Because the National Institutes of Health (NIH) has mandated the inclusion of women in clinical trials, numerous studies focusing on the health and welfare of women have been conducted. Although many of these studies are exploratory in nature, others are structured clinical trials intended to evaluate potentially therapeutic interventions in areas such as cancer prevention. With an increased focus on cancer prevention, additional clinical trials will be needed. Recruitment of participants will be a key factor in the development of new knowledge and effectiveness of prevention strategies to improve the health of women at risk for cancer.

Consistent with the requirements of NIH, all potential participants in clinical studies must be assured of their rights to self-determination. From a research and clinical perspective, an extensive explanation of the potential risks and benefits of study participation is required. The goal of providing information is to enable individuals to make informed decisions. The scientific and ethical implications of assuring the patient’s right to self-determination have been addressed from the healthcare provider’s perspective (Plank, 1994). Plank described how women make treatment decisions. There is some acceptance that informed decisions are made with consideration of the expertise that the physician and patient bring to the decision (Forrow, Wartman, & Brock, 1988; Neufeld, Degner, & Dick, 1993; Pierce, 1993).

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Purpose/Objectives: To describe the process of decision making by women considering participation in a breast cancer prevention trial (BCPT).

Design: Qualitative.

Setting/Sample: Twenty-six women considering participation in a BCPT in the Northeastern United States.

Methods: Women were interviewed one or two times over a period of one year, with each interview averaging 40 minutes in length. The grounded theory method was used to collect and analyze the data. In-depth interviews were conducted with each participant. Data were analyzed using the constant comparative method.

Main Research Concepts: Context, decision making, meaning.

Findings: The core variable of backing and forthing is a nonlinear complex process of decision making that includes reviewing life, wanting to be sure, chancing and deciding within the contexts of fear, view of self in the world, transgenerational issues, and social support.

Conclusions: The process of decision making for women considering participation in a BCPT is complex. Women tend to make decisions based on what is in their heads and hearts. They often are concerned more about others than they are about themselves.

Implications for Nursing Practice: Trust in the provider and active involvement in the process is critical to women making a decision to participate in a BCPT. Decision making is unique for each woman; however, understanding the context, the core variables, and the process will help healthcare providers to support decision making.

Key Points . . .

➤ Women make decisions to participate in breast cancer prevention trials based on fear, social support, view of self in the world, and transgenerational issues.

➤ Participants found that trusting relationships with their healthcare providers were important in their decision-making processes.

➤ Women use a nonlinear process to make decisions about participating in clinical trials.

➤ The women in the study stressed that the choice to take part in a study ultimately was theirs, even if others were consulted.

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