"I'M GOING TO DIE OF SOMETHING ANYWAY": WOMEN'S PERCEPTIONS OF TAMOXIFEN FOR BREAST CANCER RISK REDUCTION

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Objective: To investigate how ethnically diverse women who are eligible for tamoxifen prophylaxis because of their breast cancer risk decide about tamoxifen use for risk reduction.

Design: A qualitative intervention pilot study used focus groups to discuss the use of tamoxifen and to identify the concerns of ethnically diverse women about the preventive use of this drug. Focus group discussion involved exploration of the benefits and risks of tamoxifen prophylaxis, presentation of a standardized educational intervention, and focused discussion on attitudes about tamoxifen for prevention. Prominent themes emerged from iterative review of focus group transcripts.

Participants: Twenty-seven high risk African-American, White, and Latina women, 61–78 years of age, from the Sacramento area.

Results: Fear of breast cancer was not prominent, and participants were less inclined to take tamoxifen as preventive therapy after receiving information. Decisions were based on participants' understandings of competing risks and benefits. Specifically, participants expressed limited willingness to take medication with potential serious side effects for risk reduction and were unwilling to discontinue hormone replacement therapy. Uneasiness about the reliability of scientific studies surfaced in the focus groups comprised of White and Latina women. African-American women described faith as important to prevention.

Conclusions: Women were wary of taking a drug for a disease they might not develop. Women felt they had options other than tamoxifen to reduce their risk of breast cancer, including early detection, diet, faith, and complementary and alternative therapies. (*Ethn Dis*. 2005;15:365–372)

Key Words: Breast Cancer Prevention, Decision-Making, Ethnicity, Qualitative Research

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INTRODUCTION

Because breast cancer is a leading cause of morbidity and mortality, interest in methods of prevention is high.[1] One method under investigation is chemoprevention with tamoxifen, a selective estrogen receptor modifier.[2] Three recently performed randomized controlled trials (RCTs) evaluated the effectiveness of tamoxifen for prevention of breast cancer in high risk women. High risk was defined as at least the average risk of a 60 year-old White woman: 1.67% in five years. The Breast Cancer Prevention Trial (BCPT), the largest of the three, terminated early in 1998 when interim analysis demonstrated a 49% relative reduction in the incidence of invasive breast cancer.[3] Although two smaller, on-going European trials have not shown comparable effects,[4,5] tamoxifen was subsequently approved by the United States Food and Drug Administration as a preventive agent.[6]

Along with its potential benefits, tamoxifen use is associated with side effects including hot flashes, leg cramps, and vaginal discharge as well as an increased risk of endometrial cancer, deep vein thrombosis, pulmonary embolus, and surgery for cataracts, all of which may differ depending on whether women are pre-or post-menopausal while taking the drug.[7] An additional beneficial effect in the BCPT was a trend toward a decreased risk of osteoporotic fractures.[3]

In this context, tamoxifen prevention is being marketed to physicians and directly to women. Whether this preventive approach is acceptable to the large number of women in the general population who qualify as high risk is not known for certain. A small number of studies have been published about decision-making and the use of tamoxifen for chemoprevention.[21–23] These studies state that women are reluctant to take tamoxifen because they perceive the risks to outweigh the benefits of the drug. However, in these studies, accounts of decision-making about tamoxifen prophylaxis were elicited from groups of healthy women,[23] from high risk women in the context of a clinical trial,[21] or from women following a physician-driven patient information intervention.[22] The primary purpose of the clinical trial study was to examine factors related to consent and trial participation rather than to understand women's decisions related to tamoxifen prophylaxis. Limited detail about the process of decision-making and the role of different types of information has been

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reported on women's decision-making related to tamoxifen prophylaxis. The one study that attempted an educational intervention about tamoxifen for high risk women described the possibility of physician negative bias in the presentation of tamoxifen risks during the informational intervention.[22] In summary, few of the factors important to women's decisions about taking tamoxifen for breast cancer risk reduction and the information that would be most helpful to women making this decision have been described. This paper reports the results of a focus group pilot study of ethnically diverse women's perspectives on tamoxifen as a preventive therapy for breast cancer.

METHODS

The Institutional Review Board at the University of California, Davis, approved the design and administration of this pilot study as part of a larger survey study on women's perceptions of tamoxifen prophylaxis. We conducted three separate focus group interviews with African-American, White, and Latina women.

Study Participants

Women considered for inclusion in our study were >60 years of age and considered likely to be at risk of breast cancer and eligible for tamoxifen prophylaxis. The tamoxifen trial cited the average risk for a 60 year-old White woman to be 1.67% in five years.[2] All of the women selected for participation in our focus groups had to be at least 60 years of age to ensure that they would have been considered likely to reach or exceed a 1.67% risk.[3] We recruited three groups of women (African-American, White, and Latina) with no history of breast cancer but considered at risk for breast cancer according to standards used for the tamoxifen trial. To recruit participants, we relied on connections to researchers and community organizations with ties to the specific ethnic groups of interest to our study.

We recruited women into our pilot study through non-probability quota sampling, seeking to obtain White, African-American, and Latina women of diverse ages >60 years, marital statuses, educations, and incomes. A sub-sample of White women from the observational arm of the Women's Health Initiative (WHI) study at the University of California, Davis Medical Center was informed about our study by a letter from the principal investigator of this project (JM). African-American and Latina women were recruited with the assistance of the Health Education Council (HEC), a non-profit, Sacramento-based community organization with ties to both African-American and Latina groups within the Sacramento community. Members of the HEC are practiced in community outreach and versed in women's health issues and focus group research, including groups regarding tobacco use and legislation. An African-American facilitator from HEC recruited African-American women, and a Latina facilitator from HEC recruited Latina participants.

Focus group participants were recruited from several organizations. Most African-American participants were recruited through churches and the African American Task Force of the BCEDP; Latinas were recruited through the YWCA, local community clinics, and churches; White participants were volunteers from the observational arm of the WHI. Twenty-seven women, who responded to recruitment efforts and agreed to consider taking part in a focus group, met the eligibility criteria for participation. All of the women were invited to participate in one of the three focus groups (White, African-American, and Latina women) based on their race/ethnicity and primary language. The Latina group was conducted in Spanish, and effort was taken to ensure medical terminologies were properly translated. However, the women began speaking only English and expressed a preference for the bilingual moderator to conduct the group in English within approximately 15 minutes of focus group initiation.

Data Collection

The Health Education Council recruited facilitators, scheduled them for training with the multidisciplinary project team, recruited African-American and Latina participants, provided stipends for facilitators and participants, and secured meals for sessions. The council sought focus group facilitators from among women who had facilitation experience and cultural competence relevant to both the research questions of interest and focus group participant demographics. Potential facilitators were interviewed and selected by the council and given an overview of their responsibilities. Group facilitators, matched to the race and language of focus group participants, were trained by primary care physicians (JM, JN), a tamoxifen pharmacologist (MD), and a research nurse to address questions specific to breast cancer prevention therapy and tamoxifen prophylaxis.

An eight-page focus group guide, designed by the multidisciplinary team, was used during training as well as to ensure standardization in group conduct across groups. The guide included focus group questions, follow-up prompts, and a script for the intervention. Facil-

Table 1. Focus group guiding questions

1. How important is prevention of breast cancer to you? How much a worry is the possibility of getting breast cancer to you? (Probe for preventive measures)
2. Has anyone here heard of tamoxifen? If yes, how did you hear about it and what did you hear?
3. What would be important factors that might affect your decision about taking tamoxifen for breast cancer risk reduction?
4. Whose opinions would be important or influence your thinking about whether to take tamoxifen?

Tamoxifen Educational Intervention—Information about Tamoxifen and Side Effects

5. What things might influence your decision to take or choose not to take tamoxifen for breast cancer risk reduction?
6. If you had to decide now, based on what you know now, would you try to take tamoxifen?
7. What things might influence your decision?
8. Of all the things we have just talked about, which would be the most important factor AGAINST your taking tamoxifen?

itators were also instructed to encourage cooperative discussion and the input of every group participant in order to exhaust the potential range of responses participants might give to guiding questions. All focus groups were held in a conference room with an adjacent observation room (separated by one-way mirror). Facilitators of the second and third focus groups had an opportunity to observe sessions prior to moderating their own group. Focus group participants were provided a light dinner at the start of the session and a $30 stipend at the end of the session.

Group facilitators inquired about participants' attitudes toward using tamoxifen for prevention. Questions used to facilitate discussion among group members emphasized women's understandings and previous experiences with breast cancer as well as their general knowledge of tamoxifen. Focus group facilitators explored participants' knowledge of the risks and benefits of tamoxifen as a preventive therapy before discussing these aspects of the therapy. An outline of the guiding questions is presented in Table 1.

Each group began with a brief discussion of women's understandings of and experiences with breast cancer and its treatment, including their knowledge of methods for detection and risk reduction. A 15- to 20-minute educational session outlining the benefits and risks of tamoxifen as preventive therapy for breast cancer followed. The session presented results from the BCPT trial—in the form of absolute risks over 5 years—comparing the tamoxifen and placebo groups. In addition to a verbal presentation, the information was presented on large, color-coded charts and with trays containing similarly colored beads. The trays were designed to contain 1000 clear beads, representing "healthy women" with an appropriate number of colored beads to represent the absolute risk values for a given outcome. The BCPT rates for breast cancer, endometrial cancer, deep vein thrombosis, pulmonary embolism, fractures, and cataract surgery were displayed, and an explanation of each condition was provided in lay terms. Rates of hot flashes, dyspareunia, and vaginal discharge were also displayed and explained by facilitators.

During group discussions, facilitators provided summary feedback to women, ensuring accurate understanding of participants' concerns and justifications related to decision-making. All three groups were audiotape recorded and transcribed for analysis, with verbatim responses and ensuing discussion matched to the voices of focus group participants. At the end of each focus group, participants completed a brief questionnaire to assess the impact of the intervention on their understandings of and perspectives regarding tamoxifen as a risk reduction therapy for breast cancer. The questionnaire included self-assessment of women's likelihood to use tamoxifen as a preventive therapy before and after the educational intervention.

Data Analysis

Pre-/Post-Education Questionnaire Data

Descriptive statistics were used to summarize questionnaire responses. Women's ratings of their inclination toward or against tamoxifen before and after the educational intervention were compared.

Focus Group Interview Data

All focus group transcripts were reviewed by a member of the research team (DP), who listened to the audiotape while reading the transcript for accuracy before analysis of the data. The multidisciplinary team of investigators inductively developed categories that reflected prominent themes related to health beliefs. These themes emerged through an iterative process of transcript review, which began with two of the investigators (DP, SH). All members of the team examined these themes for exhaustiveness and accuracy. Individually, team members noted the patterned occurrence of specific concerns about susceptibility, specific information, barriers, and perceived risk-benefit balance reflected in participants' discussion and feedback during the focus group discussion.

Members of the qualitative analysis team (DP, SH) met on several occasions to discuss the emergent themes and patterns and how they might be categorized. They reviewed both positive and negative examples and discussed each case until there was no disagreement among them in grouping the data. Team consensus was derived through comparative review of data within and across focus groups and by critical discussion of the clinical relevance of themes to patient care and treatment options. Focus groups were not reconvened to garner participants' feedback

Table 2. Demographic characteristics of focus group participants

Race/Ethnicity	*N* (%)	Mean Age, Years (range)	Marital Status	Mean Household Size	Range Education	Income Range
African-American	8 (29.6)	70 (62-78)	Married and Widowed	1.29	11th grade to graduate degree	<$15,000 to $25,000
Latina	8 (29.6)	69 (61–77)	Widowed	1.43	No formal schooling to graduate degree	$35,000 to $50,000
White	11 (40.8)	67 (62–78)	Married and Widowed	1.45	High school to graduate degree	$25,000 to $50,000
Total	27 (100)	68.3 (61–78)	—	1.40	—	—

on the focus group results, but the accuracy of categories was measured by reviewing audiotapes and comparing the qualitative data with women's questionnaire responses regarding the likelihood to use tamoxifen as a preventive therapy before and after the educational intervention. Coding categories were developed through this iterative process of analysis and audiotape review, and all focus group data were then entered into the qualitative software program NUD*IST (QSR International, Melbourne, Australia).[8] Qualitative researchers used the software program to index and retrieve the data and to search across categories for recurring patterns and themes in the data.

RESULTS

Demographic Characteristics of Group Participants

A total of twenty-seven women participated in the three focus group discussions. Their demographic characteristics are summarized in Table 2. More White women agreed to participate in focus groups than African-American or Latina women. Latina women recruited for the focus groups had a higher mean education and income than White or African-American women. Most participants were either married or widowed. African-American participants were older and reported lower income than Whites and Latinas. Differences in demographic characteristics among women other than differences in focus group size were not statistically significant.

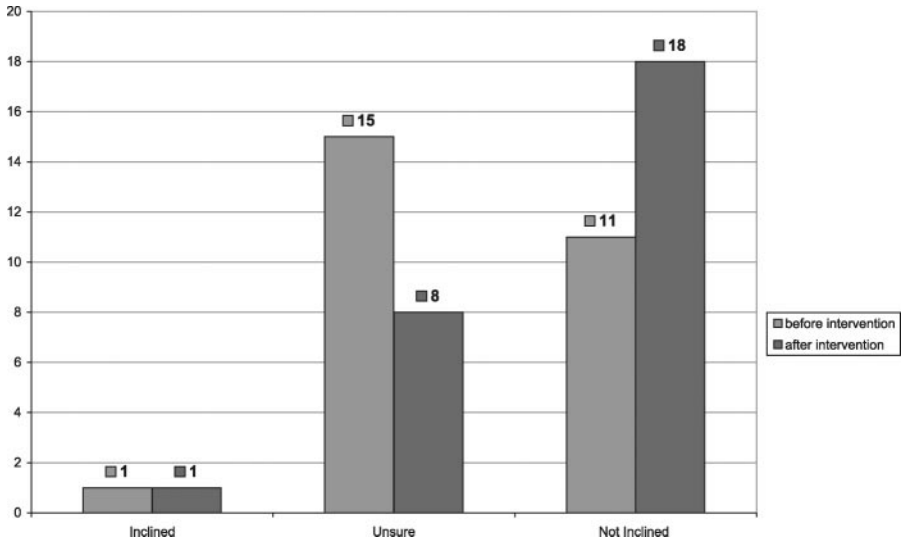

Fig 1. Inclination to take tamoxifen for breast cancer prevention before and after educational intervention

Pre-/Post-Education Questionnaire Results

Figure 1 shows the results from the pre- and post-educational intervention questionnaire for women's inclination to take tamoxifen as a preventive therapy. Overall, women reported that they were "unsure" or "not inclined to take tamoxifen" before the educational intervention. Several women reported that after the intervention they moved from the "unsure" group to being "inclined against tamoxifen." More women in the White and African-American groups changed their opinions about tamoxifen than women in the Latina group. These differences, however, did not reach statistical significance. Factors important to women's decision-making are described in results of the focus group data analysis.

Focus Group Analysis

Themes regarding women's decisions about tamoxifen for breast cancer risk reduction emerged from the focus group discussions in the following content ar-

Table 3. Selected comments on prominent focus group themes

Group	Theme	Comments
All	What comes to mind when you hear the term ''breast cancer?''	''I mean I'm terrified of cancer.''
		''I would be more afraid of metastases.''
		''I have no fear of breast cancer.''
All	Images and assumptions about breast cancer	''Disfigurement.''
All	Perceived susceptibility and risk	''Now I have lots of cancer in my family, but no one with breast cancer.''
		''My sister, she is a year younger than I, and she had breast cancer.''
		''I have had three very close friends who have been diagnosed with breast cancer. One just died. . .so to me, it's become a reality.''
Latina	On the use of tamoxifen for prevention	''I wouldn't take something that would increase my chances of getting something else to prevent something that I know I am not going to get.''
African-American	On the use of tamoxifen for prevention	''I think. . .we need to do more prevention and teaching people. . . We've got to make sure that we take our examinations. Medications, I don't even want to go there.''
African-American	Weighing risks	''I'll tell you another real big problem I have with this is that a blood clot alone will kill you faster than cancer without any warning and that within itself frightens me.''
		''I have enough medical problems already, and it seems to me that it'll be adding more problems to what I already have.''
White	Weighing risks	''My mom had severe osteoporosis so I am and have been on estrogen for many years, so I will continue taking that. For me, tamoxifen is great for people who have terrible fear of breast cancer.''
		''If your family history indicates a greater risk of, for instance osteoporosis, well this tamoxifen is supposed to help there, but particularly heart attacks where estrogen seems to help you with that. Also estrogen helps prevent osteoporosis. That would be one of those balancing factors which might lead you to decide ''yes'' I would take estrogen and say ''no'' to tamoxifen.''
Latina	Expressing doubt	''Wishy-washy doctors who don't want to say yes and I don't want to say no.''
All	Expressing doubt	''The media has promoted various medications to be 'wonder drugs' and they haven't panned out.''
African-American	Alternative modes or modifying factors	''The Lord has taken care of me thus far.''
		''I've always believed God takes care of us.''
All	Alternative modes or modifying factors	''I'm going to die of something anyway.''

eas: 1) perceptions about the meaning and impact of breast cancer; 2) self-perceived risk of breast cancer; 3) belief in the effectiveness of tamoxifen as a preventive agent; 4) comparison of the risk of breast cancer and the risk of tamoxifen; and 5) awareness of alternative modes of reducing breast cancer risk, including self efficacy in prevention and religion. Table 3 presents a summary of selected comments for each of these thematic categories. Women's images of cancer were mitigated by perceptions of their own susceptibility and risk, which included their family history and their own previous illness history, whether or not their own illness history included cancer. Participants from each group reported a close familiarity with breast cancer by way of a friend or a family member, although African-American women reported less prior experience with breast cancer than Latinas and White women participants. Experience with other forms of cancer affected women's concern of breast cancer as well as their concern of the potential, serious side effects of tamoxifen.

Independent of their perceived susceptibility, each group discussed the importance of monitoring for breast cancer through either self-exams or mammograms. Every group reported the importance of self-efficacy: eating right and exercising, positive thinking, doing one's own research, and being one's own advocate. The latter themes were especially prominent in the focus group with Latina women.

All women were wary of taking a drug for a disease they might not ever develop. This suspicion was clearly articulated in the African-American and Latina focus groups. In general, participants stated that they would be willing to put up with the risk of side effects, if they perceived their baseline breast cancer risk to be high. For example, one woman from the White focus group reasoned, "if your family history indicates a greater risk . . . that would be one of those balancing factors that might lead you to decide 'yes.'" Others reported they would consider tamoxifen only for treatment of breast cancer, rather than as a preventive measure. Participants repeatedly voiced concerns about the side effects of tamoxifen. In general, women viewed life-threatening but rare side effects, such as blood clots, more seriously than other potential side effects. Health effects they were already experiencing, such as hot flashes or cataracts, seemed

less relevant to all women interviewed than those side effects of which they had no previous or current experience.

Each group member attempted to customize her risk of side effects by considering her current health condition, her past health, and her family history. In general, White participants seemed to focus on customizing their risks more than Latinas and African Americans when discussing their perspectives on tamoxifen as a preventive therapy. As some women perceived themselves to be at increased risk for breast cancer, they believed their risk for possible side effects would be enhanced as well. Participants in each group discussed different options to tamoxifen that they felt did not have the side effects of this drug. Some of these options were outside of traditional medical interventions, for example, using herbs, positive thinking, and taking calcium. In particular, African-American and Latina women were more likely to emphasize these options and eliminate unnecessary side effects in framing their perspectives of tamoxifen prophylaxis.

Older participants and African-American women explained the impact of their age and beliefs on their decisions about tamoxifen. Participants in each group believed there to be an age when taking "risky" preventive measures is not productive. Women also articulated different expectations of health and susceptibility for increasing age, reporting that as they got closer to 70 or 80 years of age, they should have lower expectations of their health. Comments on the inevitability of aging and death were most prominent in the African-American group. A few of the African-American participants expressed faith in a larger plan rather than medication for prevention, stating, for example, "The Lord has taken care of me thus far . . ." and "I've always believed that God takes care of us."

Views regarding doctors' recommendations and tamoxifen use were varied. One participant in the Latina focus group was concerned about doctors who are unwilling to take a definitive stand regarding the risks and benefits of tamoxifen prophylaxis. An African-American woman pointed out that the African-American community tends not to trust doctors, while another woman from the same group was vocal about the need to "weigh the physician's opinion heavily." Not having that opinion, the women argued, could present problems with their own abilities to make informed decisions about the drug. Within each of the groups, some participants raised doubts about scientific studies and promotion of treatments by the media.

DISCUSSION

Our pilot study examined how diverse, risk-eligible women consider risks and benefits of tamoxifen prophylaxis. We found that education about tamoxifen decreased inclination to take tamoxifen for breast cancer prevention among the focus group participants. This finding may be due, in part, to the fact that the fear of breast cancer was not prominent among the women in our focus groups despite large BCPT trials that have identified these women as high risk. African-American participants, in particular, believed that as they grew older, they did not need to consider a preventive drug with potential side effects. Others have found that perceived threat of disease or threat of treatment effects, such as specific side effects or risks of surgery, for example, can affect individual decisions about preventive care.[9] In our study, women reported limited willingness to take medication with serious side effects for breast cancer risk reduction because they felt they had other options to reduce risk-related side effects in prevention, such as diet, exercise, and regular screenings.

The majority of women in our focus groups explained that their decisions about tamoxifen as a preventive measure were related to the extent that they perceived breast cancer to be a threat. Decisions were based on balancing one risk, such as getting breast cancer, against another risk, having blood clots, and then on balancing a perceived benefit, such as potential protective effects of tamoxifen, against the current benefits of estrogen therapy or other self-preventive measures. Rather than comparing the risks to the benefits of tamoxifen prophylaxis, women in our focus groups reported weighing the potentially negative outcomes against one another and then did the same for the positive outcomes.

Various factors, including age, call into question the ability of patients to estimate their own risk of disease and to articulate preferences based on their perceived risk.[10,11] Most individuals make choices based on available information when deciding whether or not to engage in behavior.[12,13] In a recent commentary, Katz noted that patients' preferences may be based on inaccurate assumptions about the risks and benefits of medical interventions.[10] This study suggests that individuals consider wide range of available information and do not simply accept numerical risks and benefits. Furthermore, beliefs about medical intervention significantly affect willingness to adopt preventive measures and to use healthcare services.[9,14–15]

In the past decade, African Americans were less likely to receive some sorts of preventive care than Whites.[16] Phillips et al[17] and Hubbell et al[18] showed in separate studies that perceptions of non-White women about cancer and cancer screening reflected frameworks for interpreting disease based not only on individual preferences and culture but also on historical context.[19] Understanding variation in how individuals compare and frame risks and benefits associated with preventive interventions will assist in explaining differences in patients' perceptions and plans for action. Our findings indicate that despite an extensive presentation of the evi-

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Findings from our pilot study are preliminary and limited by the nature of recruitment for the focus groups, the lack of member checks, and by the relatively small number of participants. Although the individual risk for each focus group participant was not estimated, and some of the women who participated in our pilot study may have been below the threshold necessary for participation in the tamoxifen trial, all participants were selected based on their age of 60 years or older, which has been estimated to put White women at a 1.67% greater risk of developing breast cancer in the next five years.[3] All participants in our study were predominantly English-speaking; most had a high school education, and many had some college education. Women with less education and fluency with English may experience barriers to understanding or limits in access to care that might change their interpretations regarding tamoxifen prophylaxis and preventive strategies in general as well as their needs and desires for information. African-American women who participated in our focus groups were not only slightly older and had lower mean incomes but were potentially a more religious group, having been recruited primarily from church communities, than the White and Latina women recruited for the study. This finding suggests that age and religion could be more influential factors in these women's attitudes than those expressed by Latina and White women in our study.[20] Although educational differences were not significant, differences in income could result in dramatic differences in both knowledge base and access to resources that may assist women in understanding factors relevant to risk calculation and, most importantly, in their articulation of preferences.[10]

Both African-American and Latina groups had eight participants; 11 participants were in the White focus group. Though variation in group size may lend itself to different group dynamics from small discussion groups and decreased opportunity for participation, focus group leaders were instructed to ensure the participation of every group member and to explore and exhaust the range of responses to guiding questions. Further, focus group transcripts provide evidence of individual participation in each group. Although the findings presented represent a small number of participants, consistency in findings across the three groups of women recruited from different sources and of different race/ethnicity, and the correlation of these findings with related literature in patient decision-making and self-efficacy in prevention strategies, strongly suggests that the themes discussed here are likely to resonate with many women confronted with making a decision about tamoxifen for breast cancer prevention. At minimum, these findings suggest hypotheses for further research. Whether our findings can be generalized to women eligible to take tamoxifen or other pharmaceuticals for cancer prophylaxis will require validation in larger studies with more socioeconomically and educationally diverse women.

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