Author's response to reviews

Title: Rationale and design of WEBCARE: A randomized, controlled, web-based behavioral intervention trial in cardioverter-defibrillator patients to reduce anxiety and device concerns and enhance quality of life

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Re.: Submission of manuscript

Dear Editors-in-Chief of Trials,

We would like the enclosed manuscript entitled "Rationale and design of WEBCARE: A randomized, controlled, web-based behavioral intervention trial in cardioverter-defibrillator patients to reduce anxiety and device concerns and enhance quality of life" to be considered for publication in Trials under the category “Study protocol”.

The manuscript has been prepared in accordance with the style of the journal, and all authors have approved it. The undersigned author transfers all copyright ownership of the manuscript entitled "Rationale and design of WEBCARE: A randomized, controlled, web-based behavioral intervention trial in cardioverter-defibrillator patients to reduce anxiety and device concerns and enhance quality of life" to the publisher, in the event the work is published. The undersigned warrants that the article is original, does not infringe upon any copyright or other proprietary right of any third party, is not under consideration by another journal, and has not been published previously. No conflicts of interest exist in relation to the manuscript and all potential conflicts have been declared. Medical ethics approval for the trial has been obtained in the first center (i.e., the Erasmus Medical Center as of September 8, 2009); approval at the other two participating centers is now being sought, with the procedure ethics approval for these centers being quicker due to approval from the principal (medical) center.

The implantable cardioverter defibrillator (ICD) is generally well accepted, but 25-33% of patients experience clinical levels of anxiety, depression, and impaired quality of life (QoL) following implantation. Few trials in ICD patients have investigated whether behavioral intervention may mitigate the development of these adjustment problems, and none of these have used a web-based approach. We present the rationale and study design of the WEB-based distress management program for implantable CARdioverter dEfibrillator patients (WEBCARE) trial.

WEBCARE is a multi-center, multi-disciplinary, randomized, controlled behavioral intervention trial designed to examine the effectiveness of a web-based approach in terms of reducing levels of anxiety and device concerns and enhancing QoL. The web-based approach of WEBCARE is novel in ICD patients. Consecutive patients hospitalized for the implantation of an ICD will be approached for study participation while in
hospital and randomized to the intervention arm (n = 175) versus usual care (n = 175) at baseline (5-10 days post implantation). Patients will complete assessments of patient-centered outcomes at baseline, 14, 26, and 52 weeks after implantation. Patients randomized to the intervention arm will receive a 12-week web-based behavioral intervention starting 2 weeks after implantation. Primary endpoints include (i) patient-centered outcomes (i.e., anxiety, depression, ICD acceptance, QoL); (ii) health care utilization; and (iii) cost-effectiveness. All primary endpoints will be assessed with standardized and validated disease-specific or generic questionnaires. Secondary endpoints include (ii) cortisol awakening response; and (iii) ventricular arrhythmias. WEBCARE will show whether a behavioral intervention using a web-based approach is feasible and effective in terms of reducing anxiety and ICD concerns and improving QoL in ICD patients.

We believe that these findings may be of interest to readers of your journal. We hope that our manuscript meets the high standards of your journal and look forward to learning of your decision concerning our manuscript.

Yours sincerely,

Susanne S. Pedersen
Professor of Cardiac Psychology