

A phase II pilot of St. John's wort for the treatment of hot flushes in women with a history of breast cancer.

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Abstract Disclosures

Abstract:

Background: Effective treatments for hot flush reduction among post-menopausal breast cancer survivors are sparse. We conducted a pilot study of the use of St. John's Wort in reducing the frequency and severity of hot flushes over a 4 week period. **Methods:** Participants were recruited from the CCOP Research Base of the Comprehensive Cancer Center of Wake Forest University. Women were aged ≥ 18 years, two or more years from active treatment for non-metastatic breast cancer, and with a minimum of 3 hot flushes per day or 21 per week. Women were ineligible if they were taking an aromatase inhibitor, receiving cytotoxic chemotherapy, or on medication for the management of hot flushes (e.g., estrogen, antidepressants). Participants completed a 1 week pill run-in to determine any drug intolerance and adherence concerns, and then took three 300 mg St. John's Wort capsules daily for 4 weeks. Participants completed hot flush diaries during active treatment (weeks 1-4), and for two weeks post-treatment (weeks 5-6) to assess hot flush frequency and severity. In addition, women completed quality of life assessments (SF-12 and Profile of Mood States [POMS]) at baseline, 2, 4 and 6 weeks. **Results:** 9 women were recruited and all were 100% compliant in taking the study pills and completing forms. Recruitment was hampered by the FDA requirement that no participants could be on

aromatase inhibitors while on study. All participants were Caucasian with a mean age of 53 years (range: 48-70). No adverse events were reported. Analyses indicated that St. John's Wort was not effective in reducing either the frequency ($p=0.98$) or severity ($p=0.29$) of hot flushes among the study participants. Quality of life, as assessed by the SF-12 (i.e., PCS [$p=0.80$]; MCS [$p=0.29$]), and the POMS ($p=0.08$), was also not improved by the use of St. John's Wort.

Conclusions: St. John's Wort was not effective in reducing the number and severity of hot flushes in this pilot, or in improving quality of life.