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Abstract

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PI Name: DOW, KAREN H.

PI Title: ASSOCIATE PROFESSOR AND RESEARCH COORDIN

Project Title: Quality of Life Intervention in Breast Cancer Survivors

Abstract: *DESCRIPTION (provided by applicant): Problems that negatively affect quality of life (QOL) are a major concern among more than 1.7 million breast cancer survivors in the United States. QOL is considered a multidimensional construct that incorporates dimensions of physical, psychological, social, and spiritual well-being. The purpose of this study is to test the effectiveness of an individualized, multidimensional quality of life intervention (Breast Cancer Educational Intervention [BCEI]) on QOL for women with newly diagnosed, early stage I or II breast cancer in the first year after initial treatment. The BCEI is based on extensive preliminary research studies by the investigators. The five selected QOL problems of fatigue, pain, fear of recurrence, sexuality concerns, and meaning in illness were targeted as high priority areas based on a preliminary study of 298 breast cancer survivors. The specific aim of this study is to test the effectiveness of the Breast Cancer Educational Intervention (BCEI). Three hypotheses will be tested: H1: Breast cancer survivors will experience improved QOL as a result of the BCEI. H2: Breast cancer survivors will experience improved QOL in the domains of physical, psychological, social, and spiritual well-being as a result of the BCEI. H3: The effects of the BCEI will be retained over time. The conceptual framework is grounded in the City of Hope Quality of Life Model and principles of cancer patient education. A two-group, repeated measures experimental design with a waiting control group will be used to answer the study aims and research questions. A sample of 250 women with newly diagnosed, early-stage I and II breast cancer who are completing treatment will be recruited from two clinical sites in Florida (M.D. Anderson Cancer Center Orlando) and California (City of Hope National Medical Center). Subjects will be randomly assigned to the Experimental or Waiting Control Group. The BCEI consists of a structured and individualized QOL teaching and*

skills development program delivered by advanced practice nurses using face-to-face instruction and reinforced with written materials and audiotapes. The BCEI will be administered in three face-to-face visits with three telephone reinforcements, and three evaluation visits. Data collection will occur at three time points for the Experimental Group and four time points for the Waiting Control Group using standardized instruments. Data analysis will use multivariate t-test for two groups (equivalent to MANOVA), and the generalized estimating equation (GEE) model. Study findings are expected to improve our understanding of the incidence of major QOL problems affecting breast cancer survivors, identify individually selected interventions and their effectiveness, and determine theoretically-based interventions that are realistic for implementation by clinicians who provide follow up teaching, support, and surveillance of breast cancer survivors.

Thesaurus Terms:

*breast neoplasm, cancer rehabilitation /care, education evaluation /planning, health care service evaluation, health education, nursing intervention, quality of life, women's health fatigue, fear, functional ability, longitudinal human study, pain, psychological aspect of cancer, remission /regression
female, health services research tag, human subject, medical rehabilitation related tag, patient oriented research, telemedicine*

Institution: UNIVERSITY OF CENTRAL FLORIDA
BOX 25000
ORLANDO, FL 32816

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