## EPIDEMIOLOGY

# The impact of breast cancer awareness and socioeconomic status on willingness to receive breast cancer prevention drugs

Peter A. Fasching · Gunter von Minckwitz · Thorsten Fischer · Manfred Kaufmann · Beate Schultz-Zehden · Heike Beck · Michael P. Lux · Volker Jacobs · Harald Meden · Marion Kiechle · Matthias W. Beckmann · Stefan Paepke

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#### Abstract

*Purpose* To find associations between knowledge about risk factors for breast cancer and the socioeconomic status of healthy women, as well as their attitude toward taking chemopreventive drugs.

*Patients and methods* Between April and September 1999, 7135 healthy women completed questionnaires providing information about their willingness to take chemopreventive drugs. Items in the questionnaire included the sources of the information they had, their

P. A. Fasching (⊠) · M. P. Lux · M. W. Beckmann Department of Gynecology and Obstetrics, Erlangen University Hospital, Universitaetsstrasse 21–23, D-91054 Erlangen, Germany e-mail: peter.fasching@gyn.med.uni-erlangen.de

G. von Minckwitz German Breast Group, Neu Isenburg, Germany

T. Fischer  $\cdot$  V. Jacobs  $\cdot$  M. Kiechle  $\cdot$  S. Paepke Department of Gynecology and Obstetrics, Technical University Munich, Germany

M. Kaufmann Department of Obstetrics and Gynecology, University Hospital of Frankfurt, Germany

B. Schultz-Zehden Department of Medical Psychology, Charite University Hospital, Berlin, Germany

H. Beck Offenburg, Germany

H. Meden Department of Obstetrics and Gynecology, Dislogation and a patentum Wummer

Diakoniekrankenhaus, Rotenburg, Wuemme, Germany

estimates of the population and personal lifetime risk, and risk factors for breast cancer.

Results A total of 6597 questionnaires were evaluable. The responders' median age was 44. Fifty-five percent of the women were willing to consider receiving chemopreventive drugs to lower their risk for breast cancer. Participants who estimated the population risk as being very high were more disposed to receive chemoprevention (65.3%), as were women who estimated their own breast cancer risk as being high (74.1%). A family history of breast cancer only had a low impact on willingness to receive chemoprevention. Women with a family history of breast cancer were willing to take chemopreventive agents in 57.2% of cases. The multivariate analysis showed that knowing about risk factors and having a lower educational level were factors positively correlated with willingness to consider chemoprevention.

*Conclusion* These findings emphasize the role of estimations of the risk of breast cancer for patients considering whether to accept chemoprevention treatment. To date, only a few modern models of risk estimation have been evaluated in relation to chemoprevention. There is a need for better integration of professional risk estimations into clinical practice.

**Keywords** Breast cancer prevention · Clinical trials · Chemoprevention · Survey

# Introduction

Several studies in recent years have demonstrated the efficacy of tamoxifen as a prophylactic drug in the prevention of breast cancer [1–4]. Another study

analyzed the effectiveness of raloxifene as a preventive agent [5], and an overview of prevention studies has been provided by Cuzick et al. [6]. A 38% overall reduction in the incidence of breast cancer has been reported with prophylactic medication, but rates of endometrial cancer were found to be increased, with a relative risk of 2.4. In addition, thromboembolic events and gynecologic symptoms are increased with tamoxifen treatment [6]. These side effects show that there is a continuing need to identify an optimal drug treatment in the prevention of breast cancer.

Third-generation aromatase inhibitors (anastrozole, letrozole, and exemestane) have recently been shown to be more effective than tamoxifen to prevent contralateral breast cancer given as adjuvant treatment of breast cancer [7–11]. The side effects with these agents also appear to be more favorable. Cuzick et al. estimate that there is an overall reduction of 70–80% in the rate of contralateral tumors in breast cancer patients when aromatase inhibitors are used, compared to no endocrine intervention [12].

A large prospective and randomized study on the use of anastrozole as a preventive agent is therefore being conducted—the International Breast Cancer Intervention Study-II (IBIS-II) trial—which is still open for recruitment. Another trial, coordinated by the National Cancer Institute of Canada Clinical Trials Group (NCIC-CTG), should investigate the effect of exemestane with or without celecoxib in postmenopausal women.

The importance of adequate recruitment in clinical trials has led to publications investigating predictive factors for enrolment in clinical trials and specific patient characteristics associated with participation in cancer trials [13-18]. Some of these analyses have been concerned with breast cancer in particular [19-22]. In one analysis of participants in cancer trials, the percentage enrolment was reported to be higher in younger patients (3% for patients aged 30-64) and lower in older patients (1.3% for patients aged 65–74) [16]. This study also found clear evidence that minorities such as African-American patients (odds ratio 0.71) and Americans of Hispanic origin (OR 0.72) were less likely to be represented among trial participants. In a prospective trial, only 14% (n = 39) of 276 patients diagnosed with cancer were enrolled in clinical trials. Seventy-six of the 276 patients (27.5%) met the eligibility criteria for inclusion in the study. Thirty-seven of these patients (48.7%) did not agree to participate [14]. The main reason given for declining to participate in the study was a "desire for other treatment." Apart from a reduced odds ratio of 0.34 for privately insured patients in comparison with patients receiving public insurance, no factors significantly associated with trial participation were identified. A recent study has reported that higher levels of competition for managed care are associated with lower enrolment rates [18].

An interesting survey of healthy women and breast cancer patients showed that there is a difference between the degree of willingness of healthy women to participate in breast cancer trials in case of a future diagnosis (31%) and that among breast cancer patients (15%) [20]. Willingness to participate in a trial correlated with younger age and a desire to play an active role in decision-making. Socioeconomic factors associated with areas of high poverty or high rates of unemployment, and individuals receiving Medicaid insurance, have been found to have an inverse relationship to participation in breast cancer trials among elderly women [22].

The situation in chemoprevention trials is somewhat different. Recruitment to chemoprevention trials is mainly aimed at healthy patients who are to receive treatment with potentially harmful drugs. In this situation, any study in which adequate analysis is not conducted is ethically questionable. In addition, highly sophisticated multicenter clinical trials are extremely costly, and efficient planning and fast recruitment are crucial for the successful completion of prevention trials. For example, two studies examining the effect of goserelin with raloxifene (the RAZOR trial) and zoledronate (the GISS trial) [23] had to be prematurely terminated due to poor recruitment. The main reason given by patients for declining to participate in these studies was a fear of side effects (60 of 107 patients) [24].

Various aspects of enrolment in the National Surgical Adjuvant Breast and Bowel Project Protocol P-1 (NSABP-P1) breast cancer prevention trial [2] have been examined [25-28]. The authors established a multivariate regression model to identify factors accounting for patients' decision to participate in the NSABP-P1 trial. In this model, women with a "definite concern" about not taking hormone replacement therapy (HRT) were most likely not to participate in NSABP-P1 [26]. This risk factor persisted in the model in a validation study [28]. However, the results of the Million Women Study and the Women's Health Initiative were not yet known at that time. A further model, with adjustment for advice from the physician to the patient to participate in NSABP-P1, yielded an odds ratio of 13.09 for the physician's recommendation to participate [27].

So far as we aware, no further studies have evaluated predictive factors for special patient characteristics associated with enrolment in breast cancer prevention trials. In addition to the difficulties in recruiting patients for chemoprevention trials mentioned above, there are further problems involved in the study design. If a large proportion of the individuals participating in a trial were aware of an increased risk for breast cancer before the intervention, bias in the analysis of the efficacy of prevention might result [29].

Information regarding factors that influence a patient's willingness to participate in chemoprevention trials could help improve recruitment. Evaluating the effects of the patient's awareness of risk factors and her estimation of the risk of breast cancer before she enters a clinical trial could help identify potential bias associated with the patient's awareness of risk factors. In a period in which the use of HRT is being seriously questioned, new models that do not include a covariate analysis with HRT are needed.

The purpose of the present study was therefore to assess the effects of sociodemographic factors, awareness of risk factors for breast cancer, patients' self-estimation their own risk of breast cancer, and participation in secondary breast cancer screening programs on patients' willingness to participate in studies of chemopreventive drug treatment for breast cancer.

## **Patients and methods**

The German Chemoprevention Group (*Deutsche* Arbeitsgruppe Chemoprävention, DACH) conducted a sample-based survey to estimate the willingness of women to take part in chemoprevention programs for breast cancer. This anonymous questionnaire-based study was conducted between April and September 1999.

## The DACH questionnaire

The questionnaire was designed on the basis of a consensus among experts after a review of the literature on healthy women and cancer prevention. A pilot study included 38 healthy women at the university hospital in Berlin (Charité Hospital). The questionnaire was then revised on the basis of the feedback obtained. The questionnaire was designed to distinguish between women taking part in breast cancer prevention programs and women who were not taking part in screening or prevention procedures. It included 47 items under five headings. The first part requested information about the patient's awareness of breast cancer and the sources of the information she had. The second included questions about the patient's participation status in prevention and screening programs, with special regard to reasons for participation or nonparticipation. The third section covered the women's views regarding the importance of prevention and screening programs. The fourth topic addressed the women's attendance for participation in primary prevention procedures, and the final section documented the women's sociodemographic parameters.

A consortium of six centers in northern Germany took part in the study, including institutions in Berlin, Duesseldorf, Frankfurt, Goettigen, Hildesheim, and Kiel. Gynecologists in private practice and outpatient clinics in all six areas in Germany were asked to distribute the questionnaire in their institutions. At least one individual at each center was responsible for ensuring that staff in the participating institutions were informed about the study procedures. The results regarding participation status in prevention and screening programs have been published in part elsewhere [30].

### Study sample

All women aged 18 or over who did not have a diagnosis of cancer were eligible to participate in the survey. All of the women were consulting a gynecologist at the participating centers for some reason. The women visiting one of the centers were asked to complete the questionnaire form after verbally providing informed consent. Only those patients were included in this survey who were considered to be mentally capable of understanding the questions.

Statistical analysis and variables

The target of this analysis was willingness to take drugs for chemoprevention of breast cancer. Independent variables assessed included age (<25, 25-34, 35-44, 45-54, 55–64, >64); gynecologist as a source of information about breast cancer (yes/no); general practitioner as a source of information (yes/no); television, radio, and print media as information sources (yes/no); medical books as information sources (yes/no); friends as information sources (yes/no); medical brochures as information sources (yes/no); the individual's estimation of lifetime risk (no risk, low risk, intermediate risk, high risk, unknown risk); the individual's estimation of the general population's lifetime risk of breast cancer (1-5%, 5-7%, 7-10%, 10-20%, >20%); the individual's estimation of the influence of several risk factors, namely age (yes/no), time of menarche (yes/no), time of menopause (yes/no), age at first birth (yes/no), previous breast biopsies (yes/no), childlessness (yes/ no), duration of breast feeding (yes/no), family history of breast cancer (yes/no), use of HRT (yes/no), and use of hormonal contraception (ves/no); and the individual's estimate of the cure rates with breast cancer (good, quite good, quite poor, poor, no chance of curing breast cancer). In addition, sociodemographic variables were examined as independent variables: place of residence during the previous 10 years (West Germany, East Germany, rest of the world), family status (single, married, divorced, unmarried with a partner, widowed), number of children, educational level in Germany (no school qualification; secondary school leaving certificate; middle school leaving certificate; polytechnic college, entrance certificate for an applied-sciences college, university entrance qualification), vocational training (no vocational training, student, completed apprenticeship, leaving certificate from an applied-sciences college, university degree)

and employment status (employed/unemployed). Pearson's chi-squared test was used to assess the relationship of each independent variable to the objectives of the study. A multiple logistic regression model was used, with willingness to receive chemoprevention as a dependent variable and the independent variables mentioned above. A forward stepwise selection process was used to construct the model, containing variables with a significance level of P < 0.05. The Statistical Package for the Social Sciences program, version 12.0 (SPSS, Inc., Chicago, Illinois, USA, 2003), was used for all statistical analyses.

# Results

Questionnaires were completed by 7135 patients, 6597 of which (92.5%) were evaluable. Reasons for excluding questionnaires were missing statements about the patient's attitude toward chemoprevention and impermissible double answers. A total of 3597 patients (55.3%) stated that they were willing to take drugs to reduce their risk of breast cancer.

Table 1 presents the sociodemographic data for the patients, who had a median age of 44 (standard deviation 15 years). Women with no children formed the largest group (36.6%). Most of the participants were resident in western Germany (79.4%), and most were married (55.1%). The most common educational levels represented were university entrance qualification (30.9%) and a university degree (40.8%), as well as vocational-school leaving certificates.

Table 2 shows the women's responses to the DACH questionnaire regarding the risk of breast cancer and risk estimation. As breast cancer surgery as well as chemotherapy and antihormonal treatment are carried out by gynecologic oncologists in Germany, most of the

women (48.5%) stated that the gynecologist was their source of information about breast cancer. Television, radio, and print media were mentioned in second place (43.5%). Detailed data are given in Table 2.

Univariate analysis of sociodemographic differences (Table 1)

Analysis of the age groups relative to willingness to receive chemoprevention treatment showed that patients aged 45-54 (640 of 1072; 59.7%) were more willing to receive drug treatment than the other age groups. Among the groups of married and widowed participants, 57.8% of each group were willing to receive chemoprevention, as well as women with two or three children (58.9% and 59.4%, respectively). With regard to educational qualifications and employment, women with a basic secondary-level school-leaving certificate (62.5%), those with no vocational training (61.4%), and those who were unemployed (58.7%) showed the greatest willingness to receive chemoprevention. There were no differences between participants living in western or eastern Germany.

Univariate analysis of breast cancer awareness (Table 2)

Although the group who obtained information from their general practitioners showed the greatest willingness to receive chemoprevention (62.0%), this group of patients was comparatively small, with 326 responders (5% of the total). The largest group stating that they were willing to receive chemoprevention (59.3%) consisted of patients who obtained their information from gynecologists.

A trend toward a greater motivation to receive chemoprevention was evident in association with an increasing estimation of the general population's lifetime risk of breast cancer. Forty-nine percent of participants estimating the lifetime risk as 1–5% and 65.3% of those who estimated the risk as over 20% were willing to use chemopreventive drugs. This effect was even clearer in relation to the estimation of personal risk: 41.5% of responders who considered that they had no risk for breast cancer and 74.1% of women who estimated that they personally had a "high risk" were willing to receive chemoprevention.

It is evident from the responses to questions regarding the awareness of the risk factors for breast cancer that women who had accurate information regarding the risk factors were more willing to receive chemoprevention treatment, as were women who did

## Table 1 Characteristics of the study sample and univariate analysis

Characteristic	Patients <i>n</i> (%)	Patients willing to receive CP $n$ (%)	Patients in each category willing to receive CP (%)	Р
Total	6506 (100%)	3597 (100%)		
Age				
<25	452 (6.9%)	239 (6.6%)	52.9%	0.008
25–34	1419 (21.8%)	744 (20.7%)	52.4%	
35–44	1363 (20.9%)	770 (21.4%)	56.5%	
45–54	1072 (16.5%)	640 (17.8%)	59.7%	
55-64	1326 (20.4%)	727 (20.2%)	54.8%	
65–85	727 (11.2%)	393 (10.9%)	54.1%	
Not stated	147 (2.3%)	84 (2.3%)	57.1%	
Place of residence in last 10 years				
Former West Germany	5163 (79.4%)	2825 (78.5%)	54.7%	0.422
Former East Germany	1102 (16.9%)	622 (17.3%)	56.4%	
Abroad	100 (1.5%)	59 (1.6%)	59.0%	
Not stated	141 (2.2%)	91 (2.5%)	64.4%	
Marital status				
Single	1548 (23.8%)	771 (21.4%)	49.8%	< 0.001
Married	3588 (55.1%)	2075 (57.7%)	57.8%	
Divorced	538 (8.3%)	298 (8.3%)	55.4%	
Unmarried partnership	424 (6.5%)	217 (6.0%)	51.2%	
Widowed	351 (5.4%)	203 (5.6%)	57.8%	
Not stated	57 (0.9%)	33 (0.9%)	57.9%	
Number of children				
0	2384 (36.6%)	1243 (34.6%)	52.1%	< 0.001
1	1629 (25.0%)	901 (25.0%)	55.3%	
2	1556 (23.9%)	916 (25.5%)	58.9%	
3	456 (7.0%)	271 (7.5%)	59.4%	
>3	200 (3.1%)	105 (2.9%)	52.5%	
Not stated	281 (4.3%)	161 (4.5%)	57.3%	
Educational level				
No school leaving certificate	67 (1.0%)	40 (1.1%)	59.7%	< 0.001
Secondary school leaving certificate	1405 (21.6%)	878 (24.4%)	62.5%	
Middle school leaving certificate	1903 (29.2%)	1031 (28.7%)	54.2%	
Polytechnic institute certificate	480 (7.4%)	293 (8.1%)	61.0%	
College entrance qualification	531 (8.2%)	281 (7.8%)	52.9%	
University entrance qualification	2011 (30.9%)	1005 (27.9%)	50.0%	
Not stated	109 (1.7%)	69 (1.9%)	63.3%	
Vocational training			<i>ci</i> 10/	0.004
None	503 (7.7%)	309 (8.6%)	61.4%	0.001
Attending training	431 (6.6%)	207 (5.7%)	48.0%	
Completed apprenticeship	866 (13.3%)	462 (12.8%)	53.3%	
Vocational school diploma	1156 (17.8%)	642 (17.8%)	55.5%	
College diploma	615 (9.5%)	316 (8.8%)	51.4%	
University degree	2657 (40.8%)	2657 (73.9%)	55.8%	
Not stated	278 (4.3%)	996 (27.7%)		
Employment status				
Unemployed	2031 (31.2%)	1192 (33.1%)	58.7%	< 0.001
Employed	4391 (67.5%)	2358 (65.6%)	53.7%	
Not stated	84 (1.3%)	47 (1.3%)	56.0%	

Abbreviation: CP, chemoprevention treatment

not provide statements regarding their awareness of risk factors. Experience of a case of breast cancer in the family also increased participants' willingness to receive chemopreventive drugs. Multivariate analysis (Table 3)

The multivariate model showed that certain sociodemographic factors and breast cancer awareness were

Table 2	Results	of the	questionnaire and	univariate analysis
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Characteristic	Patients n (%)	Patients willing to receive CP n (%)	Patients in each category willing to receive CP (%)	Р
Total	6506 (100%)	3597 (100%)		
Source of information	about breast cancer			
Gynecologist				
No	3348 (51.5%)	1723 (47.9%)	51.5%	< 0.001
Yes	3157 (48.5%)	1874 (52.1%)	59.3%	
Other physician				
No	6180 (95%)	3395 (94.4%)	54.9%	0.007
Yes	326 (5.0%)	202 (5.6%)	62.0%	
l elevision, radio, me	2672(5659)	2002 (55.7%)	54 50/	0.079
N0 Vec	3073(30.5%) 2833(43.5%)	2002(55.7%) 1505(44.3%)	54.5 % 56.3 %	0.078
1 es Medical books	2835 (43.3 %)	1595 (44.5 %)	30.3 /6	
No	5260 (80.8%)	2930 (81.5%)	55.7%	0.088
Ves	1246 (19.2%)	667 (18 5%)	53.5%	0.000
Friends	1240 (19.270)	007 (10.570)	55.570	
No	4930 (75.8%)	2735 (76.0%)	55.5%	0 304
Yes	1576 (24.2%)	862 (24.0%)	54.7%	0.501
Medical brochures		002 (211070)		
No	4427 (68.0%)	2391 (66.5%)	54.0%	0.001
Yes	2078 (31.9%)	1205 (33.5%)	58.0%	
Diagon antimata tha fu	an an an af huanat ann an in (			
1 5	720(11.2%)	357 (0.0%)	40.0%	<0.001
1-3 5 7	129(11.276) 1343(20.6%)	337(9.976) 723(20.1%)	49.0 %	<0.001
5-7 7_10	2033 (31.2%)	1083(20.1%)	53.3%	
10_20	1518 (23.3%)	860 (23.9%)	56.7%	
>20	770 (11.8%)	503 (13 98%)	65.3%	
Don't know	113 (1.7%)	71 (1.97%)	62.8%	
		/1 (1.57 / 10)	02.070	
Please estimate your o	own risk of breast cancer	102 (2.80/)	41.50/	0.001
NO TISK	246(3.8%)	102(2.8%) 1026(28.8%)	41.5%	<0.001
Low	2081(52.0%)	1030(28.8%) 1171(22.6%)	49.8%	
High	2091(52.1%)	(52.0%)	50.0 % 74.1 %	
Don't know	1675(25.7%)	238(7.278) 081(27.3%)	74.170 58.6%	
Not stated	65 (1.0%)	49 (1 4%)	44.9%	
		(1.170)	11.970	
Which of the followin	ng are risk factors for breast o	cancer?		
Age	25(1 (20 40/)	1200 (20 (0))	54.20/	0.222
NO Voc	2301(39.4%) 2385(52.0%)	1388 (38.0%)	54.2%	0.323
Its	560 (8.6%)	353(0.8%)	54.0 % 63.0%	
Age at menarche	500 (8.078)	555 (9.878)	03:078	
No	4951 (761%)	2615 (72.7%)	52.8%	<0.001
Yes	681 (10.5%)	424 (11.8%)	62.3%	<0.001
Unknown	874 (13.4%)	558 (15.5%)	63.8%	
Age at first birth				
No	4333 (66.6%)	2304 (64.1%)	53.2%	0.01
Yes	1296 (19.9%)	737 (20.5%)	56.9%	
Unknown	877 (13.5%)	556 (15.5%)	63.3%	
Previous benign breas	st biopsies			
No	1455 (22.4%)	754 (21.0%)	51.8%	0.014
Yes	4346 (66.8%)	2399 (66.7%)	55.2%	
Unknown	705 (10.8%)	444 (12.3%)	63.0%	
Childlessness				
No	3943 (60.6%)	2087 (58.0%)	52.9%	0.018
Yes	1711 (26.3%)	958 (26.6%)	56.0%	
Unknown	852 (13.1%)	552 (15.3%)	64.8%	
Age at menopause				
No	3792 (58.3%)	1937 (53.9%)	51.1%	< 0.001
Yes	1957 (30.1%)	1197 (33.3%)	61.2%	
Unknown	757 (11.6%)	463 (12.9%)	61.1%	

#### Table 2 continued

Characteristic	Patients n (%)	Patients willing to receive CP n (%)	Patients in each category willing to receive CP (%)	Р
Duration of breastfee	eding			
No	3673 (56.5%)	1956 (54.4%)	53.5%	0.079
Yes	2011 (30.9%)	1111 (30.9%)	55.2%	
Unknown	822 (12.6%)	530 (14.7%)	64.5%	
Contraceptive use				
No	3998 (61.5%)	2219 (61.7%)	55.5%	0.076
Yes	2208 (33.9%)	1183 (32.9%)	53.6%	
Unknown	300 (4.6%)	195 (5.4%)	65.0%	
HRT		~ /		
No	4006 (61.6%)	2209 (61.4%)	55.1%	0.486
Yes	2223 (34.2%)	1224 (34.0%)	55.1%	
Unknown	277 (4.3%)	164 (4.6%)	59.2%	
Family history of bre	east cancer	~ /		
No	1202 (18.5%)	640 (17.8%)	53.2%	0.002
Yes	3309 (50.9%)	1922 (53.4%)	58.1%	
Unknown	1995 (30.7%)	1035 (28.8%)	51.9%	
Have there been any	cases of breast cancer in you	ir family?		
No	4948 (76.1%)	2703 (75.1%)	54.6%	0.044
Yes	1460 (22.4%)	835 (23.2%)	57.2%	
Unknown	98 (1.5%)	59 (1.6%)	60.2%	
How do you estimate	the chances of curing breast	cancer?		
Good	1398 (21.5%)	808 (22.5%)	57.8%	0.013
Quite good	3239 (49.8%)	1727 (48.0%)	53.3%	
Quite poor	1409 (21.7%)	797 (22.2%)	56.6%	
Poor	238 (3.7%)	145 (4.0%)	60.9%	
No chance	75 (1.2%)	41 (1.1%)	54.7%	
Unknown	147 (2.3%)	79 (2.2%)	53.7%	

Abbreviations: CP, chemoprevention treatment; HRT, hormone replacement therapy

strongly associated with willingness to receive chemopreventive drugs. The adjusted odds ratio for participants' estimation of their personal breast cancer risk was 3.7 (95% confidence interval, 2.2–6.2). There was a stepwise increase from responders with a low estimation of risk to those with a high estimation of risk. Even patients who were not able to estimate their personal risk had an odds ratio of 2.2 (95% CI, 1.5–3.4). The second parameter that showed a strong association was the estimation of the lifetime risk in the general population. The odds ratio among patients who estimated a lifetime risk of more than 20% was 1.6 (95% CI, 1.2–2.3).

The association with lower educational status continued to be significant in the multivariate model. Participants with a basic secondary-school leaving certificate had the strongest odds ratio at 1.7 (95% CI, 1.4–2.2). The patient's levels of information regarding age at menarche/menopause, previous breast biopsies, and a family history of breast cancer as risk factors were associated less strongly with willingness to receive chemoprevention.

With regard to the information source about breast cancer, the gynecologist and medical books were positively associated with a disposition to receive chemoprevention and medical information brochures were negatively associated with it. Data for the multivariate analysis are presented in detail in Table 3.

None of the other variables persisted in the multivariate model used. Factors associated with age, marital status, place of residence, number of children, vocational education, and employment status were not significant in the model. In relation to the questionnaire, the high proportion of patients who considered that there was no chance of curing breast cancer is noteworthy.

#### Discussion

Chemoprevention treatment for breast cancer has advanced to a stage at which new drugs such as aromatase inhibitors are being investigated, following evidence from completed prevention trials clearly showing that tamoxifen administration is capable of reducing the risk of estrogen-receptor-positive breast cancer [6]. Women participating in breast cancer prevention trials

Characteristic	Р	Adjusted odds ratio	95% confidence interval	
Educational level				
University entrance qualification		1		
No school-leaving certificate	0.192	1.664	0.774	3.578
Basic secondary school	0.000	1.734	1.396	2.155
Middle school	0.275	1 111	0.920	1 341
High school	0.004	1 505	1 1 3 6	1 994
Applied-sciences college	0.661	0.938	0.705	1.248
Source of information about breast canc	er			
Gynecologist	0.000			4 450
No	0.002	1	4 0 0 0	1.472
Yes		1.267	1.090	
Medical books				
No	0.011	1		0.945
Yes		0.782	0.647	
Medical brochures				
No	0.021	1		1.422
Yes		1.210	1.029	
Patient's estimate of lifetime risk in gene	ral population			
1–5%		1		
5–7%	0.398	1.123	0.858	1.471
7–10%	0.694	1.053	0.816	1.358
10-20%	0.107	1.245	0.954	1.626
>20%	0.002	1.643	1.199	2.253
Patient's estimation of her own risk				
No risk		1		
Low risk	0.077	1.449	0.960	2.187
Average risk	0.002	1.935	1.280	2.926
High risk	0.000	3.742	2.249	6.226
Unknown	0.000	2.228	1.467	3.383
Patient's assessment of risk factors				
Age at menarche				
No	0.002	1		1.934
Yes		1.496	1.157	
Previous benign breast biopsies				
No	0.046	1		1.393
Yes		1.182	1.003	
Age at menopause				
No	0.002	1		1 528
Ves	0.002	1 296	1 099	1.520
Family history of breast cancer		1.270	1.077	
No	0.016	1		1 167
Ver	0.010	1 225	1.040	1.407
1 05		1.233	1.040	

Table 3 Multivariate model of factors associated with willingness to receive chemoprevention

are now aware that it is possible to reduce their personal risk by taking antihormonal agents. In addition, evidence of an increased risk of breast cancer and cardiovascular disease following the use of HRT has altered women's awareness in connection with this topic. Analysis of factors relating to enrolment in breast cancer prevention trials has shown that concern about not being able to take HRT is the most important factor for nonparticipation in chemoprevention trials, with an odds ratio of 12.13 [26]. In the present study, 61.4% of participants identified HRT as a risk factor for breast cancer. However, this information was not associated with a greater willingness to receive chemopreventive drugs.

In addition, in the NSABP-P1 trial, a physician's recommendation to participate in the study was associated with an additional positive factor with an odds ratio of 13.09 [27]. In the present study, with a sample of outpatients visiting a gynecologist for any reason, the fact that the patient's information source about breast cancer was generally her gynecologist increased the patient's willingness to undergo chemopreventive drug treatment. The effect was relatively small, with an odds ratio of 1.267 (P = 0.002), but the multivariate

model showed that it was significant. As mentioned above, the gynecologist is the primary physician concerned with breast cancer surgery and treatment in Germany.

The results of the present study clearly show that a patient's willingness to receive chemopreventive medication is dependent on her estimation of the risk of breast cancer. In the multivariate analysis, the patient's estimation both of the risk in the general population and of her personal risk were the factors most strongly associated with willingness to receive chemopreventive treatment. The higher any risk was considered to be, the higher was the motivation to receive chemoprevention.

In relation to the extent to which patients were well informed about breast cancer and treatment procedures, including the value of clinical trials, a better level of information correlated positively with willingness to take part in clinical trials in oncology involving innovative treatment procedures [20]. The present survey shows that better information regarding the risk factors for breast cancer was positively associated with a willingness to undergo chemopreventive drug treatment. Age at menarche and menopause, previous breast biopsies, and a family history of breast cancer were variables that continued to be significant in the multivariate model, with odds ratios of between 1.18 and 1.5.

Lower socioeconomic status has been reported to be associated with a higher enrolment rate in cancer trials [22]. In the present study, women with a basic secondary-school leaving certificate were the ones most likely to be willing to receive chemopreventive drug treatment, in addition to women who had not received vocational training and women who were unemployed.

When one attempts to summarize all of the factors analyzed in the present study, an individual participant's estimation of the risk appears to be the key factor in her willingness to undergo treatment with chemopreventive drugs. In clinical practice, counseling patients in relation to their risk of breast cancer is a complex task. Several risk factors have to be taken into consideration. Many models have been published for different data sets of risk factors [31–34]. Some of the models tend to rely more on genetic susceptibility, while others include clinical risk factors. Current studies such as the IBIS-II trial use prediction models such as the Tyrer-Cuzick risk calculator to identify risk groups [35]. Which of these models best fits the population receiving counseling is not yet clear. To date, only a few evaluation studies have been published [36, 37].

Improve in knowledge about factors determinating and influencing the patients' attitude to participate in prevention trials is needed to adapt the study design and inclusion criteria as well as to increase participation and compliance in prevention trials.

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