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Gaining control over breast cancer risk: Transforming vulnerability, uncertainty, and the future through clinical trial participation – a qualitative study

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Abstract

Concepts of disease risk and its management are central to processes of medicalisation and pharmaceuticalisation. Through a narrative perspective, this paper aims to understand how such macro-level developments may (or may not) be experienced individually, and how an algorithm that is used for recruitment into a clinical trial may structure individual notions of being ‘at risk’ and ‘in need of treatment’. We interviewed thirty-one women participating in the Study of Tamoxifen and Raloxifene (STAR), a chemoprevention trial conducted in the US between 1999 and 2006. Interviews were thematically analysed. Women in the study had experienced the threat of breast cancer and felt vulnerable to developing the disease prior to STAR participation. The diagnosis of ‘being at risk’ for cancer through an algorithm that determined risk-eligibility for STAR, opened up the possibility for the women to heal. The trial became a means to recognise and collectivise the women's experiences of vulnerability. Through medication intake, being cared for by study coordinators, and the sense of community with other STAR participants, trial participation worked to transform women's lives. Such transformative experiences may nevertheless have been temporary, enduring only as long as the close links to the medical institution through trial participation lasted.

Keywords

Breast Cancer; Randomised controlled trials (RCT); Narrative method

In the 1980s, Ulrich Beck coined the term ‘risk society’ to integrate the rise of manmade environmental hazards into sociological theory (Beck 1986). He argued that in the shift to become advanced modern societies, traditions and taken-for-granted realities were being overthrown and supplanted by increasing individualisation and choice. Social structures were becoming determined by social risk positions, referring to the ability of individuals to gain knowledge on – and thus avert – (environmental) risks. Since Beck's analysis, risk has

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become a central object of sociological research, in part due to the explosion of risk management practices across a range of organisational contexts (Lidskog and Sundqvist 2012). Skolbekken (1998) diagnosed a ‘risk epidemic’ in medicine in the late 1990s (Skolbekken 1995), partly driven by the increasing number of physical (and mental) conditions that were formerly not considered medical issues and/or in need of treatment. The increase in medical diagnoses of social deviance and the role of medicine in managing society have long been studied under the concept of ‘medicalisation’ (Conrad 2007, Bell and Figert 2012). Dumit (2012) argues that through the marketing strategies of the pharmaceutical industry, notions of health and illness have changed in everyday life. He suggests that these marketing strategies aim at and have succeeded in establishing a continuum of risk states, in which we all become in need of treatment. Greene (2007) highlights the joint emergence of the pharmaceutical industry's expansion of its markets and the shifting understanding of disease categories as statistically based. Treatment categories thus became increasingly defined by probabilistic information, which included the likelihood of developing bodily manifested diseases; high blood pressure, for instance, became a disease in its own right that required treatment.

The drive of medicalisation, initially steered by physicians and physicians’ organisations, has thus expanded significantly with the pharmaceutical industry as a major player. Such expansions have been studied under the auspices of ‘biomedicalisation’ (Clarke et al. 2003) and ‘pharmaceuticalisation’ (Abraham 2010). Researchers studying biomedicalisation are particularly interested in how medical provision changes through the influence of the pharmaceutical industry, which includes the standardisation and reorganisation of medical provision around research needs, particularly clinical trials, which has led to a problematic blurring of research and health care provision (Fisher 2009).

Linkages between the development of drugs and disease categories, which Greene (2007) alludes to, can be seen in the medical condition ‘breast cancer risk’ and the corresponding search to reduce it. However, it is a history in which not only the pharmaceutical industry is a driving force, rather it is one in which strong medical and societal forces worked together in key campaigns for greater public awareness and ever earlier detection of the disease (Aronowitz 2007, Lerner 2001). In the 1970s the introduction of mammography marked a key breakthrough in the shifting notions of disease, successfully urging women to test themselves for cancer. Mammography screening has been extremely effective in changing the face of breast cancer and women's experiences of it, leading not only to earlier diagnosis of the disease, but also bringing to the surface many breast tissue ‘states’ that are not cancer but do increase the risk of developing it. Many women diagnosed with such conditions have very similar experiences to women diagnosed with actual breast cancer (Aronowitz 2009).

The history of breast cancer risk can be understood as part of the appropriation history by the pharmaceutical industry of activities by the breast cancer movement. In particular, the cooptation of the signs and activities of the breast cancer movement through pharmaceutical influence such as the ‘pink ribbon movement’ and the pharmaceutically-oriented approaches to risk reduction have come under sociological investigation (King 2006, Klawiter 2002). For example, Fosket (2004) has shown how the use of an algorithm to determine a woman's five year risk of developing breast cancer (Gail score) became a tool to diagnose the

condition of breast cancer risk in relation to offering medications to treat the condition (Fosket 2004). As Fosket (2004) argues such a diagnosis of women “at-risk” through an algorithm and the associated pharmaceutical approaches to prevention neglect environmental factors that influence disease development. A critique also voiced by social scientists analysing the experience of breast cancer (Eisenstein 2001, Jain 2013).

In contrast to the epidemiological risk concept of an algorithm, as the percentage chance that an individual or group has of developing a particular disease, in everyday language risk signifies something more direct, such as danger, or more subjective, such as feelings of susceptibility to harm (Samerski 2002). For the purpose of this paper, we prefer the term vulnerable over risk to explain women's narrative experiences, as it better explicates how culture shapes subjective feelings (Nichter 2003) – such as the feeling of being at risk for breast cancer – and guides possible protection strategies (Jutel and Nettleton 2011). Through a narrative perspective, this paper aims to understand how discursive strategies and macro-level developments such as biomedicalisation or pharmaceuticalisation may (or may not) be experienced individually, and how an algorithm that is used for recruitment into a clinical trial may structure individual notions of being ‘at risk’ and ‘in need of treatment’. We focus on the workings of the clinical trial structure on research subjects. We argue that participants in a breast cancer prevention clinical trial in the US experienced healing and transformation through participation, due to several factors inherent to the particular research process and context, as well as the high regard in which clinical trials within US medicine and culture are held.

The breast cancer chemoprevention clinical trial on which this analysis is focused, named the Study of Tamoxifen and Raloxifene (STAR), was conducted in the US from the late 1990s to the mid-2000s (Vogel et al. 2002). Prevention trials for breast cancer such as STAR, or its predecessor in the US the Breast Cancer Prevention Trial (BCPT) (Fisher et al. 1998) and the Intervention Breast Cancer Trials in Europe (Cuzick et al. 2014, Cuzick et al. 2002), began in the 1980s. STAR was designed to compare the effectiveness and side-effects of two medications, Tamoxifen and Raloxifene, for their potential to reduce the risk of breast cancer in ‘high risk’ women (Vogel et al. 2006). The variables used in the study to calculate high risk were based on the adjusted ‘Gail score’ and included current age, age at menarche, age at first live birth, number of breast biopsies, and number of first-degree female relatives with breast cancer (Gail and Costantino 2001). Risk eligibility for participation in the STAR trial was determined by a minimum breast cancer risk equivalent to that of a 60-year-old woman, which amounted to a Gail score of 1.6 per cent over five years (Fosket 2004). STAR had a sample size of 19,747 women, who were recruited via approximately 200 clinical centres throughout the US and Canada. These centres screened 184,460 women, of which 96,368 were deemed risk eligible for participation; approximately 20% of these women had further interest in participating in STAR (Vogel et al. 2006).

Methods

Research setting

We conducted an interview study with 40 women who had been asked to participate in STAR. Of those 40 women, 20 had declined. The aim of our interview study was to learn

about the factors that influence decision-making about participation in prevention trials and to understand what being diagnosed by an algorithm, the Gail score, and being at risk for breast cancer means for women.

Participants

The data discussed in this paper focus on the narratives of STAR participants (N=20) from two clinical centres and members of the Participant Advisory Board (PAB) of the trial from across the US (N=11) (Psillidis et al. 1997). The STAR study sites from which the interview participants were chosen were selected based on their role in the clinical trial. The clinical staff at one site, located in the north-eastern US, was involved in the overall organisation of the trial, while the second site, in the southern part of the US, was chosen in the interest of sample diversity, as it was one of the STAR recruitment sites that intentionally focused on African-American women (McCaskill-Stevens et al. 2013).

Both sites were university-based cancer centres, but only the north-eastern site had a regular 'risk clinic' to counsel and treat women considered at risk for cancer. Largely from their existing patient pool, the north-eastern site contacted 220 risk eligible women, of which 39 decided to participate in STAR. From these 39 women, the STAR study coordinator selected interviewees for this qualitative study based on their availability and the interviewer's (CH) schedule (N=15). All STAR participants at the southern site were approached by the study coordinator and included (N=5). The majority of STAR participants from both sites had been participating for four to five years at the time of the interview (Table 1).

Finally, eleven PAB members were interviewed because of their role as 'participant representatives' within the trial. Since they were public figures for STAR, to preserve their anonymity we do not disclose any socio-demographic information. The members of the PAB were regular STAR participants, in that they had entered the trial in similar ways to other participants. However, they had been identified and invited by their study coordinators to serve as advisors to the national clinical trial management and organisation team. From a pool of invited candidates, the National Surgical Adjuvant Breast and Bowel Project (NSABP), the organisation that conducted the trial, selected a board of eighteen women who reflected the social diversity of trial participants in terms of ethnicity and geographic area. For the most part, the advisory role involved communicating between trial organisers and participants. For example, the advisory board was consulted regarding how best to inform participants about the approaching end of recruitment of new participants, and they were integrated into discussions on how to communicate to STAR participants about which drug they had been taking during their active participation. In addition to aiding trial organisers' communications with STAR participants, women of the PAB helped to publicise the trial through public speaking engagements, conducting interviews with the press, and helping with recruitment activities. PAB members maintained a dual role of being public ambassadors for the trial, as well as representing the 'voice' of participants to trial organisers. We chose eleven of the PAB members based on their availability for telephone interviews.

The socio-demographic characteristics and risk profile information of interviewees are displayed in Table 2.

Data collection and analysis

All in-depth interviews were conducted one-on-one at the study sites by CH. Most of the interviews lasted for about an hour, with one exception that lasted two hours. All interviews began in the same way: interviewees were asked to talk about the risk assessment they had completed to test their eligibility for STAR. The first part of the interviews followed a narrative model and was conversational in style (Honer 1993), structured by the themes that the interviewees brought into the conversation. In addition, the researchers had developed a list of themes with specific topics of interest. If these themes were not introduced by the interviewee herself, CH addressed them at the end of the narrative portion of the interview. The list included questions such as how the interviewee had learned about STAR, their assumptions regarding their own breast cancer risk, why they had completed the breast cancer risk assessment, whether the results influenced their perceptions of risk or their behaviour, and whether they had discussed their decision to participate in STAR with anyone else.

The interviews were transcribed verbatim and entered into MAXQDA for data management. As a first step, all materials were coded thematically into large segments; then a detailed analysis of the codings was conducted. All segments pertaining to clinical trials were read by CH and KW and analytically coded by KW. After completion of coding, the first two authors discussed all coded segments. Codes, emerging themes, and concepts were discussed within the research team. The interviews with PAB members and regular STAR participants at the two clinical centres did not differ with regards to the meanings they ascribed to their STAR participation; we have therefore included the PAB interviews for analysis in this paper. All analytical steps were presented to and discussed within an expert group of qualitative researchers at the Charité Universitätsmedizin Berlin.

Results

Breast cancer in women's lifeworlds

All of the women in this study bar one had felt vulnerable to developing breast cancer before they were approached about STAR, experiencing it as a danger to their health. Some of the interviewed women had a longstanding relationship with breast cancer, which included being under long-term, regular medical surveillance ‘to control’ their breasts. In their narratives, they explained factors that increased their sense of vulnerability, such as undergoing breast biopsies, having a family history of breast cancer, or a physician's suggestion that they consider an elective mastectomy.

> I think what was at the back of my mind when I first looked into [STAR] is not knowing with the lumps whether there would be anything there. (...) the gynaecologist(...) and my family doctor wanted me to have the breast taken off and have implants put in. (...) They emphasised that they didn’t feel comfortable with lumps that I had. (P25, age 56, white)

> You know, I knew I was very high risk because of the family thing, but never until I was diagnosed [with atypical hyperplasia, an accumulation of abnormal cells in

> the breast] and until I had that mammogram and,(...) all hell broke loose and the diagnosis was given. I really didn't go out and look for anything. (PAB1)

Others began their stories with memorials of all those before them who had been diagnosed with – and had sometimes died from – the disease.

> In my family, on my mother's side, my mother's mother passed away with breast cancer at age 56. My mother was one of five children. My mother's older sister passed away of breast cancer at age 62. My mother's brother passed away from cancer at age, I'd say about, close to 70. My mother came next (...) She had two mastectomies and she had ovarian cancer and she passed away before she reached her 51st birthday. (...) My mother's youngest sister passed away of breast cancer at age 29. So, it sort of runs in the family. (P18, age 51, white)

Understanding disease as genetic reshaped familial relationships in the US (Finkler 2000). A mother's breast cancer was no longer only a concern for the mother's well-being but directly influenced her daughter's health status as well, shifting the latter's categorisation from healthy to being at risk for developing breast cancer. Once a family history of breast cancer was medically accepted as increasing a woman's risk of developing the disease, the possibility was opened up for 'pre-cancerous' women to become institutionally accepted as patients and undergo close medical surveillance (Scott et al. 2005). Some cancer centres, for instance, such as the north-eastern study site, offer programs in which such women can come for regular yearly visits and mammograms. Some of the STAR interviewees had been part of such clinical programs. Thus, breast cancer was part of the interviewees' lifeworlds.

Breast cancer master narratives

Many of the STAR participants presented stories of their own and their family members' breast cancer experiences, embedding these experiences within master narratives of science and progress, and juxtaposing the conditions of past and present.

> I mean, my parents never went to the doctor's for anything and I think if she could have been on tamoxifen or this study, (...), if they knew what they know now(...) I think she'd still be alive, (...). (P 21, age 44, white)

> But now we have more knowledge and that helps survive. (P 18, age 51, white)

Women explained that at the time of their family members' experiences with – and in some cases death due to – the disease, medical practice had been insufficiently developed to treat them appropriately or no institutional setting had been available to offer good cancer care equivalent to what is provided today. Others described how they had lived with relatives who did not openly discuss their affliction or the debilitating effects it had on them.

> (...) [Her breast cancer] wasn't the primary focus at the time even though my mother was very ill with it. But you know, she was kind of a private person. She didn't really talk about it and she never let me see her scar. I never saw her scar until the day she died, (...). She just wouldn't show it to me, (...) (P 31, age 62, white)

At least one woman had experienced the changes in the medical handling of breast cancer and its associated uncertainties herself. She had had five breast biopsies over the years, the first of which were conducted during the time of the so-called ‘one-step procedure’, which meant that she had had to sign a form prior to the biopsy agreeing to a mastectomy in case breast cancer was found. A practice, she experienced as frightening and worrisome.

The interviewees’ narratives echo the master narratives of silence and isolation that surrounded breast cancer in the past, which is contrasted with openness and proactiveness in the present. It is this master narrative that was a major focus of the breast cancer movement. For the interviewees, STAR embodied several societal values within which scientific knowledge production is embedded – such as helping others, conquering fate, and the importance of objective knowledge – which formed part of a master narrative of scientific progress that prioritised the values of proactivity and defiance over fatalism and acceptance. STAR therefore also formed part of the ‘hope discourse’ observable in North American oncology (DelVecchio Good 2001, DelVecchio Good et al. 1990). It was within the context of these master narratives, as well as the women's life histories and the resulting individual experiences and perceptions, that STAR participation became a transformative experience.

Being in STAR

The experiences of interviewees prior to STAR participation had left them in a liminal state, feeling “betwixt and between” (Turner 1998). Against the background of contemporary understandings of breast cancer, its occurrence, and treatment options, the interviewed women, when reflecting on their reasons to participate in STAR, told stories of loss, of the fear of getting breast cancer in the future, and about the shock of diagnosis. STAR and the activities that the women had to perform as participants provided them with a new structure, re-embedding them within society (Turner 1995). Being in STAR meant taking two pills every day for five years. In addition, women had to undergo more detailed diagnostics, including a mammography once a year and a clinical breast exam every six months. Whenever their medication kits were empty, they had to return to the clinic to receive a new batch. This was usually timed to coincide with a follow-up visit including exams.

STAR became a viable and important option for these women to help them manage their lives at risk. But more than that, STAR participation – which involved actively taking medicines, being cared for by the study coordinators, and the new sense of community that arose in meetings with other STAR participants – was also a means to transform their suffering into a meaningful experience.

Actively taking medicine—The daily intake of trial medication had a significant impact on the women on several levels, both physically and emotionally. Physically, some experienced hot flashes and two interviewees mentioned changes in their breasts, both of which were attributed to the medication.

> Since I’ve been on STAR in the past five years there's been no more calcifications ...no fibroadenomas. (P4, age 53, African-American)

Emotionally, taking the medicine gave women a sense of security and of being in control.

> I'm taking a step. (...) by taking the pills and following it along I feel like, I'm more in control than if I were just standing back waiting and living in fear or wondering if I would develop (...) This way, I feel like I'm taking steps to prevent it. (P26, age 48, white)

As Whyte et al (2002) had suggested people take medicines because they are perceived to contain the power to transform physical or emotional states. People take medicines to control a situation and manage their lives. For the interviewed STAR participants, the medicines were used to manage their emotions in relation to their experiences of being vulnerable to breast cancer. Medicines can also change situations and modes of understanding. In this sense, STAR participation offered women the possibility to reshape their narratives, from feeling vulnerable to a frightening disease to taking control of their situation and fate.

The women described how important taking the pills was to them and how devoted they were to doing it correctly, with some interviewees invoking religious comparisons to illustrate their diligence. Almost all women stressed that they never forgot to take their pills and described how they had integrated the activity into their daily routine.

> (...) you knew you took that pill every morning and I was very diligent and religious with my pills. (...) I keep my pills in those little pill things for the day, and when one is empty it's like you lost a friend or something. (...) It was really weird when I didn't take any. (P10, age 56, white)

Many of the STAR participants differentiated between their very accurate adherence to STAR medication and a more casual or sometimes strong unwillingness to take other medications.

> I was religious about taking the pills; I'm not so good about taking my vitamins. (P23, age 56, white)

When reflecting on this, all agreed that they only took medicines that they deemed necessary. Their strong adherence to the trial medicines thus illustrates the high value they attributed to them, and the seriousness with which they took their participation.

Medicines can also be seen as agents that (re-)create social relations (Whyte et al. 2002). Because the STAR medication – as trial medicine – was an agent in a larger narrative of combating breast cancer, some women ritualised their medication intake as a way of recreating bonds to those they had lost to breast cancer.

> Every time I take it, first of all I say a prayer for my mother, and I just feel like I'm physically doing something and it makes me feel better. (P21, age 44, white)

But the medicine did not only (re-)create bonds with past (and future) kin. It also established very concretely a relationship with the medical institution and opened up the possibility of generally better health care.

The caring role of the medical institution and study coordinator—The effect that women felt more in control over the development of their bodies was influenced by – but was not only due to – the medication intake, since the women were aware that the

medication may reduce their risk, but could not eliminate it altogether. The feelings of security and empowerment that the women voiced and their sense of changing their fate were also related to trial participation overall. This included the follow-up care they received and the close relationship to the study coordinator and the clinical centre that the women experienced through trial participation.

It was the role of the study coordinator to remind the women of the trial requirements and ensure their collaboration. Study coordinators in clinical trial research bridge the gap between research and care for patients (Fisher 2006). On the one hand, STAR participants, through trial participation, felt active about challenging their fears about breast cancer. On the other hand, they shifted the responsibility for their health onto the study coordinator.

> Someone is watching over you, someone takes care of you and makes sure you are taking all of your appointments. (P33, age 53, white)

At both institutions, the study coordinators felt very indebted to their participants and provided a resource for other (unrelated) medical information and access to health care when their STAR participants or their families had problems.

> If I had any other problems with other things during that time (...) I needed a colonoscopy, the study coordinator had me come to the centre for the colonoscopy. I felt that I was taken care of. (P33, age 53, white)

A new sense of community—The women also received regular medical information through a STAR newsletter, in which they learned more about the trial and breast cancer research in general. At the north-eastern centre, staff organised a trip to the annual meeting of the National Breast Cancer Coalition for their STAR participants. In the women's narratives, these outings were portrayed as one of the events that brought STAR participants together as a group and strengthened their bond with the breast cancer movement more generally. The clinical trial, with the help of such events, became a means for women to deal with their life stories by bringing them together and encouraging a sense of community.

> The very first gathering that I went to at the clinic of the STAR participants and there weren’t many, maybe five or six, we all sat there and chatted, that's when I felt comfortable. (...) I mean, I was myself again, you know? I had questions and it was a good feeling. (...) being on the Board [the PAB] made all the difference in the world. I mean, that was absolutely the best, because then I really felt that I was doing something for womankind (...) for mankind, because we’re doing it for them [men], too. (PAB2)

Transformation through participation

For almost all interviewees, STAR participation represented a positive transformation in their experience with being at risk for breast cancer. For one thing, participation was about taking an active stance to challenge fate – both their own and that of future women. They hoped that others, including their kin, would not have to experience the many negative aspects accompanying the disease. The women discussed trial participation as a benefit to society as a whole and viewed it as part of a larger societal effort to ‘eradicate’ breast

cancer. The women's lives became significant by situating the clinical trial in the grand modern narrative of science and progress, and their lives became part of a historical line that pointed towards a hopeful future. Trial participation was thus a means to create solidarity with kin, both real and imagined.

> I have two granddaughters and they live with me and I'm very close with them and they're young, and I would love to see a cure for it in their lifetime. (P26, age 48, white)

> We really need to be more proactive to what is happening and that this is an opportunity for me to do something for myself, which may save another woman tomorrow. (P11, age 56, white)

Trial participation was not only an activity directed towards the future, it also hailed to the past by remembering those who had suffered and died from breast cancer, presenting a culturally appropriate way to honour them.

> Partly by doing this, I'm honouring her, saying, 'Mommy, you know, maybe the medical community didn't take as good of care of you as they should have and maybe you should have taken better care of yourself', but this is almost a little bit of a way for me to take care of her; to at least not let any of that have been in vain. (P27, age 48, white)

The structure of knowledge production within the STAR trial shaped and transformed women's lives and provided them with a set of practices with which to handle their vulnerability to and suffering from breast cancer risk.

The transformation that these women underwent was, however, a fragile one. For the duration of trial participation, women experienced a sense of security from the combined effect of taking medicine, having close access to a medical centre and the devoted care of the study coordinator, and a sense of community with other women (past, present, and future). This sense of security was found to be threatened in the narratives of interviewees approaching the end of their five years of active trial participation and medication intake.

The end of medication intake

The end of women's daily, sometimes ritualised, medication intake after five years marked the end of active trial participation. In many cases, this presented a further transition of status that could mark another liminal phase for the women, and thus carried the risk of a resurfacing of anxiety about breast cancer.

> When it's all over, (...) it will be a little bit of an adjustment (...) you feel like you lose the protection of the medication. (P24, age 60, white)

> I've been on it for so long, (...) I would say your security blanket is just ripped away. (P10, age 56, white)

This transition was also critical for study staff and trial management. They had to impress upon participants the necessity of continuing follow-up visits, even though they were no longer taking the medication. Trial organisers ideally wanted participants in follow-up for as long as possible (or as long as there was funding), in order to adequately assess the effects of

the medication on their bodies. Study staff thus marked and acknowledged this transition through the distribution of gifts to those who had finished ‘their five years’.

> And at the end of that study the study coordinator gave me a little key chain that said STAR on it and it's my key chain and I’m really proud of that key chain. (...) [It] really meant a lot to me. (P1, age 52, white)

Regardless of trial staff's emphasis on women's ongoing ‘participation’ at the end of the five years, however, for most participants the medication intake was the most salient part of the trial, and with its end they felt that the trial was over.

Discussion

Petryna (2007) defines clinical trials as social institutions, as they structure and organise people's behaviour within – and thus maintain and enforce – a given set of societal norms and values. By analysing the meaning research subjects invest their clinical trial participation with and the activities that the participation involves, one can learn about the types of values that are reinforced through clinical research. The activities of STAR participants functioned to create a community, which countered the troubling experience of receiving a diagnosis of breast cancer risk; furthermore, it provided a tool with which to deal with the vulnerability of developing breast cancer in a socially accepted manner, allowing the women to gain agency. STAR participants were empowered by the possibility of being active and doing something, as much as by the possibility of giving over the responsibility (to detect disease) to the medical institution.

To make STAR possible, breast cancer risk had to be understood as a treatable and diagnosable condition. It required a group of women who felt vulnerable to developing breast cancer and for whom no treatment was available. The transformation of the vulnerability into a risk diagnosis enabled trial participation. Thus the stories of the interviewees can be read as part of the shifting definition of what it means to be healthy or sick (Dumit 2012), and are illustrative of the ever increasing tendency towards (bio-)medicalization (Conrad 2007, Clarke et al. 2003) and the individualisation of the aetiology of breast cancer, instead of focusing on societal approaches to prevention (Klawiter 2002). Another critique of such risk reducing prevention approaches refers to the appropriation of the language of the breast cancer activist movement the pharmaceutical industry (Dumit 2012) in marketing tamoxifen as a risk treatment for breast cancer.

However, the women we interviewed, in addition to being active participants and creators in the study (Morris and Balmer 2006; Scott et al. 2011), were also structured and guided to behave in specific ways that helped them to gain control: taking medication twice a day for five years, attending regular medical screenings and follow-up care, participating in social events, etc. They became biological citizens and part of a biosocial community (Gibbon and Novas 2008, Rabinow 1992), through which their concerns and sufferings were collectivised. Their lives were transformed from stories of worry and sorrow into narratives of combat, strength, and proactivity. The women had become members of the fight against breast cancer, and the trial organisers were instrumental in giving them social recognition for this role. The norms and values that the trial perpetuated, combined with the high public

visibility of breast cancer and breast cancer activism, worked to make STAR participation a means to transform participants' lives. All of the above-described activities, combined with the important role of clinical research within Western societies, enabled a transformation of the women's experienced vulnerability into solidarity and community. Clinical trial participation put the individual women's histories into a grand narrative and made them meaningful by giving sense to their suffering and portraying a better future.

Such transformative experiences of security may, however, be only temporary, as some of the narratives suggest. Breast cancer risk is a diagnosis that is probabilistic based on population data, and is valued between zero and 100 per cent. An individual, on the other hand, has a binary outcome of either getting breast cancer or not. As such, a diagnosis of breast cancer risk is highly uncertain and its treatment similarly so. Thus while the diagnosis of breast cancer risk gave the interviewed women access to a health care provider (Jutel and Nettleton 2011; Scott et al. 2005), and STAR gave them a community and sense of meaning for their diagnosis, the end of trial participation and thus of treatment could not offer them hope of a certain 'cure'. Indeed, some women even felt their sense of security directly tied to "the protection of the medication", without which at the end of the trial they found themselves in the same position as before.

Critical sociology and anthropology has scrutinised the ways in which clinical trials generate knowledge (Abraham 2007) and the types of knowledge they produce (Wahlberg 2007). Such scholars have also focused on the local consequences of national regulatory policies on the conduct of clinical trials, such as the National Institutes of Health Revitalization Act (Joseph and Dohan 2012), or the societal effects arising from policies that regulate whom is studied (Epstein 2007). Others have focused on the role of STAR and its predecessor BCPT in the broader history of biomedicalisation, in particular the possibility to use its results to open up new markets through infrastructures such as direct-to-consumer (DTC) marketing (Hogle 2001). Furthermore, in the journey from the clinical trial to clinical practice and DTC, the risk thresholds defined for BCPT eligibility have been shown to have become regular diagnostic tools with the potential to redefine illness (Dumit 2012; Fosket 2002).

However, as the study of STAR participants show, this change in perception pre-dated the clinical trials and is closely associated with the medical and social responses to breast cancer throughout the 20th century (Aronowitz 2007). For STAR participants, receiving the diagnosis "breast cancer risk" through an algorithm was simply the clinical affirmation of a sense of vulnerability to breast cancer, which had developed through a series of life events such as having relatives with breast cancer, or the experience of mammography screenings or biopsies.

Salter et al. (2011) analysed older women's experiences of being diagnosed, through an algorithm, as being at risk for breaking a bone. Citing Blaxter (1978), the authors argue that the diagnostic process is 'prescriptive', as it is the possibility of treatment that makes for a satisfactory diagnosis. In this sense, risk status mimics an illness status. Salent et al. showed that not all of their interviewees agreed to the proposed medication and many reacted with bewilderment and uncertainty with regards to the diagnosis, because it was not aligned with their embodied experiences. In contrast, the interviewed STAR participants had a prior

embodied experience of vulnerability to breast cancer and the algorithm indeed enabled a 'prescriptive diagnosis' that the women did not have before. In this sense, the risk diagnosis was a means to change their overall experience, allowing them to gain agency and transform their isolating and worrisome feelings into ones of community and solidarity.

Conclusion

In this study, we have shown how the diagnosis of breast cancer risk, the uncertainty of such a "disease," and, finally, the importance of clinical trials as a feature in the master narratives of breast cancer and progress within medical science, all worked together to make participation in the STAR prevention clinical trial a deeply significant and transformative experience, offering women a means with which to handle their perceived vulnerability to breast cancer in a socially meaningful way.

The women's stories are embedded within a larger medical-scientific discourse that perpetuates the individualisation of disease aetiology and responsibility. This value system is similar to the dominant breast cancer movement, which is intrinsically connected to the pharmaceutical industry and thus shapes breast cancer perceptions and experiences in a particular way (King 2006). The STAR trial forms part of this picture. However, the perspective on meaning making within women's stories about STAR participation opens up space for a more nuanced perspective on individualising and collectivising practices and experiences to the concepts of pharmaceuticalisation and medicalisation. Similarly, to focus on the practice of clinical trials themselves helps to gain a more nuanced understanding of our changing notions of risk, health and disease and their individual-level meanings.

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Table 1

Date of STAR entry, approximated through date of risk assessment completion by STAR participants, excluding PAB members

Date of risk assessment	
1999	8
2000	8
2001	2
2004	2

Table 2

Socio-demographic characteristics of interviewees (N=20)

STAR Participants	
Race	
African-American	5
Hispanic	0
White	15
Age average (range)	54.6 (44 - 64)
Gail score average (range)	3.12 (1.71 - 7.67)
Employed	20
Education level	
High school diploma/GED	4
Some college	9
College graduate	3
Some graduate school or >	4