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Clinical Trials in Cancer Part II

Biomedical, Complementary, and Alternative Medicine: Significant Issues

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Cancer clinical trials are research studies in humans designed to answer specific questions related to cancer. Meticulously conducted cancer clinical trials are the best method to establish safe and effective preventive, diagnostic, treatment, and supportive care interventions (National Cancer Institute [NCI], 2004). Complementary and alternative medicine (CAM) has become a pervasive component in cancer care, and cancer CAM clinical trials are increasing in number and expanding in design. Oncology nurses are in the forefront of clinical supportive care for patients enrolled in clinical trials. They also are involved in designing clinical trials, accrual, monitoring, data management, analysis, and reporting results. A search for conventional biomedical and CAM clinical trials in the United States was performed. Part I of this article (Lee, 2004) offered a synopsis of how to locate active trials and published results. Part II reviews significant aspects of cancer CAM clinical trials such as accrual, ethical and methodologic considerations, use of CAM in symptom management trials, and the role of nursing in cancer CAM.

Accrual

Accrual of eligible patients into conventional biomedical clinical trials offers continual challenges for the research and practice communities. Multiple and varied viewpoints from patients, oncology nurses and physicians, and researchers with proposed plans for improvement (although without extensive success) have been published. Factors influencing enrollment decisions include perceived benefits, risks, and social benefits of participation; practical considerations (e.g., transportation, day care, time, compensation); availability of interventions outside of the trial; desirability of intervention (or placebo) in the control group; and trust in investigators, research institutions, and study sponsors (Halpern, 2002). When considering the complexity of cancer care in general, three possible patient decisions emerge: (1) the decision to use only conventional approaches, (2) the decision to forgo conventional cancer treatment in favor of alternative therapies, and (3) the decision to combine conventional with complementary approaches for treatment and supportive care.

Patients' reasons for forgoing conventional cancer treatment were examined in a qualitative study involving 14 cancer survivors (Shumay, Maskarinec, Kakai, & Gotay, 2001). Stated reasons were to avoid bodily harm, a belief that conventional treatment would not make a difference in disease outcome, and a belief that CAM is an effective and less harmful option than conventional cancer care. Verhoef, Hilsden, and O'Beirne (1999) found similar trends as 31 patients with cancer discussed factors in making a decision to refuse some, most, or all conventional treatment. Having a close friend or relative who died when receiving conventional treatment and personal experiences surrounding diagnosis (need for personal control, treatment side effects, and negative physician response when discussing alternative therapies) were main factors in this group.

Accrual of patients into cancer CAM clinical trials appears promising on the surface but may have an added challenge if the trials involve randomization to a conventional care arm. Likewise, patients who desire only conventional treatment may not be amenable to accrual into a trial involving randomization into a CAM plus conventional therapy arm. Conceivably, cancer CAM clinical trials may experience similar accrual barriers as conventional trials, although reporting of these issues in the literature is limited. Richardson, Post-White, Singletary, and Justice (1998) reviewed factors influencing recruitment and reasons for nonparticipation in cancer CAM clinical trials in 158 women with breast cancer who were invited to participate in a study requiring blood samples to assess immune function, emotional well-being, quality of life, social support, and coping strategies. A possible referral to support or imagery sessions was part of the study design. Predictors of participation in this population were age, marital status, and income. Reasons for nonparticipation were

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