



Abstract

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Project Title: PSYCHOEDUCATIONAL INTERVENTION FOR ICD PATIENTS

Abstract: *Symptom distress and persistent physical and psychological changes characterize early and ongoing recovery from ventricular dysrhythmia and treatment with an implantable cardioverter defibrillator (ICD). This study will test the effect of a psychoeducational intervention on psychological and physical outcomes in the first 12 months after ICD implantation. Primary outcome measures are anxiety, depression, and functional status. The effect of the intervention on variables that mediate adaptation and outcomes (symptoms, illness appraisal, and coping behaviors) will also be examined. Secondary aims will examine subsequent arrhythmia events (ICD delivered therapy) and health resource utilization in relation to the main outcomes. The intervention and study variables are based on stress and coping theory and previous research with ICD patients, which documented negative outcomes of ineffective coping and compelling relationships between increased emotional distress and subsequent arrhythmia events. A three-group, randomized, clinical trial with a repeated-measures design will be used. ICD patients (n=300) will be randomized to receive either the usual standard of care, symptom management training plus cognitive behavioral intervention delivered in a group format, or symptom management training plus cognitive behavioral intervention delivered by nurse provided by telephone counseling. The symptom management training component will be provided in the acute care setting and will focus on symptoms of pain, sleep disturbances and ICD shocks. The four cognitive behavioral sessions by group or telephone format will begin 6-8 weeks after hospitalization and will focus on illness reappraisal and coping skill training. Thus the intervention is designed to bridge the acute and outpatient continuum of care. A booster intervention will be provided at 4 months after implantation. Time frames for evaluations are baseline, 1, 3, 6, and 12 months after*

implantation. This study will test whether a cost-effective, accessible, theoretically-based, nurse-managed, psychoeducational intervention provides an incremental effect over usual care in improving psychological and physical outcomes in ICD patients. This study will provide data upon which future clinical practice guidelines can be based and will establish priorities for patient care according to which interventions are linked to improved adaptive processes and patient outcomes. Greater understanding of the relationships among psychological and physical outcomes, arrhythmia events, and health resource utilization are important for future studies and evaluation of clinical practice with ICD patients.

Thesaurus Terms:

cognitive behavior therapy, coping, defibrillator, health education, human therapy evaluation, nursing intervention, ventricular fibrillation anxiety, clinical trial, depression, functional ability, health care service utilization behavioral /social science research tag, clinical research, human subject

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