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Authors
Strickland, C J
Feigl, P
Upchurch, C
et al.

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Improving Breast Self-Examination Compliance: A Southwest Oncology Group Randomized Trial of Three Interventions[1,2]

C. June Strickland, Ph.D., R.N.,* Polly Feigl, Ph.D.,† Christine Upchurch, M.S.,‡ David K. King, M.D.,§ H. Irving Pierce, M.D.,¶ Patra K. Grevstad, R.N.,‖ James D. Bearden, III, M.D.,** Meredith Dawson, R.N., M.A.,†† William C. Loewen, M.D.,‡‡ and Frank L. Meyskens, Jr., M.D.§§

**University of Washington School of Nursing, Box 357263, Seattle, Washington 98195; †Southwest Oncology Group Statistical Center, Fred Hutchinson Cancer Research Center, 1100 Fairview Avenue North, MP-557, Seattle, Washington 98109-4417; ‡Southwest Oncology Group Statistical Center, 1124 Columbia Street, MP 557, Seattle, Washington 98104-2092; §Greater Phoenix CCOP, 925 East McDowell Road, Second Floor, Phoenix, Arizona 85006-2726; ¶Northwest Community Clinical Oncology Program, 1003 South Fifth Street, Second Floor, Tacoma, Washington 98405; ‖Swedish Tumor Institute, 1221 Madison Avenue, Seattle, Washington 98104; **Spartanburg Community Clinical Oncology Program, 100 East Wood Street, Suite 200, Spartanburg, South Carolina 29303-3017; ††Cancer Services, St. Charles Medical Center, 2500 NE Neff, Bend, Oregon 97701; ‡‡Wichita Community Clinical Oncology Program, 8200 West Central, Suite 1, Wichita, Kansas 67212-3661; and §§University of California Irvine Cancer Center, 101 The City Drive, Building 44, Route 81, Orange, California 92668*

Background. **Only 20–40% of U.S. women conduct breast self-examination (BSE). This Southwest Oncology Group experimental study compared the impact of three interventions on BSE compliance.**

Methods. **Subjects were randomly assigned to one of three arms: (1) physician message; (2) physician message and BSE class; or (3) physician message, BSE class, and reinforcement (phone and postcard). Compliance (frequency and accuracy) was measured by interview at intake and at 6 months and by phone contact at 1 year. Logistic and multiple regression were employed.**

Results. **This analysis included 2,233 subjects from six institutions. At 1 year the percentages of women doing BSE were 59, 62, and 78% for Arms 1–3, respectively; gains over intake frequency (27% average) were significant within each arm ($P \leq 0.0001$). At both 6 months and 1 year the differences between Arm 1 and Arm 2 average accuracy scores and the differences between Arm 2 and Arm 3 in the percentage of women doing BSE were significant ($P \leq 0.0001$). Findings within institutions were consistent with the overall findings.**

Conclusions. **The addition of a BSE class increased accuracy over physician message alone; physician message, BSE class, and reinforcement gave the highest percentage of women doing BSE.**

Key Words: **patient compliance; breast self-examination and training; health education; breast self-examination and reinforcement; breast self-examination and physicians.**

INTRODUCTION

Breast cancer is the most common malignancy among North American women. The incidence is increasing about 2% annually and mortality rates remain unchanged since the 1930s [*3,69*]. Although debate continues about the efficacy of breast self-examination (BSE), a number of studies have found that BSE has improved early detection and reduced mortality [*17,22,27*]. For example, Foster et al. [*22*] found that performers have a breast cancer mortality that is 50% that of nonperformers; however, after over 2 decades of research only 20–40% of the women in the United States conduct BSE as recommended and there is little evidence that it is conducted accurately [*14*].

BSE compliance studies have reported only about 40–50% compliance rates in the United States [*7,14,59*]. Much current BSE research has been compromised by weak designs and variable outcome measurements that hamper comparisons across studies. Many studies have been descriptive or retrospective in nature, have focused on the individual, and have relied on individual health-related theoretical models [*14,19,21,31,50*]. The cumulative interactive influences that occur within systems of care, in contrast, have been neglected. It is imperative that we gain greater understanding of the most efficient means of influencing women particularly, in this time of concern about cost containment. The purpose of this randomized trial conducted in the Southwest Oncology Group was to compare the impact of three approaches that have

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[2] Address reprint requests to the Southwest Oncology Group (SWOG-8807), Operations Office, 14980 Omicron Drive, San Antonio, Texas 78245-3217.

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varying degrees of intensity on women's BSE compliance: (1) physician message (Arm 1), (2) physician message and a BSE class (Arm 2), and (3) an integrated systems approach: physician message, BSE class, and reinforcement (Arm 3). On the basis of adoption theory, it was hypothesized that: (1) BSE compliance would improve on all three study arms and (2) Arm 3 (physician message, a BSE class, and phone calls/postcard reinforcement) would have the greatest impact on BSE compliance followed in order by the physician message and BSE class and the physician message only. This study is unique in that it provides a large prospective, randomized study of BSE. It is also the first study to compare the additive impact of three interventions that are known to have a significant impact on BSE compliance and tests the extent to which adoption theory may offer a midlevel paradigm for addressing BSE compliance.

BACKGROUND/REVIEW OF RELATED LITERATURE

This literature review focuses on the contributions most relevant to the interventions under investigation, provider influence, education programs, and reinforcement. We will also consider demographic characteristics, the theoretical framework, and the efficacy research.

Influence of the Provider

The attention and care of the provider has been linked to BSE practice [*7,9,42,49,51,62*] and has been positively and significantly related to BSE compliance [*42,51*]. Amsel et al. [*4*] reported a 39% frequency compliance in a study involving physician instruction and follow-up reinforcement. Baines et al. [*7*] found a 55% frequency and a 70% accuracy among those receiving provider instruction and follow-up reinforcement.

Education Programs/Materials

Researchers have considered the content of the message, as well as the approaches used in BSE education programs. Attention has been given to the way BSE should be done, for example, vertical versus concentric circles, sliding the fingers versus small circular motions [*6,66,67*]. In more recent work, researchers suggest that the vertical format may be more useful in ensuring that women reach the axial area and that the small circular approach may produce fewer false-positive identifications of lumps [*6,66,67*]. In examining the kinds of information that need to be included in a BSE class, researchers have addressed three methods of BSE recommended: (1) shower, (2) mirror exam, and (3) supine [*68*]. Researchers have found that knowledge increases proficiency or accuracy, that information provided through pamphlets and videos needs to be augmented with education programs and practice, that cognitive learning styles may need to be matched with the teaching approach, that behavior contracting increases compliance, and that knowledge alone may not be expected to result in maintenance of doing BSE as recommended [*1,12,14,29,32,33,38, 39,52,61,66–68,72*].

Pamphlets, brochures, and flyers alone do not affect BSE compliance; a combination of educational approaches using audiovisuals, support groups, behavior contracting, and demonstrations with positive feedback was positively and significantly related to BSE compliance [*1,12,14,29,33,38,39,52,61*]. BSE compliance rates achieved through BSE class instruction range from 40 to 55% in terms of frequency of conducting BSE and 50 to 70% in terms of degrees of accuracy [*15,36,52,54*]. Instruction provides the knowledge and skills and contributes to the sense of self-confidence that has been identified as a major variable related to women doing BSE [*49,66,67*]. BSE education programs may have the greatest influence on accuracy, but may not necessarily have an equal impact on frequency of BSE, unless they are combined with other interventions.

Behavior contracting has been recognized as an important aspect of influence in health-related behavior change and has also been recognized in BSE education, in that support partners have been asked to contract and commit to support the partner in doing BSE [*38,39*]. The impact of asking women to contract for change, however, has not been examined. Reports from other compliance studies support the potential value of behavior contracting in BSE interventions [*16,18*]. In a study of diabetic patients, Etzwiler [*18*] achieved a 59% compliance rate through the use of written contracting.

Follow-Up Reinforcement

Studies show that women feel that they would be more likely to do BSE if they were provided reminder prompts [*25,49,56,62*]. In early works the impact of telephone calls and postcard reminders was examined [*4,7,23,24,35,47*]. In more recent work, researchers have added to this understanding by examining and comparing the impact of partners to provide reminders and by considering innovative ways to reach women with prompts, such as providing messages in their oral contraceptives [*20,38,39,46*], and have achieved a significant impact. Follow-up reinforcements such as postcards, monthly stickers, and follow-up visits or phone contact are positively and significantly related to BSE compliance [*4,7,23,24,35,47,72*]. A 58% compliance in BSE frequency was reported by Grady et al. [*24*] in a study that included instruction and reinforcements; Mayer and Frederiksen [*47*] found phone contacts to be a stronger reinforcer than mailings in influencing BSE frequency. With these and a number of other studies, it has been noted that the effect of being studied may also provide reinforcement.

Characteristics / Variables Related to BSE Compliance

Perceived susceptibility, perceived benefits, perceived confidence, previous BSE education, age, culture, education, and socioeconomic status are significant predictors of BSE class attendance and of BSE compliance [*1,7,9–12,15,24,26,28,29,37,43,49,56,58, 60,63,66,67*].

Theoretical Framework

A major shortcoming in BSE compliance research has been the failure to link interventions in a unified theoretical paradigm. This is not to suggest that theory has not been employed in the study of BSE, but rather to highlight the importance of integrating theories. Most useful for this study in achieving a more unified theoretical paradigm is adoption theory [*8,34,44,57*]. Researchers outlined key steps in the adoption decision process: (1) raise awareness of a need to change; (2) provide knowledge and skills, obtain commitment and personalization; and (3) provide follow-up reinforcement once the change has been undertaken. An integration of these works holds promise in providing an overarching, integrated framework, a paradigm to guide the influence of BSE compliance behaviors. As noted by Leventhal and Cameron [*41*], programs that integrate the key components of the behavior change models hold the most promise in influencing compliance behaviors. The interventions proposed in this study represent an integration of the adoption theory [*34,44,57*] linked with the classic work in health-related behavior change. The physician message raises the awareness of the need to change. The BSE class provides the knowledge and skills, addresses barriers, allows for behavior contracting, and supports the sense of self-efficacy in providing opportunities to practice BSE with positive reinforcement. Contracting achieves the personalization and, finally, the follow-up reminders provide the reinforcement for continuation of the behavior. As may be seen, the goal of this research is to test the adoption theory model to gain further understanding of its power in the influence of BSE behaviors and to thus contribute to building and integration of theory.

BSE Efficacy Issues

Researchers have compared BSE with mammography and clinical breast exam and aimed to determine if regular BSE practice results in earlier detection of breast lesions, improved survival rates, and reduced breast cancer morbidity [*17,22,28,48,55,65*]. Results have been inconclusive. Foster et al. [*22*] and Ellman et al. [*17*] found that BSE significantly reduced breast cancer mortality. Likewise, Hakama et al. [*27*] found that breast cancer mortality among those who were screened with mammography and taught to do BSE was lower. Preliminary data from the World Health Organization study in Russia [*65*] suggest that there is no significant difference in those who perform BSE and those who do not in terms of the size of the tumor at detection; information about the relation between BSE and cancer mortality will not be available until 1999. Mittra [*48*] addressed factors to consider in breast health screening programs and noted that screening approaches must be linked to efficacy as well as practical considerations in implementation.

Researchers recognize the need to continue the investigation of BSE efficacy. Crucial to this effort is the development of BSE programs that may be subsequently used to support randomized clinical trials to evaluate BSE efficacy; such was the intent of this research.

METHODS

Design and Interventions

This experimental study was designed as a limited institution study in the Southwest Oncology Group, involving nine institutions, with a target enrollment of 400 subjects per institution. This was a three-arm randomized trial design; within each arm, subjects were assessed pre- and postintervention. Six of the nine institutions that initiated the study provided sufficient data for analysis: (1) Spartanburg Community Clinical Oncology Program (CCOP), Spartanburg, South Carolina; (2) Virginia Mason CCOP, Seattle, Washington; (3) Northwest CCOP, Tacoma, Washington; (4) Wichita CCOP, Wichita, Kansas; (5) Greater Phoenix CCOP, Phoenix, Arizona; and (6) Puget Sound Oncology Group, Seattle, Washington. Subjects were randomly assigned to one of three treatment arms: (1) Arm 1, the physician message (the physician simply stated that BSE was important to do). In this intervention the message was delivered in the exam room as a one-to-one communication between the woman and her primary physician as part of her routine annual exam. (2) Arm 2, the physician message and a 45-min BSE class (a video, group discussion of barriers, behavior contracting, and BSE practice). Behavior contracting was achieved by having the women sign a statement of agreement that they would address identified barriers. A full discussion of the BSE class is not possible in this paper; additional information and a copy of the BSE instructor materials may be obtained on request. (3) Arm 3, the physician message, the BSE class, and follow-up reinforcement that included postcard and phone call contacts. Standardization was achieved through the use of a documented education program manual for instructors and participants and standardized materials for reinforcements on follow-up cards and in the phone calls. Subjects were identified by office assistants in physicians' offices. Data managers

screened for eligibility and obtained human subject consents and demographic data. Human subjects approval was obtained through the Institutional Review Boards of each participating institution. Physicians provided the message of BSE importance to all subjects and determined that women entering the study had no breast abnormalities. Subjects were equally randomized to one of the three treatment arms and sent to the institution's education center staff. The compliance instrument was administered to all subjects; subjects assigned to the BSE class were scheduled for class. Those subjects assigned to Arm 3 were asked to stay after class. They were given calendar stickers and informed that they would also receive follow-up calls and postcard reminders. Those on Arm 3 were called and sent reminder cards quarterly using a standardized message.

Subjects

Participants were selected based on eligibility criteria from among women who were regularly seeking preventive health screening—physical exams with family practice, internal medicine, or gynecological physicians. The eligibility requirements were that subjects be 20–65 years of age, with no evidence or previous history of breast cancer, with no evidence of learning disability or visual and hearing handicaps, and with no language barriers that might prohibit their participation in the BSE class. We did not exclude women who reported that they were doing BSE frequently because we wanted to study BSE *accuracy* as well as frequency in the population of women who were routinely seeking preventive care. The primary goal of this effort was to gain more information about the impact of the theoretical model.

Assessment of Compliance and Endpoint Measurements

Compliance was measured in terms of frequency and accuracy. One staff person in each institution not involved in the interventions was assigned to conduct the endpoint evaluation measurements. To ensure consistency in data collection, these individuals were trained and provided a protocol to follow in collecting the data, both in the individual interviews using the accuracy score sheet and in the telephone follow-up communications. Telephone scripts were provided. Data were collected in person at intake and at 6 months. At 1 year, data were collected by a phone interview. *Frequency* was measured with the following questions: Do you do BSE? How often do you do BSE? Estimate the number of times you conducted BSE in the past 6 months. Responses were dichotomized into two categories for analyses. If the subject indicated that she conducted BSE five times or more in the past 6 months, her response was recorded as "yes." If her response fell into the category of fewer than five times, her response was recorded as "no." *Accuracy* was measured using the Lierman [*40*] instrument which has a construct validity of $r = 0.82$, interrater reliability of $r = 0.99$, and Cronbach α reliability on the demonstration section of the instrument of $r = 0.82$. Accuracy was measured on an 8-point scale for the interview and a 5-point scale for the demonstration. In the demonstration, the subject held a breast plate in front of her chest. Questions were the same for the demonstration and the interview assessment, except that the interview contained three items about the location/position for doing BSE that were not applicable to demonstration. The accuracy instrument included the following questions: (1) *Location/position:* What position do/should you use or where do/should you perform BSE? Lying down, in the shower, or at the mirror? (on interview only, 3 points possible); (2) *Finger position:* What part of your fingers do/should you use in doing BSE? (1 point possible); (3) *Areas covered:* Describe the area of your breast that you should cover in doing BSE (options were covering the entire breast and checking the arm pits; 2 points possible); (4) *Pattern:* Describe the pattern you do/should use in checking your breast (1 point possible); (5) *Opposite breast check:* Which hand do/should you use to check the right breast, left breast? (1 point possible). Each answer was assigned a score of 1 or 0. These were totaled to arrive at the score for accuracy. The range of score on demonstration accuracy was 0–5; the range of score for interview accuracy was 0–8. It may be noted that accuracy as presented in this study does not represent the woman's technical accuracy compared with a physician, but rather accuracy as it is defined in the current research literature on BSE compliance. It is important to maintain this definition of accuracy to ensure comparison across studies. We recognize that the terms proficiency and quality have also been used in the literature as end point measurements and that ability to identify breast lumps in a model has also been used [*67,72*]. We elected to avoid using detection of lumps as an endpoint measurement to prevent focusing on detection of abnormalities, breast cancer, and the fear arousal that may be associated. In all phases of the education program, the emphasis was on women taking charge of their health and on gaining a sense of the normal breast, a focus on wellness.

Statistical Methods

Logistic regression was used to analyze the dichotomous BSE frequency variable indicating whether a subject reported doing BSE five or more times in the past 6 months. Separate analyses were conducted for the 6- and 12-month data. Overall (across-institution) logistic models included eight covariates: five indicator variables for the six institutions, two indicator variables for the three study arms, and one indicator vari-

able for BSE frequency at study enrollment. Odds ratios comparing study arms were calculated using Arm 2 as the reference category with adjustment for the other covariates. Chi-squared tests of the logistic regression coefficients were used to test the hypothesis of equal BSE frequency for all three study arms and to compare Arm 1 to Arm 2, and Arm 3 to Arm 2. Analogous multiple regression models and tests were applied to the BSE accuracy scores employing the same eight covariates, except that enrollment BSE accuracy scores were substituted for BSE frequency. The same models were applied to data within each of the six institutions, omitting the institution covariates. All statistical tests comparing study arms controlled for BSE frequency or accuracy at study enrollment. Paired procedures were used to test within-arm increases in BSE frequency (the sign test) and accuracy (paired t test) over time. Subject level covariates (e.g., age) were added singly to the overall logistic models to assess their value as predictors of doing BSE after adjustment for institution, study arm, and BSE frequency at enrollment. All computations were performed using SAS Version 6 [*64*].

Follow-up rates differed among the three study arms due, in part, to a tendency for institution staff members to selectively drop contact with subjects who failed to take the BSE class. For this reason, analyses were undertaken to see how robust the study conclusions are to different assumptions about the BSE behavior of women who did not complete the study. Procedure 1 is the standard approach—all available data were used and missing observations ignored. This approach is consistent with the assumption that drop-outs behave like subjects who complete the study. In Procedure 2, data were restricted to patients who entered the study after the protocol was amended to stress equal follow-up procedures for all subjects. Missing observations were ignored. In Procedure 3, intervention arm averages were calculated under the assumption that, as a group, the subjects with missing BSE outcome data at 6 or 12 months would have responded like Arm 1 (physician message only) subjects who provided outcome data at the same time point. No significance testing was done. In Procedure 4, a subject's own individual enrollment BSE value was inserted whenever her 6- or 12-month BSE outcome value was missing, which assumes that a woman who dropped out had the same BSE behavior at 6 and 12 months as she did at enrollment. Arm differences were calculated under this imputation scheme and tested for significance by rerunning the logistic and multiple regression overall models.

None of the P values shown are adjusted for multiple comparisons. If the reader wishes to apply a conservative adjustment, a Bonferroni factor of 10 is suggested, e.g., declaring significance at the 1% level when $P \leqslant 0.001$ [*2*]. The rationale for this suggestion is that there are 10 overall (across-institution) statistical tests based on five key endpoints and two key intervention comparisons. The five endpoints are BSE frequency at 6 and 12 months, interview BSE accuracy at 6 and 12 months, and BSE demonstration accuracy at 6 months. The two intervention comparisons are: (1) Arm 1 vs Arm 2, which measures the impact of adding the BSE class to physician message, and (2) Arm 2 vs Arm 3, which measures the impact of adding reinforcement to the physician message and BSE class. The P values for individual institution analyses should be regarded as descriptive only.

RESULTS

Accrual and Follow-Up

The accrual period was May 1989 to December 1993. Three of the original nine institutions did not complete the study. Two of these three institutions registered 27 and 38 subjects, while the third registered 151 but obtained 6-month BSE data for less than 10% of the subjects. The remaining six institutions randomized 2,235 women. Data from two subjects from Institution A were excluded because they provided no BSE intake information and immediately refused further study involvement. Thus the total number of subjects analyzed was 2,233. Five institutions met the accrual goal of 400 registrations each. The sixth institution enrolled 230 subjects. Overall, the 12-month follow-up rates were 81% for the 6-month visit and 84% for the 12-month telephone interview. Follow-up was better for Arm 1 (physician message) than for the arms with the BSE class.

Table 1 provides information on follow-up rates by institutions and treatment arms. At 12 months the drop-out rate was twice as high for Arms 2 and 3 as for Arm 1 (19% vs 10%). The 19% dropout rate in Arms 2 and 3 is related to the 18% of women who refused or were otherwise not scheduled for the required BSE

TABLE 1

Number (%) of Subjects with BSE Outcome Data[a] by Study Arm and Institution

	Arm 1 MD message only $n = 764$	Arm 2 MD message + BSE class $n = 743$	Arm 3 MD message + BSE class + reinf $n = 726$
6-month data	651 (85%)	593 (80%)	571 (79%)
12-month data	688 (90%)	608 (82%)	585 (81%)
12-month data by institution			
A $n = 398$	129/149 (87%)	98/128 (77%)	98/121 (81%)
B $n = 401$	116/136 (85%)	95/130 (73%)	90/135 (67%)
C $n = 400$	145/147 (97%)	117/130 (90%)	113/123 (92%)
D $n = 400$	117/124 (94%)	129/144 (90%)	119/132 (90%)
E $n = 404$	119/139 (86%)	100/124 (81%)	108/141 (77%)
F $n = 230$	62/69 (90%)	69/87 (79%)	57/74 (77%)

[a] Outcome data at 6 months = BSE frequency or interview accuracy or demonstration accuracy. Outcome data at 12 months = BSE frequency or interview accuracy.

class. Some of these women were erroneously taken off study when they did not attend the BSE class. On April 1, 1991 (with enrollment 51% complete), the protocol was amended to clarify that ALL enrollees were to be followed for 12 months. Prior to the protocol amendment the 12-month drop-out rates for Arms 1, 2, and 3 were 12, 24, and 25%, respectively. Subsequently, they dropped to 8, 13, and 13%, respectively. Within each institution the pattern of better Arm 1 follow-up is seen, but it is pronounced in Institutions A and B, which registered over 90% of their subjects before the amendment. The influence of the differential drop-out rates on outcome is considered below.

Subject Characteristics

As a group, the women studied were predominately middle aged (median 41 years) white (90%), married (68%), and well educated (73% had some college). Three quarters came from families with an annual income of over $25,000. The randomized study arms agreed well on these variables. Of greater concern is whether the 16% of subjects who dropped out of the study differed from those who completed. Table 2 compares the characteristics of the "completers" and the dropouts. A completer is defined as a subject providing 12-month (telephone) data on BSE frequency or accuracy. The dropouts are somewhat younger, less apt to be married, and less affluent than the completers, but overall the demographic differences are not extreme. Prior exposure to a BSE education program was experienced by 4% of each group and about one-fifth of each agreed or strongly agreed with the statement, "My chances of getting breast cancer are high." The percentage of women who reported doing BSE on enrollment to the study was 27% for the completers and 26% for the dropouts. Marked differences were seen between the two groups with respect to enrollment before the follow-up protocol amendment date of April 1, 1991 (48% vs 65%), 6-month data (94% vs 15%), and attendance at the BSE class (90% vs 45%).

TABLE 2
Characteristics of Subjects with/without 12-Month BSE Outcome Data

Item	Completers[a] n = 1,881	Dropouts[b] n = 352
Demographics		
Age, median in years	41 (1,881)	38 (352)
25th, 75th percentiles	34, 49	31, 47
Menopausal status, pre	75% (1,818)	78% (339)
Race, white	90% (1,881)	92% (351)
Marital status, married	69% (1,872)	64% (348)
Education, beyond high school	74% (1,869)	72% (350)
Annual family income, >$25,000	75% (1,822)	68% (344)
Breast cancer action/beliefs		
Prior BSE education program	4% (1,870)	4% (350)
Believes "my chances" of breast cancer high	20% (1,868)	22% (347)
Study variables		
Doing BSE at enrollment		
Arm 1 MD message only	29% (686)	25% (76)
Arm 2 MD message + BSE class	24% (608)	28% (135)
Arm 3 MD message + BSE class + reinf	26% (584)	26% (141)
Enrolled before April 1, 1991, follow-up amendment	48% (1,881)	65% (352)
6-month BSE data available	94% (1,881)	15% (352)
Attended BSE class (Arms 2 and 3 only)	90% (1,178)	45% (271)

Note. Values in parentheses are sample sizes with known values for data item.

[a] A completer is defined as a subject with 12-month (telephone) data on BSE frequency or accuracy.

[b] A dropout is a subject missing 12-month (telephone) data on both BSE frequency and accuracy.

Outcome Data—BSE Frequency

Figure 1 presents the results of the overall logistic regression analysis of BSE frequency based on all available data for the six institutions. The graphs plot the percentage of women who reported doing BSE more than five times in the previous 6 months, against time. Also shown are associated odds ratios adjusted for institution and BSE frequency at study entry. About a quarter of the women reported doing BSE when they entered the study and this did not differ statistically significantly among the three study arms (P = 0.15).

Six months later the percentage of women doing BSE

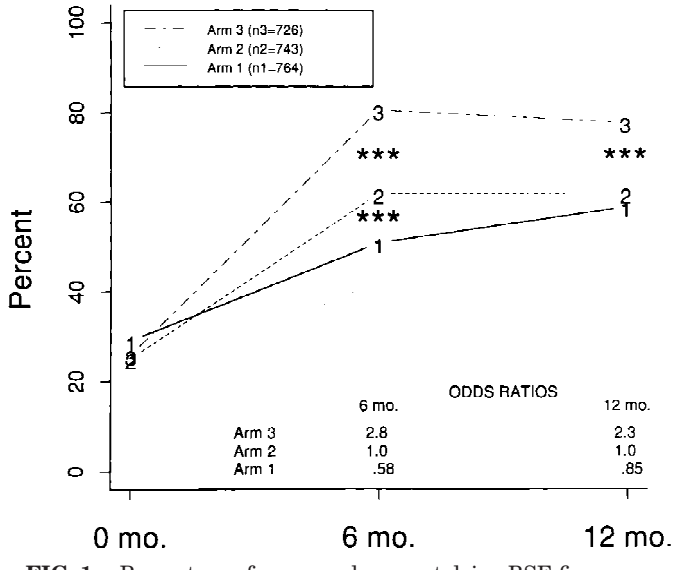

FIG. 1. Percentage of women who report doing BSE five or more times in the past 6 months, by study arm. Arm 1, physician message only; Arm 2, physician message plus BSE class; Arm 3, physician message plus BSE class plus reinforcement. The n's are numbers of subjects randomized. Sample sizes over time equal those for interview accuracy score (Table 3) to within 1%. Odds ratios and P values were calculated from separate logistic models at 6 and 12 months with adjustment for institution and doing BSE at study enrollment. Odds ratios are relative to Arm 2. Confidence intervals are given in the text. ***$P \leq 0.0001$.

did differ among the three study arms ($P \leqslant 0.0001$) and the increases in BSE frequency from enrollment were highly statistically significant within each of the three study arms by the sign test. At 6 months, 51% of women in Arm 1 (physician message only) and 62% of women in Arm 2 (physician message and BSE class) reported doing BSE, a difference of 11 percentage points ($P \leqslant 0.0001$). In Arm 3 (physician message plus BSE class and reinforcement), 81% of women reported regular BSE, 19 percentage points more than in Arm 2 ($P \leqslant 0.0001$). The observed differences in BSE rates between study arms can be interpreted in terms of odds ratios with the same P values. The odds of a woman in Arm 1 doing BSE were 42% lower than for one in Arm 2 (odds ratio = 0.58, 95% confidence interval 0.46, 0.75). The odds of doing BSE were 2.8 times greater for a subject in Arm 3 than for one in Arm 2 (odds ratio = 2.8, 95% confidence interval 2.1, 3.8).

By 12 months the class difference (Arm 1 vs Arm 2) in BSE rates had shrunk to 3 percentage points, which is not significantly different from 0 ($P = 0.19$). However, the 16-percentage-point reinforcement difference (62% for Arm 2 vs 78% for Arm 3) was significant ($P \leqslant 0.0001$). The odds of doing BSE were 15% lower in Arm 1 than in Arm 2 (odds ratio = 0.85, 95% confidence interval 0.70, 1.1). For a woman in Arm 3, the odds of doing BSE were 2.3 times as high as for a woman in Arm 2 (odds ratio = 2.3, 95% confidence interval 1.7, 3.0).

Figure 2 shows BSE frequency plots separately for each of the six institutions in order to display the variation among them. The BSE frequency patterns differ from institution to institution but there is a consistent tendency for Arm 3, the systems approach, to show the highest BSE frequencies. Five of the six institutions show a significant Arm 2 vs Arm 3 difference at 6 months using the traditional 5% level. Institution F, the institution with the low sample size, is the exception. Institution F and four others show a significant Arm 2 vs Arm 3 difference at 12 months. Consistent Arm 1 vs Arm 2 differences are not seen at either 6 or 12 months.

Outcome Data—BSE Accuracy

Table 3 provides information on accuracy in conducting BSE as measured at study intake, at 6 months by in-person interview and demonstration, and at 12 months by telephone interview. Results are shown overall for the six institutions combined and, in less detail, per institution. P values are from the multivariate regression analyses.

For all six institutions combined, mean interview accuracy score did not differ significantly among the three study arms at enrollment ($P = 0.39$) but did so at Month 6 ($P \leqslant 0.0001$) and Month 12 ($P \leqslant 0.0001$). On the 8-point scale, subjects started at a fairly high level, scoring an average of about 5.3. Average gains in scores from study intake to 6 months were significant by the paired t test within each study arm ($P \leqslant 0.0001$). The Arm 1 vs Arm 2 difference in mean interview accuracy scores was 0.68 points at 6 months ($P \leqslant 0.0001$). At 12 months the comparable difference was 0.54 points ($P \leqslant 0.0001$). Within the six institutions, the Arm 1 vs Arm 2 differences for 6-month interview accuracy ranged from 0.03 to 1.12 and five of the six were significant at the traditional 5% level. At 12 months the per-institution interview accuracy Arm 1 vs Arm 2 differences ranged from 0.12 to 0.88 points and were significant in five institutions. The interview accuracy differences between Arms 2 and 3 did not tend to be statistically significant at either time, contrary to the results for BSE frequency. In sum, the addition of a BSE class to physician instruction does appear to improve BSE accuracy as measured by interview, but reinforcement does not further improve accuracy.

Data on BSE accuracy as measured by subject demonstration at enrollment (after physician instruction) and the 6-month visit are also given in Table 3. Again, subjects started at a fairly high level of accuracy, averaging 4.0 on a 5-point scale. The mean demonstration accuracy scores did not differ significantly among the three study arms at intake ($P = 0.32$) but did so at 6 months ($P \leqslant 0.0001$). Average gains in scores from study intake to 6 months were significant by paired t test for all study arms ($P \leqslant 0.0003$ for Arm 1 and $P \leqslant 0.0001$ for Arms 2 and 3). Starting with an enrollment score of 4.0, maximum possible improvement would be 1 point. Subjects in Arms 2 and 3 on average improved by ½ point from enrollment to 6 months. At 6 months, the overall "class effect" for demonstration accuracy was 0.33 points ($P \leqslant 0.0001$). Arm 1 vs Arm 2 differences for the six separate institutions ranged from 0.01 to 0.77 points with four of the six differences being significant at the 5% level. The overall and five of the six institutional Arm 2 vs Arm 3 differences were not statistically significantly different from 0, indicating that the addition of reinforcement reminders to the BSE class was not influential with respect to accuracy as measured by demonstration.

Predictors of Doing BSE

Six subject level predictors (covariates) were considered: (1) age in years at enrollment, (2) postmenopausal (yes/no), (3) some college education (yes/no), (4) annual family income over $25,000 (yes/no), (5) previous involvement with a BSE program (yes/no), and (6) subject feels vulnerable to breast cancer (yes/no), i.e., agreed or strongly agreed with the statement: "My chances of getting breast cancer are high." These variables were added (singly) to logistic regression equations predicting the percentage of women doing BSE at enrollment, 6 months, and 12 months. The models

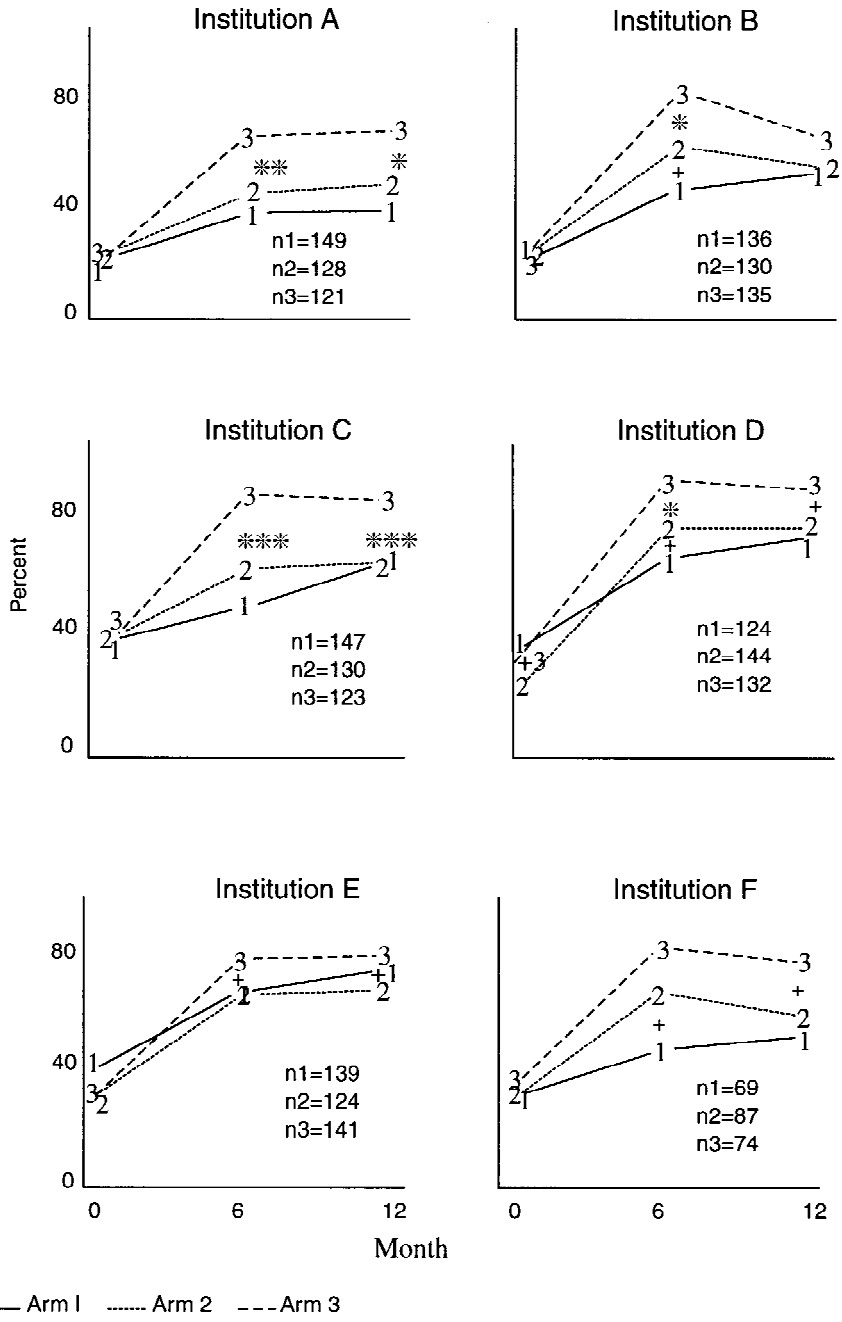

FIG. 2. Percentage of women who report doing BSE five or more times in the past 6 months, by study arm and institution. Arm 1, physician message only; Arm 2, physician message plus BSE class; Arm 3, physician message plus BSE class plus reinforcement. The *n*'s are numbers of subjects randomized. Sample sizes over time equal those for interview accuracy score (Table 3) to within 4%. Odds ratios and *P* values were calculated from separate logistic models at 6 and 12 months for each institution with adjustment for doing BSE at study enrollment. Odds ratios are relative to Arm 2. Confidence intervals are given in the text. $^{+}P \leq 0.05$, $^{*}P \leq 0.01$, $^{**}P \leq 0.001$, $^{***}P \leq 0.0001$.

included dummy variables for institution and treatment arms.

At enrollment the vulnerability covariate had an associated *P* value of 0.04. Among the 21% of subjects who felt vulnerable, 31% reported they were already doing BSE vs 25% for the nonvulnerable. The other five covariates were nonsignificant predictors of BSE frequency at enrollment ($P > 0.05$) although the *P* value for age in years was 0.065. At Months 6 and 12, the strongest predictor of doing BSE was doing BSE at enrollment ($P \leq 0.0001$). For example, 87% of women who did so reported doing BSE at 6 months contrasted with 55% of women who did not do BSE at study enrollment. Therefore for the purpose of identifying covariates that predict doing BSE after the interventions, separate analyses were done for subjects who

TABLE 3

BSE Accuracy: Interview and Demonstration Scores

				Arm 1 MD message only (n = 764)		Arm 2 MD message + BSE class (n = 743)		Arm 3 MD message + BSE class + reinf (n = 726)
Mean interview score,[a] (n)								
Intake, all subjects				5.3 (764)		5.3 (742)		5.4 (723)
Intake, completers				5.3 (688)		5.4 (607)		5.4 (582)
6-month				5.8 (651)		6.5 (593)		6.7 (571)
12-month				6.0 (688)		6.5 (608)		6.6 (585)
Differences[b] between means, P								
6-month, overall					0.68***		0.16†	
6-month, by institution								
	(n1	n2	n3)					
A	(129	99	97)		0.74***		0.42†	
B	(118	101	99)		1.12***		0.13	
C	(133	116	102)		0.31†		0.46†	
D	(115	128	117)		0.67***		−0.16	
E	(106	91	107)		0.03		0.10	
F	(50	58	49)		0.76***		0.03	
12-month, overall					0.54***		0.11	
12-month, by institution								
	(n1	n2	n3)					
A	(129	98	98)		0.61***		0.26	
B	(116	95	90)		0.88***		0.09	
C	(145	117	113)		0.12		0.14	
D	(117	129	119)		0.63***		−0.04	
E	(119	100	108)		0.24		0.14	
F	(62	69	57)		0.33†		0.31	
Mean demonstration score,[c] (n)								
Intake, all subjects				4.0 (763)		3.9 (742)		4.0 (724)
Intake, completers				4.0 (687)		4.0 (607)		4.0 (583)
6-month				4.1 (651)		4.5 (593)		4.5 (571)
Differences[b] between means, P								
6-month, overall					0.33***		0.07	
6-month, by institution[d]								
A					0.53**		0.14	
B					0.77***		0.01	
C					0.05		0.26†	
D					0.10†		0.00	
E					0.01		0.00	
F					0.30†		0.00	

[a] The standard error for each mean is 0.05 except Intake, completers Arms 2 and 3, where it is 0.06.

[b] Differences between mean scores are shown for study arms in adjacent columns. P values are from multiple regression equations with terms for study arms, intake accuracy score, and institutions. (n1 n2 n3), per institution sample sizes for Arms 1, 2, and 3.

[c] The standard error for each mean is 0.04.

[d] Sample sizes identical to 6-month figures above.

† $P \leq 0.05$, **$P \leq 0.001$, ***$P \leq 0.0001$.

reported that they were/were not doing BSE when they entered the study.

Among the quarter of women already doing BSE at study enrollment, none of the six covariates was a strong predictor of doing BSE 6 or 12 months later (i.e., of continuing to do BSE). At 6 months the women who answered "yes" to the breast cancer vulnerability question were somewhat more likely to (still) be doing BSE than the ones who answered no, 93% vs 86% (P = 0.05), but the significance disappeared at 12 months.

Among the three-quarters of the women not doing BSE at enrollment, age was the strongest predictor of doing BSE at 6 and 12 months ($P \leq 0.0001$) for both times and for both age covariates. Older women were more likely than younger women to move from not doing BSE at entry to doing BSE at 6 or 12 months. As an example of the strength of the association, 66% of the postmenopausal women reported doing BSE at 6 months vs 52% of the premenopausal. Education was a weaker and negative predictor. The majority of the women (74%) had some college education. These women were less likely to move from not doing BSE at enrollment to doing so (53% at 6 months and 55% at 12 months) than were those without college, where the

figures were 63 and 66% ($P = 0.06$ at 6 months, $P = 0.03$ at 12 months).

In summary, among the well-educated, high-income subjects in this study, a quarter were already doing BSE when they entered the study. The best predictor of this behavior was perceived vulnerability to breast cancer. Vulnerability was also a weak predictor of which of these women would continue to practice BSE. Among the three-quarters of women not doing BSE at study entry, the best predictors of doing BSE 6 or 12 months later, i.e., success of the interventions, were age (positive association) and some college (negative association).

Influence of Differential Drop-Out Rates on Conclusions

Table 4 compares intervention arms under four treatments of missing data. Procedure 1 results have been presented above (Outcome Data sections). In Procedure 2 data were restricted to observations on the 49% of subjects enrolled after April 1, 1991, the date of the amendment stressing that all subjects were to be followed for 1 year. For this group the drop-out rates by arm were much lower and more nearly equal than for subjects enrolled before the amendment (see Accrual and Follow-Up). Consequently Procedure 2 is less subject than Procedure 1 to the bias of differential follow-up and free of the arbitrary missing data assumptions of Procedures 3 and 4.

In Table 4 the impacts of the BSE class and reinforcement are usually greatest when missing data are ignored (Procedure 1) and smallest in the "missing-like-intake" analysis (Procedure 4). For example, in column 1, the Arm 3 vs Arm 2 difference at 6 months was 19%, indicating that the percentage of women doing BSE in Arm 3 was 19 percentage points higher than for Arm 2. In columns 2 through 4 the comparable differences were 16, 15, and 13%, respectively, reflecting the increasing degree of conservatism of the missing data assumptions.

DISCUSSION/IMPLICATIONS

This study supports the hypothesis that an integrated approach to BSE (the physician message, a BSE class, and reinforcement/follow-up reminders) based on adoption theory improves BSE compliance more than the physician message alone or the physician message and a BSE class. The physician message raised the individual's awareness of a need to change, the first step in the adoption theory. Adding the BSE class achieved the next stage in the adoption theory, i.e., the participants gained knowledge/skills and committed to do BSE. Finally, the addition of phone and mail contacts achieved the third phase of the adoption theory by providing reinforcement.

This study supports previous research findings in terms of the interventions under investigation and adds to the understanding by showing that the addition of a BSE class to the usual physician message improves BSE accuracy, and the integration of the phy-

TABLE 4

Differences between Intervention Arms[a] Using Four Missing Data Procedures

Endpoint difference between Arms	Procedure 1	Procedure 2	Procedure 3[b]	Procedure 4
% of women doing BSE				
Arm 2–Arm 1, 6 months	11%***	12%**	9%	7%**
Arm 2–Arm 1, 12 months	3%	2%	2%	0%
Arm 3–Arm 2, 6 months	19%***	16%***	15%	13%***
Arm 3–Arm 2, 12 months	16%***	15%***	13%	12%***
Mean interview accuracy				
Arm 2–Arm 1, 6 months	0.68***	0.35***	0.54	0.50***
Arm 2–Arm 1, 12 months	0.54***	0.32*	0.44	0.35***
Arm 3–Arm 2, 6 months	0.16†	0.17	0.12	0.15†
Arm 3–Arm 2, 12 months	0.11	0.11	0.08	0.11
Mean demonstration accuracy				
Arm 2–Arm 1, 6 months	0.33***	0.10	0.27	0.25***
Arm 3–Arm 2, 6 months	0.07	0.12	0.05	0.09

Note. Procedure 1, all subjects included, missing observations ignored;[c] Procedure 2, excludes subjects enrolled before protocol amendment, missing observations ignored;[d] Procedure 3, all subjects included, Arm 1 means at 6 (12) months substituted for missing 6 (12)-month observations;[e] and Procedure 4, all subjects included, individual's intake value substituted for missing 6 (12)-month observations.[f]

[a] Arm 1, MD message only; Arm 2, MD message + BSE class; Arm 3, MD message + BSE class + reinforcement.

[b] No tests of significance were performed for Procedure 3.

[c] Total sample size 1,815 at 6 months, 1,881 at 12 months.

[d] Total sample size 909 at 6 months, 967 at 12 months.

[e] With imputation total sample size 2,233 at 6 and 12 months.

[f] With imputation total sample size 2,233 at 6 and 12 months.

† $P \leq 0.05$, *$P \leq 0.01$, **$P \leq 0.001$, ***$P \leq 0.0001$.

sician message, BSE class, and reinforcement improves frequency. Findings in this study appear similar to previous work that has shown that the *physician message* has a major impact on BSE compliance. In this study, the physician message (Arm 1) resulted in a *frequency* compliance (percentage of women doing BSE) of 51% at 6 months and 59% at 12 months (which were significant gains over enrollment percentages) compared with 39–55% reported in earlier studies [*4,7*]. Average participant scores on Arm 1 for accuracy were 73 and 75%, respectively at 6 and 12 months compared with previous studies in which the physician message achieved accuracy scores of 77% [*7*]. It is important, however, to recognize that the significant gains in frequency are likely magnified by the reinforcing effect of being studied; accuracy scores may also have been magnified in that women may have sought answers to questions they did not know.

This study confirms previous findings that a *BSE class* increases frequency and accuracy in doing BSE and also shows that the BSE class increases accuracy over the physician message alone. BSE compliance achieved through education materials and classes has been reported at 40 to 55% in terms of frequency and 50 to 70% in accuracy [*1,10,12,14,18,29,33,36,52,61*]. BSE frequency in the current study was 62% at 6 and 12 months for subjects receiving the physician message and BSE class. For subjects receiving the physician message only, the 6 month BSE frequency was 11 percentage points lower than for those receiving the physician message and the BSE class, demonstrating a significant effect of the BSE class. The 12-month frequency class effect was not significant, again suggesting that being studied had a reinforcement effect. BSE *interview accuracy* was 81% at both 6 and 12 months for subjects on Arm 2 compared with 73% at 6 months and 75% at 12 months for those on Arm 1, showing a significant impact of the BSE class at both times. Those subjects assigned to Arm 2 had interview accuracy scores that were significantly higher than those on Arm 1 for four of the six institutions at 6 months and five of the six institutions at 12 months. For *demonstration accuracy,* those on Arm 1 had an average score of 80% at 6 months compared with a 90% score at 6 months for those on Arm 2.

The *reinforcement* impact on BSE frequency was highly significant in this study even with imputations for missing data. The percentage difference between Arm 2 and Arm 3 was realistically estimated at about 16 to 17%. The percentage reporting doing BSE in the reinforcement arm (Arm 3) of this study was 81% at 6 months and 78% at 12 months compared with frequency compliance rates of about 58% reported in previous research where reinforcement alone or in conjunction with some level of education was offered [*7,23,35,47*]. Reinforcement did not appear to contribute to accuracy in doing BSE and there was no reason to expect that it would.

Limitations of the study are that the population comprised women who were primarily middle income, Caucasian, and prevention oriented, with no previous history of breast cancer or learning disabilities. Thus results are generalizable only to this population. As was noted, three institutions were not able to complete the protocol. These three institutions were large, located in urban settings, had multiethnic populations, and had limited staff. A descriptive contribution is in progress that examines the conditions under which this protocol is possible.

Additional studies are needed and are currently being conducted to address the needs of the elderly, minority, and underserved populations [*9,13,32,38, 39,49,56*]. Methodological studies [*68*] and work on cognitive style [*32*] may also be expected to provide greater understanding of the needs of special populations. In future studies it may be important to address cost reduction by exploring alternative ways of providing reinforcement; current research on reinforcement that involves partnerships [*20,38,39,46*] holds promise in this respect. This study makes an important contribution to the understanding of BSE compliance in providing a prospective randomized clinical trial that supports the importance of an integrated theoretical model.

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