

## **Dr. Alfred Neugut**

While adjuvant hormonal therapy is very effective in improving mortality for women with hormone-receptor positive, localized breast cancer, studies have shown that 30-50% of women who are prescribed this therapy for 5 years discontinue their therapy early. This results in reduction or loss of the survival benefits. We have established a multidisciplinary team focused on this important issue in breast cancer quality of care, with several contributions in defining the extent and causes of non-adherence and early discontinuation. In this letter, we propose a randomized trial to test an intervention to ameliorate this significant problem.

Our specific aim is to conduct a randomized trial among women who have initiated adjuvant anastrozole therapy. They would be randomized to receive text messages by cell phone versus usual care, with planned follow-up for 2 years. Text messages have been previously used to influence patient behavior with regard to clinic attendance, tobacco cessation, weight loss, and medication adherence. The primary endpoint would be presence of anastrozole in a urine specimen collected every 3 months. We would randomize 1032 women to have the power to detect an early discontinuation rate of 25% in the usual care group vs 17.5% in the intervention arm (HR 1.50). Secondary aims include analysis of outcomes by important subgroups and assessment of comparative effectiveness of the intervention.

Our study has been pre-approved to be conducted and enroll subjects within the Southwest Oncology Group (SWOG), the largest clinical trials consortium in the US. SWOG would coordinate recruitment, enrollment, and data management for the study using SWOG funds, while funds from this grant would pay for the assays, the urine storage and shipment, and study personnel costs, allowing grant funds to be used in a very cost-effective fashion.

The results of this trial would both present a viable cost-effective means of improving adherence for an important breast cancer therapy and improving the quality of patient care. A successful trial would also establish a methodology for testing other interventions to improve adherence. The results of these studies could also be applied to the growing number of oral oncology medications and treatments.