

# Pilot Study of Cranial Stimulation for Symptom Management in Breast Cancer

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**A**lthough breast cancer mortality rates have declined, partly as a result of multidrug systemic chemotherapy, the morbidity associated with breast cancer and its treatments remains a significant public health problem.

Patients with breast cancer experience multiple concurrent symptoms, particularly during chemotherapy. Although symptom management research in oncology traditionally has targeted the reduction of individual symptoms, current research has focused on the phenomenon of symptom clusters, defined as three or more concurrent symptoms (Dodd, Miaskowski, & Lee, 2004) that may share a common biologic mechanism (Miaskowski & Aouizerat, 2007). This article reports the results from a biobehavioral pilot study that examined the feasibility of the protocol (safety, acceptability, and ability to recruit and retain study participants) and the preliminary outcomes of cranial electrical stimulation (CES) for reducing symptoms of depression, anxiety, fatigue, pain, and sleep disturbances in women receiving chemotherapy for breast cancer. Secondary aims were to explore the inter-relationships at baseline (prior to chemotherapy) of inflammatory biomarkers (proinflammatory cytokines interleukin-6 [IL-6], tumor necrosis factor alpha [TNF- $\alpha$ ], and interleukin-1 beta [IL-1 $\beta$ ]) and C-reactive protein (CRP) and symptoms of depression, anxiety, fatigue, pain, and sleep disturbances.

## Background and Literature Review

### Concurrent Symptoms

The symptoms of pain, depression, and fatigue commonly co-occur in patients with cancer (Agency for Healthcare Research and Quality, 2002). Such symptoms have been called “sentinel symptoms” because they are the most prevalent symptoms across cancer types, and as more of these symptoms are present, negative patient outcomes become more likely (Barsevick, 2007). Pain, depression, and fatigue do not appear to be cancer type- or stage-specific, and the symptoms have been noted in patients with cancer undergoing treatments and in cancer survivors (Reyes-Gibby, Aday,

**Purpose/Objectives:** To examine the feasibility, relationships among variables, and preliminary outcomes of a self-directed complementary modality, cranial electrical stimulation (CES), for symptom management in women receiving chemotherapy for breast cancer.

**Design:** Biobehavioral pilot feasibility study.

**Setting:** Two university-based cancer centers.

**Sample:** 36 women with stage I–IIIA breast cancer scheduled to receive chemotherapy.

**Methods:** Data were collected via interview, questionnaires, and interactive voice technology (IVR). Biomarkers were measured from a blood sample taken prior to the initial chemotherapy.

**Main Research Variables:** Symptoms of depression, anxiety, fatigue, pain, and sleep disturbances; biomarkers (proinflammatory cytokines interleukin-6, tumor necrosis factor alpha [TNF- $\alpha$ ], interleukin-1 beta) and C-reactive protein [CRP]; and CES.

**Findings:** CES appears to be a safe and acceptable modality during chemotherapy. Recruitment and retention were adequate. IVR was associated with missing data. Symptoms of depression, anxiety, fatigue, and sleep disturbances were highly correlated with each other, and most symptoms were correlated with CRP at baseline. Depression and TNF- $\alpha$  had a positive, significant relationship. Levels of depression increased over time and trended toward less increase in the CES group; however, the differences among groups were not statistically significant.

**Conclusions:** The data support the feasibility of CES. Further testing in larger samples is needed to examine the efficacy of CES for symptom management of multiple, concurrent symptoms and to further develop the biobehavioral framework.

**Implications for Nursing:** Interventions that are effective at minimizing more than one target symptom are especially needed to provide optimal symptom management for women with breast cancer.

Anderson, Mendoza, & Cleeland, 2006). In women with breast cancer, anxiety and sleep disturbances also may be present during the chemotherapy treatment phase. The prevalence of depressive disorders in patients with breast cancer ranges from 0%–46% (Kissane et al., 2004). In addition to elevated depressive symptoms,