

crisprpd 1.0



## Abstract

**Grant Number:** 5R01NR005261-02

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**PI Title:**

**Project Title:** VENLAFAXINE FOR HOT FLASHES FOLLOWING BREAST CANCER

**Abstract:** *Hot flashes are the most severe and fourth most prevalent menopausal symptom reported by women with breast cancer. Hot flashes affect over 65 percent of this population, with 59 percent rating the symptom as severe and 44 percent reporting they are extremely distressed by the symptom. Despite the high prevalence, severity and distress associated with this symptom, the scientific basis for managing hot flashes in women with breast cancer is limited. This randomized, double-blind, placebo-controlled crossover trial examines the effectiveness and toxicity of sustained release venlafaxine hydrochloride (37.5 mg po qd) on hot flashes in women following treatment for breast cancer. Venlafaxine is a phenylethylamine derivative that potently inhibits the reuptake of neuronal serotonin and norepinephrine and weakly inhibits the reuptake of dopamine. A secondary aim of this project is to examine the impact of hot flashes on psychological, behavioral, and physical outcomes. This study is based on the Wickham Symptom Management Model which depicts interrelationships between symptoms, symptom management strategies, and symptom management outcomes. Participants (n = 80) who are at least one month post-completion of surgery, radiation, and/or chemotherapy and who have been on tamoxifen (if prescribed) for at least 6 weeks will complete a 2-week baseline hot flash assessment and be randomized to one arm of the crossover trial. At the end of the first 6-week arm, participants will crossover to the opposite study arm for an additional 6 weeks. Outcomes to be assessed include effectiveness of the intervention (hot flash frequency, severity, distress and magnitude), toxicity of the intervention (subjective preference, side effects), psychological outcomes (mood disturbance), behavioral outcomes (quality of life, interference with daily activities) and physical outcomes (fatigue*

*and sleep disturbance). Hot flashes will be measured daily, using a subjective, prospective diary methodology, and weekly, using objective state-of-the art 24-hour physiological monitoring of sternal skin conductance. Other outcomes will be measured weekly. Compliance with the intervention/placebo will be assessed weekly using medication blister pack cards. Timing of outcome assessments is based on limitations of the physiological monitoring device and expected timing of treatment effects. Summary statistics (i.e., mean, slope, maximum response, range, proportion, achievable difference) will be used to effectively reduce the design to a 2 X 2 crossover and data will be analyzed accordingly (i.e., t-tests, linear regression, GEE, mixed model). Study findings will significantly contribute to the scientific basis of hot flash management in women following treatment for breast cancer.*

**Thesaurus Terms:**

*breast neoplasm, chemotherapy, human therapy evaluation, serotonin inhibitor, sign /symptom  
clinical trial, neoplasm /cancer therapy, tamoxifen  
clinical research, female, human subject*

**Institution:** VANDERBILT UNIVERSITY  
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