Buddy Program for Breast Cancer Clinical Trials

Final Report

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This work was funded by Grant # CA70596 from National Cancer Institute, in conjunction with the National Action Plan for Breast Cancer.

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Background

Clinical trials are the principal tool for achieving and demonstrating progress in the treatment and prevention of breast cancer. They are used also to assess the impact of risk, disease, treatment and ongoing care on the psychosocial and clinical outcomes of breast cancer patients and their families. Results are used to design and deliver more effective and cost-efficient health care to prevent, detect, diagnose, treat, and facilitate recovery from breast cancer.

As with most diseases, progress in treatment of breast cancer is best accomplished through well-designed, prospective clinical trials. However, patient accrual to clinical trials can be a difficult problem (Mayer et al., 1991; Agras and Bradford, 1992; Wittes & Friedman, 1988; Friedman, 1987; Hunter et al., 1987; Friedman & Cain, 1990). It has been estimated that total accrual to NCI-supported cancer treatment trials in adults represents a small fraction (less than 10%) of the number of patients potentially available (Wittes & Friedman, 1988; Vogelzang et al., 1988). It has been further estimated that Cooperative Group adjuvant trials accrue 1% to 2.5% of potentially available patients (Friedman, 1987; Gotay, 1991). Three major NCI-supported studies had average rates that were 32% to 100% slower than planned projection rates (Wittes & Friedman, 1988).

Slow accrual causes the study to take longer, with several repercussions: (1) access to treatment outcome information is delayed; (2) the trial is more expensive; and (3) ongoing medical progress may alter patient selection, thus biasing results. In addition, women of color, poor women, and those with limited education are underrepresented in clinical trials.

Factors Related to Clinical Trial Participation

Reasons For Participation. Researchers have identified a number of reasons why people participate in clinical trials, including principally: personal benefit (to get better medical care), for science (a belief that research is important), altruism (to benefit others), and doctor's recommendation (Morrill & Avis, 1996; Roberson, 1994; Cunny & Miller, 1994; Cassileth et al., 1982; Mattson et al., 1985; Nealon et al., 1985; Thornton, 1992). Access to trials depends on their being available, affordable, accessible, and acceptable (Petchers, 1988; McCabe, Varricchio & Padber, 1994).

Obstacles to Participation. Obstacles to participation in clinical trials may be categorized as research-related, economic, sociocultural, or individual (Swanson & Ward, 1995). Research-related and economic obstacles include lack of access to centers performing trials, and lack of funding that pays for participation. Although the prospect of free medical care is not a strong draw (Morrill & Avis, 1996; Schron, Wassertheil-Smoller & Pressel, 1997), perceived cost is a deterrent among the economically disadvantaged (McCabe, Varricchio & Padberg, 1994), and transportation an issue for women, older patients, blacks, and the less educated patients (Schron, Wassertheil-Smoller & Pressel, 1997). Sociocultural obstacles have been less commonly advanced, and few studies compare clinical trial motivations across ethnicities. It has been shown that patients who are less educated and less likely to make routine use of medical services are less likely to participate in trials (Hunninghake et al., 1987). Larson and McGuire (1990) found that fewer patients with low education said they would join a study. Patients with less education were more likely to join a study only if there were some personal benefit. Roberson (1994) found that members of minority groups knew little about clinical trials and had limited

opportunity to participate. Although those surveyed had generally positive attitudes toward the benefits of clinical trials, they did identify mistrust of white people, and the prospect of being treated like a guinea pig, as potential deterrents to participation.

Researchers have identified numerous obstacles that pertain to the individual patient, such as: disapproval or belief that clinical research is not important, lack of adequate information, inconvenience such as cost, transportation, or time, anxiety and fear of the unknown, possible risks or discomfort, randomization, feeling like a guinea pig, and lack of family support (Roberson, 1994; Millon-Underwood, Sanders & Davis, 1993; Passkett et al, 1996; Cassileth et al., 1982; Larson & McGuire, 1990; Mayer et al., 1991; Nealon et al., 1985; Cunny & Miller, 1994; Joseph, 1994; Schain, 1994; Mattson et al., 1985; Bujorian, 1988; Hohansen et al., 1991; Lacher, 1981). Mayer et al. (1991) studied 299 patients who were eligible to participate in specific immunotherapy protocols. They found that patient-related obstacles to participation included lack of information about trials, feelings about disease, logistical concerns, and decision-making about medical care.

Attitudes. Larson and McGuire (1990) studied patients' attitudes towards research, desired knowledge about research, and involvement in clinical research. A total of 277 patients from various services (oncology, gynecology, surgery, and medical) of a large tertiary care facility who had participated in clinical research completed a questionnaire about their perceptions of the informed consent process and the research experience. Attitudes towards research were generally positive: 91% thought research helps to improve patient treatment, and 90% thought research was a good idea. However, 22% thought research should not involve sick people, 12% thought they would be used as guinea pigs, and 24% thought patients did not have a choice with respect to participation. Sixty percent stated that they would consider joining a research study whether or not there were personal benefit, but 25% said they would join only if there were some personal benefit.

Lack of Understanding. Cassileth et al. (1982) presented patients with hypothetical cases regarding participation in clinical trials and found that 70% of subjects thought that physicians had prior knowledge of the efficacy of each treatment. Studies have shown that many patients who do participate do not adequately understand the informed consent process. Grossman, Piantadosi and Covahey (1994) used readability software to assess 88 clinical trial informed consent forms. The mean grade level was between 11th and 14th; eighth-grade level was found in 6% or fewer. As many as one-fourth of patients who sign consent forms have been reported to be unaware that they were participating in research (Bergler et al., 1980; Cassileth et al., 1980; Reicken and Ravich, 1982). Cassileth et al. (1980) found that 40% of study participants could not recall the purpose and nature of the procedure they had consented to, despite having read a written consent form and having received a verbal explanation. In a survey by Penman et al. (1984), 90% of those who agreed to participate believed that refusing to consent would seriously endanger their health. Another 43% had no doubt whatsoever that the treatment would be beneficial. In the Larson and McGuire (1990) study, 35% reported not receiving adequate information about a research study; the percentage from the oncology service, however, was 66%.

It is thus well-established that recruitment to clinical trials is difficult and time consuming. Research suggests that many people do not adequately understand the nature of clinical trials and have various anxieties and fears that are often unfounded. Johansen et al. (1991) have recommended that public information should focus on the definition, purpose, and

significance of clinical trials and the importance of randomization. They further recommended that strategies to improve recruitment focus on both education and validation of feelings of fear, anxiety, denial and uncertainty.

Peer Support for Decision-Making about Clinical Trials

Given these challenges, there is much to be said for using a peer support model–built on theories about social support and social learning–combined with an understanding of the nature of decision-making. It is well established that social support can lessen destructive physical and emotional effects of negative life events (Cohen, 1985; Cohen, 1988), and improve health in the face of stress (House, Landis & Umberson, 1988; for reviews, see: Berkman, 1985; Kessler, Price and Wortman, 1985). Studies of women with breast cancer in particular have found that 10-year survival rates were better for women with a spouse (Neale, Tilley & Vernon, 1986), and emotional support was found to be the best predictor of positive adjustment to breast cancer (Delay, 1992). Peer support, then, could help a patient adjust better to breast cancer, and might even benefit her health. This could in turn facilitate the clinical trial decision by reducing stress that might otherwise interfere with the decision-making process.

The decision-making process typically involves the consideration of three elements: (a) the alternatives faced by the individual, (b) potential outcomes of each alternative and its probability, and (c) the value of each outcome to the individual (Payne, Bettman, and Johnson, 1990; see also Morrow, Hickok & Burish, 1994). Cognitive research suggests that the strategy one uses in making a decision depends to a great extent on the criteria used to evaluate the various alternatives (e.g., Russo and Dosher, 1983). If there are only a few critical decision criteria, decision-makers tend to consider all of them. If, however, many dimensions are relevant to making a decision, decision-makers tend to select certain attributes and ignore others in an effort to reduce the amount of cognitive effort required to make the decision.

According to learning theory, one of the most common yet most powerful modes of learning is modeling. While modeling can entail mere imitation, learning is greatly enhanced if the learner identifies with the model. Identification is facilitated when the two persons share common characteristics. Hence, a "buddy" (a peer who has already participated in a clinical trial) can not only provide support but also serve as a role model for the patient, thereby enabling the patient to imagine herself more easily as a trial participant.

Social support may involve several components: informational support, instrumental or problem-solving support, and/or emotional support. A buddy can offer all three. A buddy can help to elucidate and reinforce information the patient receives from health professionals; such support in the rational aspect of decision-making increases the likelihood that the patient will consider all relevant decision criteria, and weigh this information in a rational manner. More importantly, the buddy can supply personal information about the subjective experience of trial participation. And, she can provide emotional support, which was rated as the most important form of support by breast cancer patients in the Delay (1992) study. For instance, a buddy might be able to help the patient imagine herself in a particular situation (e.g., anticipate how she might feel if she learns that she has been receiving a placebo). The more subjective types of social support can facilitate the process of placing values on potential outcomes.

Adding a buddy offers several advantages over standard recruitment by health professionals alone:

1. The buddy has credibility based on personal experience of both breast cancer and clinical trial participation.
2. The candidate can identify with the buddy, and therefore receive information at an emotional as well as cognitive level.
3. The buddy can spend extra time with the candidate beyond that devoted by the health professionals.
4. The buddy communicates verbally and in lay terms, and therefore may be more easily understood by candidates with limited education.
5. Since the buddy is not responsible for covering all of the elements of informed consent, she can focus on personal concerns identified by the candidate as important, while health professionals focus on medical concerns.
6. The buddy does not have any stake in the clinical trial, and can offer an objective voice.

Two programs have demonstrated that peer support can be instrumental in improving health care utilization in underserved populations—poor people and members of ethnic minorities—including, specifically, cancer patients.

The Harlem Cancer Education and Demonstration Project developed a "patient navigator" program to help address the barriers that poor people have in trying to obtain clinical follow-up services for an abnormal finding or cancer diagnosis. The program focused on the time between the abnormal or suspicious cancer screening finding and its diagnostic and therapeutic resolution. The patient navigators acted as proactive patient advocates, to identify, anticipate and help patients overcome barriers before they became an obstacle to prompt diagnostic and treatment resolution of the abnormal or suspicious finding. Of the 131 screening patients referred to navigation, 88% completed recommended breast biopsies, compared to 57% of those without a patient navigator. Moreover, of those who completed biopsies, patients with a navigator did so in significantly less time. In short, having a navigator increased patients' completion of diagnostic workup and reduced delay in that process (Freeman, Muth and Kerner, 1994).

A second community demonstration project, the Atlanta Project, was designed by community coalitions to improve availability, acceptability and accessibility to screening, increase client awareness of the importance of screening, and increase use of screening. Its broader goal is to empower African-American women to accept responsibility for their health maintenance. One component is "Partners for Life," a patient advocacy program to support women with positive results of screening examinations and/or questions and concerns about cancer. Women are matched with a partner to maximize and individualize empathy and concern. Partners are trained volunteers who provide emotional support and education, and assist in arranging transportation, patient follow-up, and guidance throughout follow-up clinic visits and meetings. Before the project began, women in focus groups thought of cancer as a progressive fatal disease from which one does not recover. The Partners for Life project promotes a positive, supportive image of living with breast and cervical disease through the use of caring volunteers and cancer survivors. The same approach also helps women to keep follow-up appointments at the clinic for prescribed therapy and treatment (Curry, Moen, Morris and Scheivelhud, 1994).

The American Cancer Society also operates the "Reach to Recovery" program for women who have had a lumpectomy or mastectomy. Volunteers who completed breast cancer treatment at least one year ago are trained to offer "common sense support," as well as practical

information (for example, about different types of prostheses and where to purchase one) and referrals.

The Buddy Program

The purpose of this pilot project was to develop, evaluate and refine a buddy program for women with breast cancer who are eligible to participate in breast cancer clinical trials. The "buddy" is a woman who has already participated in a breast cancer clinical trial. The Buddy Program paired trial candidates with a buddy who provided information and support through the decision-making process.

The ultimate goal of the Buddy Program was to increase enrollment of women in breast cancer clinical trials. An additional goal was to increase enrollment of women from ethnic minorities and women with limited education.

The Buddy Program was designed to augment existing recruitment strategies. The buddy was to reinforce, in lay terms, the information provided by health professionals, and supplement it by describing her own experience. The intent was to help the candidate to be better prepared for trial participation—not only cognitively, but also emotionally.

There were three phases of the Buddy Program: development, implementation, and evaluation/refinement. The aims of the development phase were to:

- Develop the buddy recruitment protocol and buddy training program
- Implement buddy recruitment and training
- Develop protocols for candidate recruitment, buddy-candidate assignment, and buddy support.

The aims of the implementation phase were to:

- Recruit eligible candidates
- Assign an appropriate buddy for each candidate
- Provide peer support to the candidate until she reaches a decision.

The aims of the evaluation/refinement phase were to:

- Evaluate the structure and usefulness of each component of the Buddy Program, including its impact on the clinical trial decision and decision-making process
- Refine the design of the Buddy Program in light of the evaluations.

Having completed the pilot project, the Buddy Program can be replicated, and tested in a larger, randomized study of its effectiveness as a recruitment tool.

Method

Participants and Recruitment

Buddies

To identify potential buddies who had been in a breast cancer clinical trial, clinical staff at the first collaborating site sent a letter to all women who had completed a breast cancer clinical trial within the past year. The letter explained the program, indicated that the recipient may qualify to be a buddy, and asked her to return a postcard if she would like someone from

NERI to contact her to explain more about the program. NERI staff invited respondents to an orientation session to meet project staff and learn more about it before they were asked to commit to lengthy training. Those who were interested completed a volunteer application form and a date was set for the buddy training session.

Clinical staff at the five later sites recruited buddies more informally. They contacted potential buddies by phone or in person, explained the project, and when there were enough interested buddies, they established a date for the training session. Because most women approached about the project had no difficulty deciding whether or not they wished to attend a training session, the orientation was deemed an unnecessary extra step. They completed the volunteer application at the training session.

We continued to recruit and train new buddies throughout the years of implementation. In order to serve candidates for the Study of Tamoxifen and Raloxifene ("STAR") prevention trial, in the final year we recruited and trained several "graduates" of the tamoxifen prevention trial and two women who had been in the STAR trial for at least six months. (Six months was deemed to be enough experience to qualify as a buddy, and was longer than the length of some treatment trials).

Candidates

The original plan had been to recruit candidates from two collaborating clinical facilities over a two-year period. Oncologists would offer the Buddy Program to all women who qualified for an adjuvant treatment trial at the time they presented a trial to the candidate. However, Lahey Clinic failed to approve the protocol, and the number of referrals from Boston Medical Center was inadequate. Therefore, a number of changes were made to enhance recruitment.

New sites were added throughout the four years of implementation, and the Buddy Program protocol was ultimately approved at eleven clinical facilities. The first avenue was to contact 21 Principal Investigators of Community Cooperative Oncology Programs (CCOPS), as well as representatives of Eastern Cooperative Oncology Group (ECOG), National Surgical Adjuvant Breast and Bowel Project (NSABP), and Southwest Oncology Group (SWOG). Also during this time, several Web sites began posting lists of open clinical trials, eligibility criteria, and the names of Principal Investigators. From this information source, we located and contacted 67 Principal Investigators of breast cancer clinical trials. Of the investigators who spoke with us but did not collaborate, the most common reasons given were:

(1) Current rates of trial enrollment were acceptable
(2) Oncologists objected to their patients having contact with patients of other physicians
(3) Insufficient staff resources to take on any added responsibility
(4) No one person knows when women are presented with a trial, and/or too many clinicians present trials to patients
(5) There was already a comparable informal procedure in place
(6) Too few individuals were expected to be eligible.

To improve the likelihood of referral, we worked directly with clinical research nurses who were willing and able to take responsibility for recruitment to the Buddy Program. A total of 23 candidates were recruited from clinical sites.

Another challenge to Buddy Program recruitment was the changing number of open trials. A major NSABP trials was suspended for an extended period of time during this study.

To compensate for the smaller number of adjuvant trials, the Buddy Program criteria were expanded to include candidates for the STAR prevention trial and treatment trials for patients with metastatic cancer.

In addition to recruiting via clinical sites, we pursued several avenues whereby women could refer themselves to the Buddy Program directly. An announcement was sent to National Breast Cancer Coalition State Coordinators in nine states in the Northeast and Florida, and to Regional Breast Cancer Support Groups listed in the National Association of Breast Cancer Organizations Breast Cancer Resource List. Y-Me in Chicago distributed a flyer of the program with its newsletter to 100 members. A Web page was launched. To make the Web site known, we submitted it to numerous search engines and applied to approximately 12 relevant Web sites to ask that they place links to the Buddy Program Web site. The following organizations established links at our request: NABCO, SWOG, and (after 3 years' delay) CancerNet (NCI). An unknown number of other Web sites may have added links without our having requested them. A total of 133 inquiries were received from the Web site. Of those respondents, 21 were eligible for the Buddy Program and 20 participated.

Ineligible Respondents

Most of the people who inquired via the Web were not eligible for the Buddy Program, usually because they were not eligible for a breast cancer clinical trial. Typically, ineligible respondents were searching the Web to find a clinical trial. A few of the respondents did not have breast cancer, and/or were inquiring on behalf of a loved one with breast cancer; a few more had already been in a clinical trial and wanted to volunteer as a buddy.

Given the volume of responses to the Web site, we were determined to learn about the experiences of the ineligible breast cancer survivors who were searching the Web for information about clinical trials. Including these respondents would allow us to expand the scope of research by making some additional comparisons, for example, women who seek out a clinical trial versus women who are first approached by a provider, and women who were did and did not have a buddy. Therefore, we invited these respondents to complete a written questionnaire. The instrument was similar to the follow-up telephone interview administered to the eligible candidates taking part in the Buddy Program, but questions about the buddy were omitted. Of the Web inquiries, 97 were female breast cancer survivors for whom we had a mailing or email address. Replies were received from 33 women. Of these ineligible respondents, five had subsequently been invited to participate in a breast cancer clinical trial, and 28 had not. These respondents were not paid, and returning the survey was deemed to constitute informed consent.

Because this part of the research was not part of the original plan, analysis of these results was deferred until completion of the original project. A manuscript is planned that will include those results.

Procedures

Buddies

Women who volunteered to serve as buddies attended a structured training session. Training of the initial group of buddies was conducted at Boston Medical Center by an oncology social worker who was Director of Family Services at the American Cancer Society, together

with the Principal Investigator. At Sylvester Comprehensive Cancer Center training was conducted by the Clinical Director. At the remaining four sites training was conducted by the Principal Investigator. The training sessions were approximately 4 to 4½ hours long, including a ½-hour break for a meal. Most were scheduled on a weekday evening, around 5 p.m. The sessions were held at the medical facility in a conference room, with the exception of one that was in a private room at a restaurant.

Before the training session, each buddy signed an informed consent form, as well as an oath of confidentiality. Training addressed the following topics: the buddy's role and possible role conflict, what kinds of information the buddy can best provide and when to refer to a health professional, types and amount of contact to expect, potential problems and trouble-shooting, confidentiality, records and filling out the evaluation report and ending the buddy-candidate relationship. Group discussion on each of the topics was stimulated by passing out a card describing a potential situation or problem that might arise, asking the recipient to indicate how she might respond, and then asking others for their thoughts. Participants received a manual that contained a summary of the program and the research, a description of procedures, a list of support groups in the relevant state and other potential referrals, samples of all consent forms and interviews, blank contact records and reimbursement forms, and a packet of informational literature about breast cancer and clinical trials. At the end of a training, each buddy received a certificate of achievement.

Buddies were asked to be available for as many as 5 candidates in the course of a year. Buddies were not paid, in order to avoid any appearance that they were professional recruiters. At the end of the project they received as a token of appreciation: $50 if they had no referrals, $100 if they had one or two referrals, and $200 if they had more than two referrals.

Three of the women who had been trained (from three different sites) decided soon afterwards that they did not wish to participate. Two indicated they were over-committed and one concluded the program was not what she had expected. Thus, the final number of buddies was 28 (7 from prevention trials and 21 from treatment trials).

Candidates

When a candidate was referred from a clinical site, site staff would obtain informed consent, then forward referral information to NERI. During the initial phone call from NERI, each candidate completed a 20-minute baseline interview. When candidates referred themselves, the NERI interviewer would send a consent form to the candidate, usually by overnight delivery. A release form was included, to allow NERI to send a letter to the woman’s physician to describe the program and ask the physician to verify that the patient was eligible for a breast cancer clinical trial.

Upon receipt of the signed consent form, the intervention (described below) was implemented. Soon after the candidate reached a decision about clinical trial enrollment, she would complete a 30-minute follow-up telephone interview. A decision to enroll was considered final upon signing the trial consent form. Of the original 43 candidates who enrolled and completed a baseline interview, 31 (72%) completed a follow-up interview. Of the 12 who did not complete the follow-up, all but one were self-referrals via the Web: three were lost to follow-up, three were ineligible (one because there was no prevention buddy available yet, and two reached a decision before the buddy was able to make contact), and six withdrew. The most

common reason for withdrawal was that the person found someone local with whom to discuss her options and no longer felt a buddy was needed.

Candidates were paid $15 upon completion of the baseline interview, and $25 upon completion of the follow-up interview.

Intervention

Using the information from the baseline interview, the principal investigator or project coordinator selected and prioritized several potential buddies, and determined their availability. Candidates for the prevention trial were always matched with a buddy from a prevention trial. Otherwise, the match was generally based on a combination of type of breast cancer and surgery, age, marital status, and number and ages of children. Selection was not based primarily on matching the trial, which might pose greater temptation for the pair to focus on medical information. Immediate availability of the buddy was often a determinant. Upon receiving the signed consent form from the candidate, the researcher gave the candidate's name and phone number to the buddy who was standing by.

When matched with a candidate, the buddy initiated the first contact by telephone, and was available by telephone until the candidate reached her decision about whether to enroll in the breast cancer clinical trial.

Measures

Buddies

In the volunteer application, buddies reported their sociodemographic characteristics and gave pertinent information about their health and/or breast cancer or risk factors for breast cancer and their clinical trial experience.

To assess the training, buddies completed a brief evaluation, including their assessment of the appropriateness and usefulness of the topics covered and the materials provided. Questions in the evaluation of the first training were all open-ended. The version used to evaluate subsequent training sessions included responses on a 5-point Likert-type scale, ranging from 1="not at all" to 5="extremely."

To monitor buddies' interactions with candidates, buddies completed a brief report of each contact. They reported who initiated each contact, whether it was in person, by telephone, or written, and a summary of the candidate's concerns and how the buddy responded.

Finally, buddies assessed the program in a final meeting or, for those who were unable to attend, by completing a written feedback form.

Candidates

In the baseline telephone questionnaire, candidates reported their sociodemographic characteristics, and background about their health and breast cancer or risk for breast cancer, and the trial they were considering. To assess understanding, candidates were asked their opinion (on a scale from 1="strongly disagree" to 5="strongly agree") as to whether doctors know privately which treatment under investigation is best. They were also asked how well informed they felt about what a clinical trial was, on a scale from 1="not at all" to 5="very well."

Candidates reported what they believed to be the benefits and drawbacks of participating in breast cancer clinical trials. After recording the open-ended answers, the interviewer read a list of 10 factors that respondents in previous NERI research had identified as benefits, and asked respondents to indicate how much of a benefit they believed each to be, on a scale from 1="not at all a benefit" to 5= "very much a benefit." Then, the interviewer read a list of 13 factors that respondents in previous NERI research had identified as drawbacks of trial participation, and asked them to indicate how much of a drawback they believed each to be, on a scale from 1="not at all a drawback" to 5= "very much a drawback." An average benefit and average drawback score were created using the means of the items on each list.

After reaching a decision about clinical trial enrollment, each candidate completed a 30-minute follow-up telephone questionnaire. The follow-up questionnaire included most of the same questions asked at baseline. However, the questions about the list of benefits and drawbacks, instead of being hypothetical, were rephrased to ask how important each item was in their own personal decision, on a scale from 1="not at all important" to 5="very important." Two items were added to each list, to gage the importance of influence by health care providers and those close to the respondent. Candidates were also asked how well informed they felt about six aspects of clinical trials (again, items from previous NERI research were used), from 1="poorly informed" to 5="very well informed." An additional section of the follow-up questionnaire asked about the candidate's experience with the buddy – how many times they spoke, what topics they discussed, how helpful the discussions were and why. Similar questions were asked about discussions with providers and others.

Clinical sites

To understand patterns of trial recruitment, clinical sites were asked to provide summary information for July and August, 2000, about open trials, the number of potentially eligible candidates, and the main reasons for not referring candidates and for candidates declining referral to the Buddy Program.

Analyses

Because of the pilot nature of this study, most of the data were qualitative. They were collected in a systematic way, and summarized giving greater emphasis to responses that were repeated by more than one respondent. Quantitative data were analyzed using primarily descriptive statistics. Difference of means tests were used to detect changes in continuous measures from baseline to follow-up.

Results

Participants and Recruitment

Recruitment of buddies was easier than expected. A total of 31 buddies were recruited and trained at the six sites listed (in chronological order) in Table 1. There were almost always several potential buddies on a waiting list in case another training were to be scheduled.

Recruitment of candidates was more difficult than expected. A total of 43 candidates were recruited: 23 from six of the 11 clinical sites (five recruited no candidates at all) and 20 from the Web site.

Table 1. Number of Buddies and Candidates, by Recruitment Site and Trial Type

Site	Buddies (n=31)		Candidates (n=43)	
	Treatment	Prevention	Treatment	Prevention
Boston Medical Center (Boston, MA)	6	–	1	–
Sylvester Comprehensive Cancer Center (Miami, FL)	5	–	0	–
Yale Cancer Center (New Haven, CT)	4	–	12	–
University of Massachusetts Medical Center (Worcester, MA)	–	–	0	1
Lone Star Oncology (Austin, TX)	–	–	0	–
Marin Oncology Associates (Greenbrae, CA)	–	–	0	–
Montefiore Medical Center (Bronx, NY)	–	–	0	–
Ocala Oncology (Ocala, FL)	–	–	0	–
Sir Mortimer B. Davis Jewish General Hospital (Montreal Quebec, Canada)	2	3	0	0
Baystate Medical Center (Springfield, MA)	6	3	2	1
Beth Israel Deaconess Medical Center (Boston, MA)	–	2	–	6
World Wide Web			18	2
Total	21	8	33	10

The original approach for recruiting candidates to the Buddy Program was not successful. Reports from the sites indicate that in July and August, 2000, when a total of 8 candidates joined the Buddy Program from clinical sites, roughly 10-12 women a month may have been eligible but were not offered the Buddy Program, and a similar number declined. A variety of reasons were given.

At several sites, the oncologist liked the idea of the project, but didn't take the time to offer it. Only one referral was made by an oncologist. Successful recruitment at clinical sites occurred only when clinical research nursing staff approached the candidate. Although some women enrolled in the clinical trial immediately, most were referred to support staff for a follow-up appointment. (When the physician did not initiate the referral, however, support staff did not know who has been offered a trial). Given that this appointment often occurred several days later, many candidates were lost because they had reached their decision about trial enrollment by the time they first learned of the Buddy Program. At some sites, staff adopted the practice of enclosing a flyer about the Buddy Program with all promotional and consent materials that the oncologists use when presenting a trial.

Economics were a factor in Boston. Third party payers excluded coverage treatment under investigation because it was deemed "experimental." This ruling virtually shut down trial recruitment at Boston Medical Center, which serves a very large portion of indigent patients.

One site felt that the need had decreased because candidates are better informed and more receptive: "Initially … we frequently had inquiries from many women about decision-making for clinical trials. It is obvious that the trend has changed and women are much more accepting, at this centre, to be part of a study. Women seem to be better informed and seek out centres that offer the trials. It appears to be a more sophisticated and educated population." Now, women come to that program asking to speak with a volunteer after they have begun the trial.

The most commonly cited reason for women declining the Buddy Program was that women who are considering a trial are often already overwhelmed with new people, information, and paperwork, and do not want to talk with one more stranger at that time. Others were already certain that they would or would not enroll in the trial. Some felt they already had enough support available, and a few were simply too busy.

The Web site was by far the most effective recruitment source. By the end of the study, the Web site was generating an average of two inquiries a week. Self-referrals from the Web produced nearly half of the candidates who participated.

Participant Characteristics

The sociodemographic characteristics of the buddies and candidates are set forth in Table 2. Participants were, on average, highly educated: all had completed at least high school. A similar percent were employed. The candidates were also relatively well-to-do: more than half had annual household income over $50,000 (income information was not provided by the buddies). Only two buddies were of minority ethnicity (Armenian and African American) and one candidate (Hispanic). Sadly, the African American buddy died during the end of the project. Ethnic homogeneity is typical of Massachusetts, where 17 of the 31 buddies and 10 of the 43 candidates were recruited; in the Eastern Massachusetts area, African Americans comprise the largest minority population (5%) and less than 1% are Hispanic. The ethnic homogeneity is also probably related to the class bias in the samples. Boston Medical Center was to have been the main source of low-income and minority candidates.

Table 2. Sociodemographic Characteristics – Buddies and Candidates

Variable	Buddies (n=28) % (n)	Candidates (n=43) % (n)
Age	Range 31-71	Range 32-73
	49 (9.5)	49 (10.9)
Relationship status		
Single	4% (1)	23% (10)
Married	75% (21)	77% (33)
Divorced/widowed	18% (5)	0% (0)
Children		
0	18% (5)	18% (7)
1-2	50% (14)	45% (18)
3/+	32% (9)	38% (15)
Education		
High school degree	11% (3)	16% (7)
Some college	39% (11)	42% (18)
College degree	21% (6)	23% (10)
Graduate school	35% (8)	19% (8)
Employed		
Full-time or part-time	36% (10)	35% (15)
Unemployed	{ 64% (18)	42% (18)
Retired	{	19% (8)
Other		5% (2)
Annual Household Income*		
Below $10,000		8% (3)
$10,000 to $50,000	Not	33% (12)
$50,000 to $100,000	available	33% (12)
$100,000 or more		25% (9)

* n = 36.

Health background information is set forth in Table 3. It is notable that more of the buddies than candidates with breast cancer had been diagnosed at an early stage of cancer, and fewer had had a mastectomy. In spite of their breast cancer, most candidates for treatment trials rated their current health at baseline as "excellent" or "very good," and rated their life satisfaction as 6 or 7. Nearly half had missed no days of work or other usual activities in the past month due to illness. Candidates for the prevention trial reported better health and greater satisfaction with their lives than candidates for treatment trials.

Table 3. Health Background – Buddies and Candidates

Variable	Buddies - Treatment (n=21) % (n)	Candidates Treatment (n=33) % (n)	Candidates Prevention (n=10) % (n)
Stage of Cancer			
0		4% (1)	NA
I	8% (1)	12% (3)	
II	66% (8)	38% (9)	
III	25% (14)	33% (8)	
IV		12% (3)	
Missing	– (9)	– (10)	
Treatment*			
Lumpectomy/partial mastectomy	57% (12)	47% (15)	NA
Axillary node dissection	24% (5)	88% (29)	
Mastectomy	48% (10)	67% (22)	
Breast reconstruction	24% (5)	27% (9)	
Days of work/usual activities missed last month due to illness	–	36% (12)	89% (8)
None		24% (8)	11% (1)
1-15		40% (13)	–
16-30			
Self-reported health status			
Excellent		33% (11)	30% (3)
Very good	–	30% (10)	50% (5)
Good		21% (7)	20% (2)
Fair or Poor		15% (5)	–
Life Satisfaction (1 to 7**)			
1-2		2% (6)	–
3-5	–	48% (16)	40% (4)
6-7		45% (15)	60% (6)

* Totals exceeds 100% because categories are not mutually exclusive.

** 1=Complete dissatisfaction to 7=Complete satisfaction

Buddy Training

Twenty-one of the buddies completed and submitted an evaluation of the training session. The buddies were in general quite enthusiastic about the training. Several remarked that they appreciated an isolated setting and the informal atmosphere, which was enhanced by sharing a meal, although one buddy would have preferred to dispense with all social aspects of participation. The interactive aspects of the training were rated as more useful than the written materials (see Table 4 below). In particular, comments in earlier sessions asked for more of the role-playing exercises. As the implementation phase progressed, new "situation card" exercises

were added based on actual experiences of buddies. In the later sessions participants remarked on how stimulating and useful the exercises were.

Table 4. Evaluation of Buddy Training

	Appropriate		Useful	
	Mean	**(SD)**	**Mean**	**(SD)**
How appropriate and useful was each topic? (1 to 5*):				
Goals of program and research	4.0	(0.40)	4.0	(0.39)
Buddy relationship and what to expect	4.0	(0.40)	4.1	(0.40)
How to handle questions that might come up	4.0	(0.38)	3.9	(0.40)
Completing paperwork	4.0	(0.39)	3.8	(0.40)
How appropriate and useful were written materials? (1 to 5*):				
Main text of manual	3.5	(0.50)	3.6	(0.48)
Interpersonal techniques	3.8	(0.44)	3.8	(0.42)
Sample of candidates' consent form and interviews	3.5	(0.48)	3.5	(0.47)
Contact records and reimbursement forms	3.9	(0.43)	3.9	(0.44)
Brochures [general info about breast cancer]	3.8	(0.44)	3.5	(0.39)

* 1=Not appropriate/useful to 5=Very appropriate/useful

After the training most of the buddies felt quite well prepared. When asked "How confident do you feel in your ability to be a buddy?," using the same 1-5 scale, the average response was 3.9 (sd=0.38).

The buddies expressed a desire to meet again on a regular basis, at least during their first months serving as a buddy. Although this was not done because of the slow referral of candidates, it definitely would be advisable in an expanded program.

Candidates' Information Sources and Understanding of Clinical Trials

Buddy-Candidate Interactions

All of the buddy-candidate pairs managed to make contact. We obtained information about these contacts both from the buddies (who submitted reports on contacts with 27 of the 31 candidates), and from all 31 candidates who completed the follow-up interview. According to protocol, the buddy always initiated the first contact by telephone. On average, buddy-candidate pairs had 1.6 contacts (about one-third of the pairs had more than one contact) and communicated for a total of 45-65 minutes. Nearly all subsequent contacts were initiated by the buddy as well. In only two instances did the pair meet in person.

By far the most common topic of candidates' concern was possible side effects (e.g., pain, hair loss, nausea, menopausal symptoms), raised by 13 of 23 candidates for treatment trials, and six of eight candidates for prevention trials. Buddies usually described their own trial experiences, qualifying them with a statement that everyone is different. The majority of

candidates mentioned the buddy's experience as a topic of discussion, and cast it in a favorable light.

Aside from a shared concern about side effects, however, the discussions differed sharply between the treatment and prevention candidates. The treatment candidates were more likely to ask the buddies about their own experience (e.g., their breast cancer, treatment, how they handled it, did they work, why did they enroll)(n=9). They also had more questions in general – about the protocol (6), its safety (3) and efficacy (3), and insurance coverage or expenses (6). And seven of the treatment candidates were especially appreciative of practical tips offered by the buddies. By contrast, the prevention candidates had fewer questions. Although they did discuss a few positive and negative features of trial participation, some also questioned whether their personal risk for breast cancer warranted participation. Three indicated they felt a lack of urgency, and had "put the decision on the back burner." Buddies described three of the prevention candidates as "resistant" to the their efforts to be helpful.

Other sources of information

Candidates spent similar amounts of time discussing their trial decision with clinical staff and with their buddy (see Table 5). Most (n=24) also discussed it with someone else. About half of these were discussions with a second member of the clinical staff, and about half were with a lay person (usually a friend or peer). Eighty percent of the candidates reported receiving materials, almost always written materials, about the trial, such as the consent form. They rated all of the discussions and the materials as roughly comparable in terms of how helpful they were in the candidate's reaching a decision about trial participation

Table 5. Sources of Information about the Clinical Trial

Variable	Discussions with Buddy Mean (SD)	Discussions with Staff Mean (SD)	Discussions with Other** Mean (SD)	Materials Received Mean (SD)
Number of discussions about trial	1.6 (0.89)	2 (1.1)	6.5 (8.6)	– –
Total minutes of discussion	55 (46)	46 (41)	23 (34)	– –
How helpful were discussions /materials (1 to 5*)	4.0 (1.3)	4.2 (1.2)	4.3 (1.7)	4.4 (0.91)

* 1=Not at all a helpful to 5=Very helpful

** n=24

Understanding of clinical trials

At baseline, all but three, or 93%, of the candidates felt they understood well (4 or 5 on a scale of 1 to 5) what a clinical trial is, and only 19% of the candidates believed (1 or 2 on a scale from 1 to 5) that doctors know privately which treatment under investigation is best. At follow-up, the average ratings on these items did not change significantly.

When asked at follow-up about specific aspects of clinical trials (see Table 6), candidates felt well informed about the benefits and risks, and their involvement, but felt poorly informed about what aspects of the treatment would or would not be covered by insurance.

Table 6. How Well Informed Candidates Felt about Clinical Trials at Follow-Up

Aspect of Clinical Trial	Mean* (SD)
The nature and purpose of the clinical trial	4.58 (0.56)
What your involvement would be	4.50 (0.82)
Benefits of participation	4.23 (0.92)
Risks of participation	4.13 (0.99)
The time commitment required	4.10 (1.12)
Which expenses would and would not be covered by insurance	3.26 (1.48)

* 1=Poorly informed to 5=Very well informed

Candidates' Attitudes toward Clinical Trials

Benefits/factors in favor of participation

At baseline, the highest rated benefits of trial participation were altruistic ones: a belief that research is important, and a desire to help others with breast cancer or at high risk for breast cancer (Table 7). Rated only slightly lower were personal medical concerns, such as getting the newest treatment or best medical care. Less important benefits included the opportunity to get more information, have one's health followed more closely or see providers more often. The lowest rated benefit was the possibility of free treatment or care.

Table 7. Perceived Benefits/Factors in Favor of Participating in Clinical Trail

Benefit/Importance of Factor in Favor	Baseline Mean (SD)	Follow-up Mean (SD)	T	p
A belief that research is important	4.72 (0.70)	4.58 (0.76)	-1.36	0.18
Helping others who have breast cancer or high risk for breast cancer	4.70 (0.77)	4.42 (0.93)	-2.44	0.02
Chance to get the newest treatment	4.53 (0.77)	4.32 (0.94)	-0.52	0.61
Being involved in developing new ways to treat or prevent breast cancer	4.51 (0.80)	4.35 (0.88)	-1.65	0.11
Getting the best medical care	4.44 (1.00)	4.35 (1.20)	-0.78	0.44
Doing something positive for yourself	4.40 (1.05)	4.52 (0.92)	0.15	0.88
More chance to ask questions or get more information	4.26 (1.05)	4.16 (1.07)	-0.81	0.42
Your health being followed more closely	4.09 (1.21)	4.10 (1.25)	-1.23	0.23
Seeing your health care providers more often	3.65 (1.31)	3.65 (1.47)	-1.31	0.20
Possibility of free treatment or health care	3.37 (1.60)	2.65 (1.72)	-2.92	0.006
Your health care provider recommended it	N/A	3.81 (1.38)	N/A	N/A
A family member or friend recommended it	N/A	2.55 (1.63)	N/A	N/A
Overall	**4.27 (0.69)**	**4.11 (0.75)**	**-2.81**	**0.009**

At follow-up, when asked how important each item was in the candidate's own decision, the ratings of individual items were not very different. Only helping others or the possibility of free treatment or care were rated significantly lower. Doing something positive for oneself, with a slightly higher rating, moved up the ladder of priorities. The two newly added items, recommendations of a provider or family member or friend, were ranked quite low in importance. Overall, however, the average rating of benefits declined significantly, by 0.16.

Drawbacks/factors against participation

The most serious drawback was the possible side effects of treatment. Risks of the experimental treatment, uncertainty and the prospect of not getting the best treatment were also high on the list, as were insurance concerns. Practical considerations were the least worrisome.

Table 8. Perceived Drawbacks of/Factors Against Participating in Clinical Trail

Drawback/Importance of Factor Against	Baseline Mean (SD)	Follow-up Mean (SD)	T	p
Possible side effects of treatment	3.95 (1.09)	3.52 (1.41)	-0.78	0.44
The experimental treatment might be risky	3.79 (1.30)	3.47 (1.28)	-1.31	0.20
Treatment might not be covered by insurance	3.65 (1.48)	2.73 (1.72)	-3.50	0.0015
May not get the best treatment	3.56 (1.50)	2.67 (1.49)	-3.16	0.003
Not knowing which treatment you'll receive	3.37 (1.50)	2.87 (1.52)	-1.87	0.07
It requires more clinic appointments	2.77 (1.46)	2.13 (1.41)	-2.71	0.01
Mistrust of research, feeling like a guinea pig	2.40 (1.35)	2.13 (1.12)	-1.25	0.22
Takes too much time or disrupts daily routine	2.33 (1.21)	2.06 (1.34)	-1.13	0.27
Loss of privacy or confidentiality	2.33 (1.23)	1.81 (1.05)	-3.32	0.002
There is no direct personal benefit	1.95 (1.31)	1.77 (1.10)	-1.03	0.31
Getting transportation to appointments, or arranging childcare	1.93 (1.18)	1.60 (1.28)	-1.51	0.14
May change relationship with health care provider	1.93 (1.08)	1.94 (1.26)	-0.52	0.61
You preferred a different treatment*	NA	2.30 (1.55)	NA	NA
A health care provider advised against it**	NA	2.29 (1.49)	NA	NA
A family member or friend opposed it	NA	1.57 (1.14)	NA	NA
Overall	**2.83 (0.78)**	**2.39 (0.77)**	**-3.52**	**0.0014**

*n=23

**n=17

At follow-up, when asked how important each item was in the candidate's own decision, the ratings of four individual items were significantly lower: the prospect of not getting the best treatment, insurance concerns, the number of appointments and loss of privacy. Overall, the average rating of drawbacks declined by 0.44.

Thus, although the average ratings of benefits went from 4.29 at baseline to 4.11 at follow-up, the average rating of drawbacks declined more sharply, from 2.83 to 2.39. A comparison of the change in the two average ratings was not quite significant (t=1.99, p=.06).

Trial enrollment decision

Overall, 86% of the treatment candidates and 44% of the prevention candidates decided to enroll in the clinical trial (see Table 9). Four of the candidates considering prevention trial (44%) had not yet reached a decision by the end of the project (the window allowed was quite long).

Table 9. Enrollment Decision by Type of Trial

Enrolled	Treatment (n=22)	Prevention (n=9)
No (n=4)	14% (3)	11% (1)
Yes (n=23)	86% (19)	44% (4)
Undecided (n=4)	– (0)	44% (4)

The prevention candidate who decided not to enroll cited other medical problems. She also remarked that she "could still change my mind at any time." Of the three treatment candidates who did not enroll, one did not want to enter unless the trial had already reported favorable results. One was already undergoing a regimen of chemotherapy that had been successful for many other patients and was not available in one arm of the trial offered. The third did not have confidence that the principal investigator (who had not been her oncologist) would carry out her own best interests. Given the small number who declined, statistical tests comparing participants who did and did not enroll are of questionable validity, and were not performed.

Refinement of the Program

Feedback about the program was collected at the final meeting attended by six of the buddies and one provider, and by written feedback forms submitted by nine buddies and two provider. Two of the buddies died before the end of the program.

Speaking of their experience, many buddies remarked that it was enjoyable and fulfilling; they liked the opportunity to do something for others, to "give something back." It was also easier than expected, and not overly demanding. They had expected more questions about the specifics of the trial, but found that candidates understood the protocol fairly well. This allowed the buddies to help with more practical, non-medical issues, with which they felt comfortable. Still, each referral was an emotional experience and a learning experience for the buddy. In some instances the candidate had already decided to enroll, but just needed someone to answer some additional questions before they signed the trial consent form. A comment expressed by most buddies was that it was difficult to sense whether they had been helpful, as there was no formal way of obtaining feedback or closure.

The buddy experience was different for prevention pairs and treatment pairs in that the women with breast cancer were more scared. Also, while timing is critical for the treatment trials (of which there were more different types), there was no rush to reach a decision on entering a prevention trial.

When asked what worked well, the buddies felt that they and the candidates were well prepared for what to expect of each other and the program. The buddies received enough useful information about candidates being referred, and the matches worked well. The buddies felt there was enough support available from staff.

When asked what could be improved, many were disappointed not to receive more referrals and have more chance to use their training and build on experience. They agreed strongly that institutional change – getting doctors to believe that this is something important, (and look at more than just the disease) – is essential. They suggested doctors ask at each initial

visit "Do you want to talk with someone who has been through it?" Although the reporting of their contact with the candidate was not burdensome, conversations did not always fit the project's forms; a checklist might have made it easier. The buddies would definitely like to receive feedback from the candidates and be notified when a decision had been reached and what it was. They also wanted to continue the relationship beyond the initial decision – for treatment trials until the trial ends, and for prevention trials, through the first six months.

All of the buddies expressed a willingness to continue to serve if the program could be extended beyond the research phase, provided funding could be found for someone to continue the process of screening candidates, selecting an appropriate match, and monitoring the number of referrals to each buddy. While they did appreciate receiving a gift, many commented that it was unnecessary, they were glad to help someone.

Conclusions

The Buddy Program is a good concept, very worthwhile and satisfying for those who participated, but recruitment of candidates from clinical sites is quite problematic. For recruiting women with breast cancer, due to the urgency of treatment, timing is critical. If a buddy is to be of help, she must be available to the candidate immediately. Oncologists who present trials to eligible candidates clearly have the best (if not the only) access at the critical juncture of time, yet did not offer the Buddy Program. Clinical research nursing staff can be counted on to offer a buddy program, but their success is hampered by any delay in the oncologist's referral to support staff. In short, for a buddy program to recruit effectively at clinical sites, institutional change would be necessary.

To the extent that candidates who declined the Buddy Program were deterred by the prospect of yet another research program, a buddy program that is purely service-oriented, and not part of a pilot research study, would presumably be received (and therefore, presumably, promoted) with greater enthusiasm.

Timing is not critical for prevention trials, and other than side effects, candidates have fewer and mostly different concerns. For these reasons, a buddy program for prevention trials should be separate from a buddy program for treatment trials.

By contrast, there were many inquiries from women searching the Web – indeed, many were looking for breast cancer clinical trials. The Web could prove to be a powerful recruitment tool for clinical trials themselves. It is clearly a more feasible path for finding candidates who want a buddy. One disadvantage is that a class bias is introduced because only more affluent and educated people have regular access to the Internet; however, this is changing.

Candidates who took part in the Buddy Program were quite well informed about clinical trials. Only 19% believed that doctors knew which treatment was best, compared to 70% in the 1982 Casileth et al. study. Perhaps this reflects a fairly aggressive seeking of information among those who initiated contact via the Web. They also felt themselves to be well informed – except about insurance coverage. Hence, the main impact of participation seems to be on attitudes rather than on knowledge.

Contact usually consisted of one or two phone calls initiated by the buddy. For candidates the contact with a buddy was useful as an adjunct to other sources of information, rather than supplanting other sources. Side effects were the most commonly mentioned concern of candidates and their highest ranked drawback of participation. Buddies typically responded

by describing their own experience; they also gave useful practical tips. At follow-up, candidates were much less deterred by drawbacks of participation in general (although also less encouraged by benefits). They were especially less deterred at follow-up by the vagaries of insurance coverage and the prospect of not getting the best treatment.

Both the buddies and candidates reported that the experience was worthwhile. Training of the buddies has been refined over the course of six repetitions, and can be easily replicated. Pay is not important for the buddies, who are satisfied being of help. They did feel that closure was lacking. A better system would continue through the trial (or for the first 6 months of a prevention trial), provide feedback to the buddy, and have a formal ending.

This pilot project was not expected to find a measurable effect on candidates' trial enrollment decisions. Although there was no comparison group, 86% enrollment among the candidates for treatment trials is a desirable rate. This program, refined according to these recommendations, is now suitable for replication and testing in a randomized trial.

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