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13. ABSTRACT (Maximum 200 words) Symptoms of estrogen deprivation commonly occur in breast cancer survivors as a result of natural menopause, or menopause that is precipitated prematurely by chemotherapy or anti-estrogen therapy with tamoxifen. In this research program we are evaluating the role of a comprehensive menopausal assessment (CMA) and intervention program for management of menopausal symptoms in breast cancer survivors. During the past funding year we have recruited and trained our research staff, developed the intervention and outcome assessment procedures, and pilot-tested the intervention in 9 subjects. We are about to initiate the randomized trial in which we will assign symptomatic postmenopausal breast cancer survivors to an experimental or usual-care group. The experimental group will receive immediate assessment and intervention for their symptoms while the control group will receive no menopause related intervention during a four month period of observation. Systematic assessment of each breast cancer survivor assigned to the intervention will permit treatment of multiple symptoms simultaneously with a variety of non-estrogen pharmacologic, educational and behavioral interventions. We will be assessing the impact of the intervention on quality of life and the resolution of specific menopausal symptoms.			
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Patricia Gentry 10/17/95
PI - Signature Date

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Introduction

Breast cancer is the leading cause of cancer in women, affecting 1 in 9 women in the US. According to the most recent SEER data, women with breast cancer have a relative 5-year survival rate of over 75%. Earlier detection of breast cancer, as well as improvements in post-operative adjuvant therapies, have enhanced the long term survival for women with this diagnosis. Symptoms of estrogen deprivation commonly occur in breast cancer survivors as a result of natural menopause, or menopause that is precipitated prematurely by chemotherapy or anti-estrogen therapy with tamoxifen. Hormone replacement therapy, the most efficacious treatment for these symptoms, is generally contraindicated in breast cancer survivors because of its potential risk of inducing a recurrence of breast cancer. Thus, many breast cancer survivors endure considerable morbidity and impaired quality of life (QL) as a result. This research program will evaluate the role of a comprehensive menopausal assessment (CMA) and intervention program for management of menopausal symptoms in breast cancer survivors. Using a randomized controlled design, we will assign symptomatic postmenopausal breast cancer survivors to an experimental or usual-care group. The experimental group will receive immediate assessment and intervention for their symptoms while the control group will receive no menopause related intervention during a four month period of observation. Systematic assessment of each breast cancer survivor assigned to the intervention will permit treatment of multiple symptoms simultaneously with a variety of non-hormonal pharmacologic, educational and behavioral interventions. The intervention program will be portable, and suitable for implementation in a variety of health care settings. We will evaluate the impact of the intervention on QL and the resolution of specific menopausal symptoms. QL will be assessed using standardized measures of health status, mood, sexual functioning, and dyadic adjustment. Menopausal symptoms will be monitored using self-report diary cards. Our primary hypothesis is that the intervention program will lead to significant improvement in QL for breast cancer survivors.

Progress report on first year of funding

Although the investigators were prepared to launch this study shortly after receipt of funding, two key staff positions (data manager and nurse practitioner) were not filled until early 1995. This delayed the start-up of the project by 3 months. In addition, after several months of employment, it became clear that the nurse practitioner lacked enough research experience to fulfill the job requirements. Thus a search for another candidate was undertaken, with a new nurse practitioner hired in August of 1995. This individual is performing very well, and we have now recouped some of the time lost earlier in the year.

At this point in time we have developed an operations manual for the project, including all forms, randomization and data tracking procedures. All of the outcome instruments and diary cards have been developed and pilot tested, and procedures for handling of laboratory specimens have been standardized. Thus far, in our pilot work, we have screened by telephone a total of 14 breast cancer survivors, of whom 12 were seen for an in-person screening visit. Of those, 4 are in process of further evaluation, 5 have gone on to receive the CMA and intervention, with 1 breast

cancer survivor completing the entire 4 month intervention program. This subject had severe nocturnal hot flashes that were extremely disruptive. By the time the study was completed, her hot flashes were nearly completely resolved on one of the study medications.

Recruitment of subjects has been informal during this pilot phase. With breast cancer awareness month (October 1995), we have obtained some newspaper coverage of the research, and we are beginning our recruitment through physicians offices and clinics. We anticipate initiation of the randomized trial in the coming weeks. As of this time we have no data or findings to report. We expect that we will have no difficulty recruiting subjects for this study and that over the course of the next three years we will complete the randomized trial as planned.

Conclusions

This past year has been devoted to the hiring and training of research staff, the development of the research procedures and operations manual for the study, as well as pilot-testing of all aspects of the intervention prior to initiation of the randomized trial. Recruitment of subjects for the randomized trial will be the major focus of the next year, with implementation of the full research study in the next few months. There are no data to report from the pilot study at this time.