current study will be to evaluate treatment effectiveness on disease specific patient reported outcomes. Generic questionnaires, are universal and are used in many different situations and studies. They are not as specialized as disease-specific questionnaires, which are focused on specific diseases (Garin et al., 2009). These questionnaires are more sensitive to changes in the condition of patients and thus are more

suitable to evaluate treatments than generic questionnaires as they show a better discriminator abilitly (Ades, Lu, & Madan, 2013; Al-Ahmad, Al-Sa'di, Al-Omari, & Al-Bitar, 2009; Tullis & Guyatt, 1995). For this reason, disease specific symptoms of patients with an ICD are monitored in the current study.

The research question of the current study is: Has the online intervention WEBCARE effect on the psychological consequences of having an ICD? Based on previous studies, we hypothesize that the online intervention will have a positive effect on the disease-specific outcomes of ICD patients.

Methods

Study design

The clinical characteristics and psychological characteristics of the patients were assessed at the time of implantation. The disease-specific questionnaires used to measure the psychological characteristics were the Florida Shock Anxiety Scale (FSAS), the ICD patient concerns questionnaire (ICDC) and the Florida Patient Acceptance Survey (FPAS).

Besides treating existing distress in patients, the trial was also designed to prevent the onset of distress. There were four time points at which patients had to fill in a set of standardized and validated questionnaires, namely baseline, 3-, 6- and 12 months. The current study only used the baseline and 3 months follow-up data, because the short term effectiveness of the intervention was evaluated. Medical ethics committees of the participating hospitals approved the study protocol and the trial was registered on http://www.ClinicalTrials.gov (NCT00895700).

Patient recruitment

Patients implanted with a first-time ICD between April 2010 and February 2013 were included in the study cohort. They were referred from six Dutch hospitals: Amphia Hospital,

Breda; Canisius-Wilhelmina Hospital, Nijmegen; Catharina Hospital, Eindhoven; Erasmus Medical Center, Rotterdam; Onze Lieve Vrouwe Gasthuis Hospital, Amsterdam; Vlietland Hospital, Schiedam. The inclusion criteria were admission for a first-time ICD implant and age between 18 and 75 years. The exclusion criteria were history of psychiatric illness other than affective or anxiety disorders, significant cognitive impairments (e.g., mental retardation), life-threatening comorbidities (e.g., cancer), life expectancy less than 1 year, being on the waiting list for heart transplantation, lack of internet or computer skills, and insufficient knowledge of the Dutch language. WEBCARE was designed as a prevention and reduction (of primarily anxiety) trial, therefore patients were included regardless of their psychological distress levels.

Procedure

Prior to or briefly after the ICD implantation the ICD nurse of technician approached the patients to inform them about the study both personally and in writing. If the patients were willing to participate and all inclusion criteria and none of the exclusion criteria were met, they signed the informed consent form and were provided with the first set of questionnaires. Patients returned the filled-in questionnaires in a pre-addressed, stamped envelope to Tilburg University that served as core-lab for the trial. Patients received up to 3 reminder phone calls, if the questionnaires were not returned within 2 weeks. The second set of questionnaires were send to the patients by mail for follow-up assessment. They were asked to return these to Tilburg University within one week. They received up to 3 reminder phone calls, if patients had not returned the second questionnaires within this first week.

Randomization

Patients were randomized when they returned the baseline questionnaires, prior to opening the envelope, on a 1:1 basis. This was done by drawing a sealed envelope for each patient containing the condition WEBCARE or Usual Care. The computer was used for block

randomization, randomizing 20 patients per hospital, at each time point. An independent, blinded, statistician generated the randomization list which was sealed by a research assistant. The health care providers were blinded whether patients were assigned to the WEBCARE or Usual Care condition. Given the nature of the study, blinding the participants and coaches (to provide online feedback to the patients, master level psychologists were trained according to a standardized protocol to be coaches) was not possible.

Intervention

Patients assigned to the WEBCARE condition received a 12-week fixed, online course. This course consisted of six lessons, which were based on problem solving therapy in combination with cognitive behavioral components, in addition to usual care. The intervention was based on the online course 'Everything under control' (Alles Onder Controle) (Warmerdam, van Straten, Twisk, Riper & Cuijpers, 2008). This course has shown to be effective in reducing psychological distress in a depressed, physically healthy population (van Straten, Cuijpers & Smits, 2008; Warmerdam et al., 2008). In order to make the course fit for the current study, there were a few adjustments made in collaboration with the Dutch ICD patient organization STIN. Two major modifications were the addition of a lesson on psycho-education with regard to living with an ICD and making the cases that are presented in the homework assignments specific for patients with an ICD in order to increase patient identification and adherence.

Patients could plan the six lessons themselves to complete them in own time and pace. However, they could only proceed to the next lesson if they had finished the former and sent the homework assignment to their coach. In turn, the coach provided the patients with feedback. If patients did not submit their homework, they received automatic reminder e-mails every two weeks. The account of each patient was closed after 12 weeks.

Patients assigned to the control group received standard care from the hospital, similar to patients that were not enrolled in this study. There were no restrictions applied to care as usual.

Measures

Shock anxiety.

The Florida Shock Anxiety Scale (FSAS) was used to measure shock anxiety (Ford et al., 2012). The disease-specific questionnaire FSAS has 10-items which are rated on a 5-point Likert scale ranging from 1 (never) to 5 (always). Higher scores means higher levels of shock anxiety (Kuhl, Dixit, Walker, Conti & Sears, 2006). A total scale score was calculated and used in the current study. Studies have shown that the FSAS is a reliable measure with a Cronbach > of .89 (Ford et al., 2012).

Patient concerns.

Patients' concerns about the ICD were measured by the Dutch version of the ICD Patient Concerns (ICDC) questionnaire (Pedersen, Domburg, Theuns, Jordaens & Erdman, 2005). The ICDC consists of eight items which 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. A higher score means patients have more and severe concerns (Frizelle, Lewin, Kaye & Moniz-Cook, 2006). Studies have shown that the ICDC has an internal consistent scale with a Cronbach > of .91 (Pedersen et al., 2005).

Device acceptance.

The acceptance of the ICD device was measured with the Florida Patient Acceptance Survey (FSAS) (Versteeg et al., 2012). The abbreviated 12-item version was used in the current study, which has been validated in Dutch and Danish ICD patients (Pedersen et al., 2008; Versteeg et al., 2012). 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. A higher score means higher

acceptance. The FSAS has an internal consistency with Cronbach > of .82 and .85 for Dutch and Danish ICD populations (Pedersen et al., 2008; Versteeg et al., 2012).

Statistical analysis

Discrete variables were compared using the χ^2 test, which are represented as percentages, and continuous variables were compared using the independent samples t-test, which are presented as mean values and standard deviations. The continuous variable distress after three months was analyzed per disease-specific questionnaire by analysis of variance (ANOVA) and analysis of covariance (ANCOVA), while controlling for gender, age, education and distress on baseline. Significance (2-tailed) was assigned at a level of $p < .05$.

Results

Participants

A total of 1024 patients which had an ICD implanted between April 2010 and February 2013 were assessed for eligibility. A total of 735 patients were excluded because of three reasons. First, 492 patients did not meet the inclusion criteria (lack of internet, age > 75 years, language barrier). Second, 192 patients refused to participate. Last, 51 patients did not return their baseline measures. In the end 289 patients were randomized to the WEBCARE (n = 146) versus usual care (n = 143) condition. A number of patients were lost to follow-up in the WEBCARE group (n = 43) and usual care group (n = 25), leaving 221 patients for analyses (Figure 1). Technical problems, time constraint, feeling fine, and intervention did not meet patients' needs were the most frequent reasons for dropouts mentioned by patients.

Baseline Characteristics

Table 1 shows information on demographic and clinical variables. The total sample size had a mean age of 58.4 with a standard deviation of 10.0 and 81.3% of the sample were men. Both groups, WEBCARE and usual care, were similar at study entry (baseline) and did not differ

on demographic and clinical characteristics (Table 1). The groups also did not differ on the psychological measures at baseline (Table 2).

Disease specific outcomes

Univariate analyses

The univariate analyses showed no significant effect of the WEBCARE treatment on the outcome measures: FPAS, $F(1, 224) = 0.009$, $p = .924$, $\eta_p^2 < 0.001$; ICDC, $F(1, 224) = 0.096$, $p = .756$, $\eta_p^2 < 0.001$; FSAS, $F(1, 224) = 0.285$, $p = .594$, $\eta_p^2 = 0.001$.

Multivariate analyses

After controlling for age, gender, education, and distress (anxiety and depression) at baseline the effect of the WEBCARE treatment on the outcome measures remained non-significant: FPAS, $F(1, 215) = 0.113$, $p = .737$, $\eta_p^2 = 0.001$; ICDC, $F(1, 215) = 0.759$, $p = .385$, $\eta_p^2 = 0.004$; FSAS, $F(1, 215) < 0.001$, $p = .993$, $\eta_p^2 < 0.001$.

Discussion

The findings of this study show no significant difference in disease-specific outcomes between the experimental and the control group. The analyses show that after three months there is no difference on the FPAS, ICDC, and FSAS whether patients received usual care or usual care plus WEBCARE. This suggests that the WEBCARE intervention has no positive effect on the disease-specific outcomes of ICD patients.

Other studies on web-based interventions have found positive results (Paul, Carey, Sanson-Fisher, Houlcroft, & Turon, 2013; Trompetter, Bohlmeijer, Veehof, & Schreurs, 2015). However, these studies are done with different patient groups than ICD patients, which may indicate that web-based approaches are not generally suitable for all kinds of patient groups (Paul et al., 2013). Compared with other studies, the mean age of this study is also relatively high (Paul et al., 2013). A higher mean age is associated with lack of technology

efficacy, which can be an obstacle for a number of patients (Archer et al., 2014). As a result, they may not get the most out of the online intervention. Kiropoulos et al. (2008) compared an online intervention with face-to-face cognitive behavioral therapy for people with panic disorder. They found a positive effect of their online intervention, but they noticed that patients in the control group had higher compliance to the treatment and understood the treatment material better than the online intervention group. They argue that this is a result of the face-to-face contact patients had in the control group. The lack of face-to-face contact in the WEBCARE intervention may act disadvantageous too.

There are also a couple of points that are unlikely to explain the insignificant results. First, the number of patients involved in the study was sufficient. According to Hinkle, Wiersma, and Jurs (2003) there were enough subjects in order to carry out the analysis. Second, the randomization had successfully taken place. Table 1 shows there were no significant differences between the experimental and control group on a number of characteristics at baseline. Thus it is not likely there is a bias in the randomization procedure which possibly causes the insignificant results.

It is worth noting that we used the variable distress at baseline as covariate. We have controlled for this variable in comparing distress after three months for the experimental and control group. The results indicate that distress at baseline is significant as a covariate, which means that this variable may be a confounding or interacting variable. Future studies should examine the relationship between the distress patients have in the beginning, before they start with their treatment. There may be a more complex relation among these variables than what is studied in this article.

In this study disease-specific questionnaires were used, because they are more suitable to evaluate treatments than generic questionnaires (Ades, Lu, & Madan, 2013). However, many disease-specific questionnaires have yet to be studied more to evaluate their

effectiveness (Schellingerhout et al., 2012). The claim that disease-specific questionnaires are more sensitive to changes in the condition of patients than generic questionnaires is not always the case (Garster, Palta, Sweitzer, Kaplan, & Fryback, 2009). In future studies generic questionnaires can be included to compare results between the two different types of questionnaires and to be sure that no effect is overlooked.

Another concern is the duration of the intervention. Patients had used WEBCARE for only three months when their distress was measured again. This seems like a very short time for a treatment to have effect. Studies of treatments for other psychological burdens have already shown that it is better to treat a patient for a longer period, which can go up to several months or even years (Ryan, 2003). A recommendation for further research is to extend the duration of WEBCARE, to make sure that the potential of the intervention is utilized as much as possible.

A couple of implications for the field follows from this study. It seems that the use of web-based interventions needs a lot of development and further research to maximize their usefulness. The several advantages (low cost, portability, timeliness, efficiency, mobility, accessibility, less stigmatising) of web-based interventions seem to have potential. Since seven out of ten Dutch people own a smartphone, this also seems a suitable medium to be part of a web-based intervention (Archer et al., 2014; Centraal Bureau voor de Statistiek, 2014). Last, medical psychologist and doctors should look for a so called goodness of fit in interventions for their patients. According to Chess and Thomas (1999) goodness of fit is the result of a good interaction between the environment (e.g. an intervention) and an organism's capacities and characteristics. The intervention WEBCARE is a step in this patient-tailored direction. The goodness of fit approach is recommended by several more studies (McClowry, Rodriguez, & Koslowitz, 2008; Park, Sacco, & Edmondson, 2012; Simeonsson, Huntington, & Comfort, 1986).

This study was conducted to find out if the web-based intervention WEBCARE was effective in reducing distress in patients with an ICD. The findings of this study showed no difference with the usual care that is given nowadays. However, the emergence of web-based interventions is still in its early stages and further research needs to be done to examine ways this new medium might help us.

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Figure 1

Flowchart patient recruitment

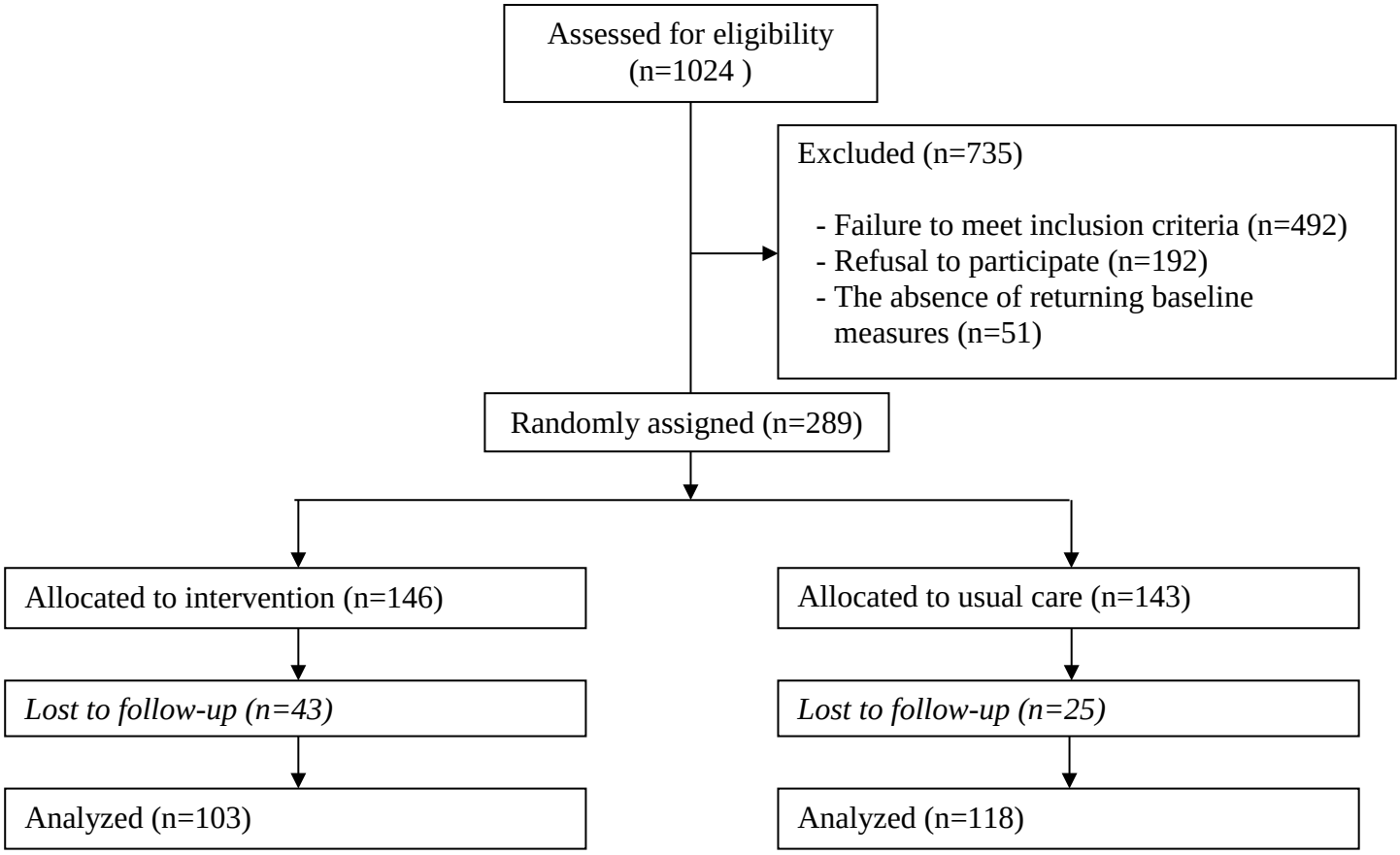
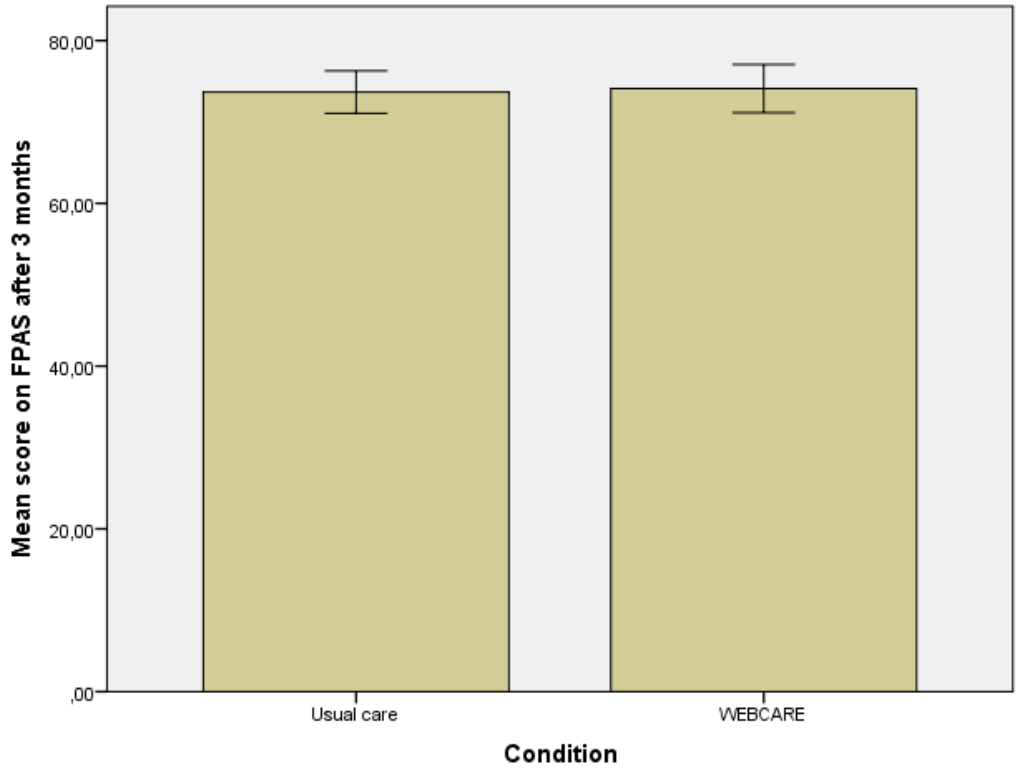
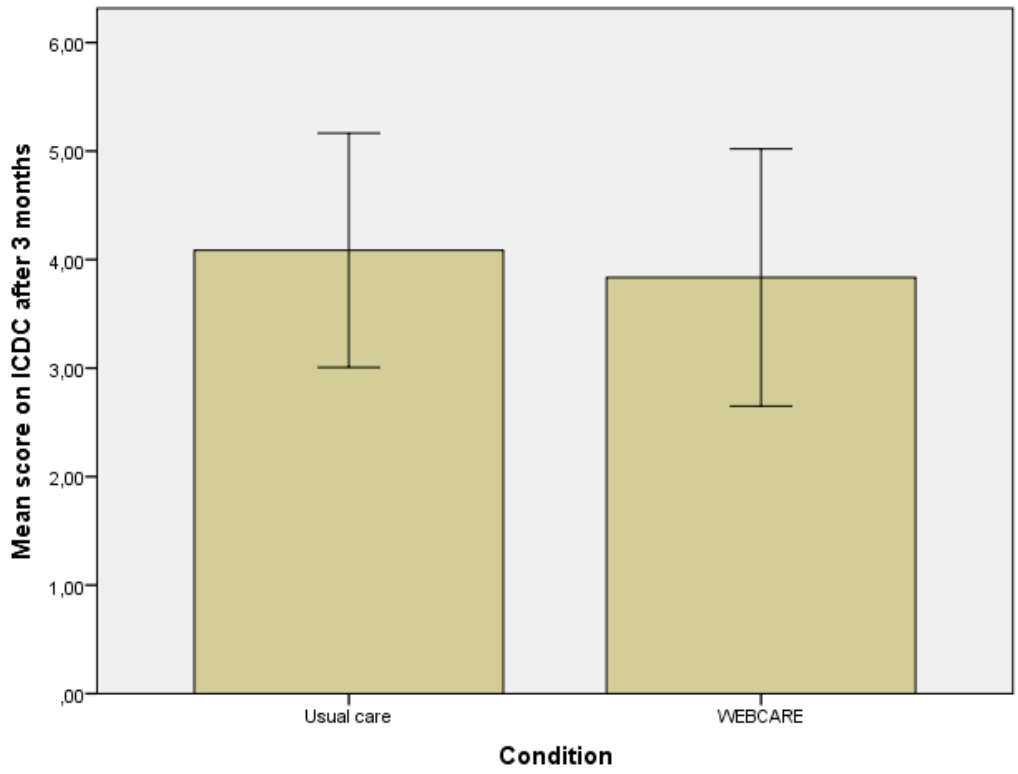


Figure 2

Bar graphs of mean scores on the disease specific questionnaires after three months, including error bars representing 95% confidence intervals





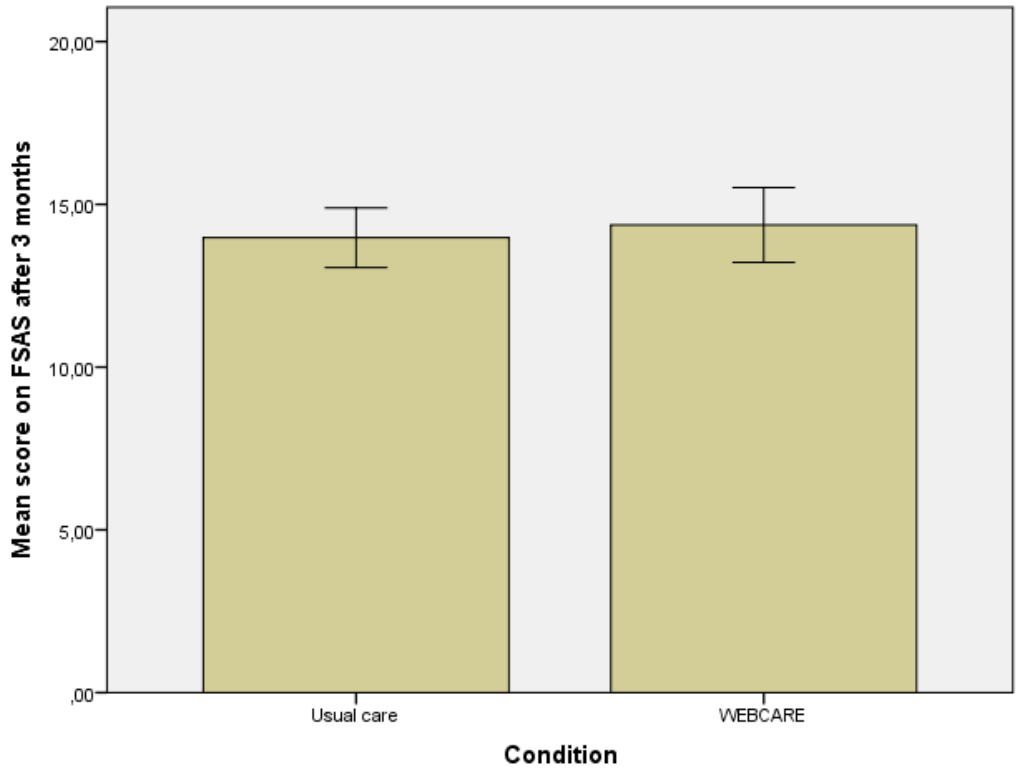


Table 1

Baseline demographics and clinical variables for the total sample and stratified by treatment condition

	Total (n = 289)	WEBCARE (n = 146)	Usual care (n=143)	p
Age	58.43 (10.01)	58.23 (9.87)	58.63 (10.19)	.73
Sex (male)	235 (81.3)	120 (82.2)	115 (80.4)	.70
Education (high*), n = 285	208 (73.0)	106 (73.1)	102 (72.9)	.98
Partner (yes), n = 288	244 (84.7)	124 (84.9)	120 (84.5)	.42
Children (yes), n = 287	237 (82.6)	125 (85.6)	112 (82.6)	.17

Working (yes), n = 288	141 (49.0)	68 (46.6)	73 (51.4)	.56
Smoking (yes), n = 288	40 (13.9)	21 (14.4)	19 (13.4)	.81
Myocardial infarction (yes)	142 (49.1)	71 (48.6)	71 (49.7)	.86
Heart failure (yes)	212 (73.4)	102 (69.9)	110 (76.9)	.18
Peripheral artery disease (yes)	4 (1.4)	1 (0.9)	3 (2.1)	.30
Diabetes (yes)	49 (17.0)	20 (13.7)	29 (20.3)	.14
Dementia (yes)	1 (0.3)	0	1 (0.7)	.31
COPD (yes)	19 (6.6)	9 (6.2)	10 (7.0)	.78
Connective tissue disease (yes)	7 (2.4)	4 (2.7)	3 (2.1)	.72
Peptic ulcer disease (yes)	5 (1.7)	2 (1.4)	3 (2.1)	.64
Hemiparesis (yes)	0	0	0	
Kidney disease (yes)	8 (2.8)	4 (2.7)	4 (2.8)	.98
Lymphoma (yes)	1 (0.3)	0	1 (0.7)	.31
Tumor in the past 5 years (yes)	10 (3.5)	5 (3.4)	5 (3.5)	.97
Leukemia (yes)	1 (0.3)	1 (0.7)	0	.32
Liver disease (yes)	1 (0.3)	1 (0.7)	0	.32
AIDS (yes)	0	0	0	
Cerebrovascular	8 (2.8)	4 (2.7)	4 (2.8)	.98

accident (yes)				
Psychological care (yes), n = 287	15 (5.2)	8 (5.5)	7 (5.0)	.85
Participating cardiac rehabilitation (yes), N = 287	34 (11.8)	20 (13.8)	14 (9.9)	.30

*High = MBO (community college), HBO (university of professional education) and WO (university of science)

Table 2

Psychological Profile for the Total Sample and Stratified by Treatment Condition at Baseline

	Total (n = 289)	WEBCARE (n = 146)	Usual care (n=143)	p
FPAS, n = 288	70.73 (13.29)	70.84 (14.12)	70.62 (12.43)	.89
ICDC, n = 287	6.33 (6.48)	6.53 (6.68)	6.12 (8.28)	.59
FSAS, n = 287	16.37 (5.74)	16.73 (6.13)	16.00 (5.32)	.28