A1.1: Biobehavioral Pilot Study of CES for Symptoms in Women with Breast Cancer

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Abstract:
Introduction: Breast cancer patients experience multiple concurrent symptoms, particularly during chemotherapy. This biobehavioral pilot, feasibility study examined the feasibility of the protocol (safety, acceptability, and the 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 disturbance in women receiving chemotherapy for breast cancer. Secondary aims were to explore the inter-relationships of symptoms and inflammatory biomarkers (proinflammatory cytokines and C-reactive protein).

**Method(s):** Randomized, double blinded clinical trial over three cycles of chemotherapy. Measures included the Hospital Anxiety and Depression Scale [HAD-S], the Brief Pain Inventory (BPI), the Brief Fatigue Inventory (BFI), and the General Sleep Disturbance Scale (GSDS). A 3 cc blood sample was collected for biomarker analysis. Cytokine levels were analyzed using the Bio-Plex® (Bio-Rad; Hercules, CA). Levels of CRP were determined using a high-sensitivity ELISA assay (ALPCO).

**Results:** Recruitment and retention were adequate. Interactive voice technology (IVR) was associated with missing symptom data. Symptoms of depression, anxiety, fatigue and sleep disturbances were highly correlated with each other and most symptoms were correlated with CRP. Depression and TNF-α were significantly correlated while no other symptoms were significantly correlated with cytokine levels. Preliminary outcomes show that levels of depression and sleep disturbances increased over time and trended towards less increase in the CES group than the other two groups but the differences were not statistically significant.

**Discussion & Conclusions:** The pilot data are supportive of the feasibility of CES during the chemotherapy period in women with breast cancer. Relationships among the symptoms and biomarkers support the biobehavioral framework. Further testing, in larger samples, is needed to examine the efficacy of CES for symptom management of multiple, concurrent symptoms.

**Abstract History:**
This abstract has not been presented or accepted for presentation in whole or in part at the SNRS or other scientific meeting.

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**FDA Disclosure:**
The FDA has cleared all pharmaceuticals and/or medical devices for the use described in this presentation.

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