Available online at www.sciencedirect.com

SCIENCE DIRECT®

Gynecologic Oncology 99 (2005) S226 – S231

Gynecologic Oncology

www.elsevier.com/locate/ygyno

Original Research Report

Participant recruitment and motivation for participation in optical technology for cervical cancer screening research trials

Olga M. Shuhatovich[a], Mathilde P. Sharman[a], Yvette N. Mirabal[a], Nan R. Earle[a], Michele Follen[a], Karen Basen-Engquist[b,*]

[a]*Biomedical Engineering Center, UT M.D. Anderson Cancer Center, Houston, TX 77030, USA*
[b]*Department of Behavioral Sciences, UT M.D. Anderson Cancer Center, 1515 Holcombe Blvd., Unit 1330, Houston, TX 77030, USA*

Available online 6 September 2005

Abstract

In order to improve recruitment for cervical cancer screening trials, it is necessary to analyze the effectiveness of recruitment strategies used in current trials. A trial to test optical spectroscopy for the diagnosis of cervical neoplasia recruited 1000 women from the community; the trial evaluated the emerging technology against Pap smears and colposcopically directed biopsies for cervical dysplasia. We have examined women's reasons for participating as well as the effectiveness and efficiency for each recruitment strategy. Reasons for participation were identified and compared between trials. The recruitment method that resulted in the most contacts was newspaper reportorial coverage and advertising, followed by family and friends, then television news coverage. The most cost-effective method for finding eligible women who attend the research appointment is word of mouth from a family member or friend. Recommendations are given for maximizing the efficiency of recruitment for cervical cancer screening trials.

Keywords: Patient recruitment; Patient motivation; Clinical trials; Cervical screening; Cancer prevention

Background

New technology advances the mission to make cervical cancer preventable through early detection and treatment of cervical dysplasia. Evaluation of new technology requires extensive clinical trials, which provide valuable information about effectiveness, logistics, and technical troubleshooting. The new technology must be tested against the current standard of care, colposcopically directed biopsy, for validation. Participant recruitment is crucial for the execution of clinical trials; therefore, it is important to develop effective recruitment methods based on common motivations for participation. Because the clinical screening trials require many healthy participants, recruitment is challenging. Many women are reluctant, embarrassed, or fearful of current cervical cancer detection procedures. Furthermore, because the target population is made up of healthy women, they are not motivated to participate in order to ameliorate serious disease. There is abundant literature on patient recruitment for drug studies [1], palliative care studies [2], and for ongoing clinical trials [3]. Previous trials that evaluated drugs for treatment of cervical intraepithelial neoplasia (CIN) grade II or grade III revealed several important recruitment strategies: having multiple testing sites, creating a trusting relationship between potential patients, nurse practitioners and research investigators, and contacting patients multiple times [4]. Most studies of recruitment focus on patients who need some form of treatment for a health condition. There is a lack of studies on the motivation for participation and recruitment of healthy populations, such as those needed for trials of emerging technology for cervical cancer screening.

Studies on the recruitment of minority populations highlight some of the barriers to trial participation and suggest strategies for optimizing recruitment. For example, while the African American population has a 33% higher mortality rate and higher incidence for all cancers than the

* Corresponding author. Fax: +1 713 745 4286.
E-mail address: kbasenen@mdanderson.org (K. Basen-Engquist).

0090-8258/$ - see front matter © 2005 Published by Elsevier Inc.
doi:10.1016/j.ygyno.2005.07.093

Caucasian American population [5], they have lower rates of participation in cancer clinical trials. Reasons include lack of physician participation [5], economic disadvantages [6], lack of transportation [7], and lack of information [7]. Including a representative sample of minority women for cervical cancer screening trials is imperative.

There are various reasons that patients in general choose not to participate in clinical studies. Some are not aware of available studies [8]. Others may harbor fears that the treatment will not be as effective as existing treatment or may want to expedite the treatment process beyond constraints of the research project. Trials often require multiple visits that conflict with a patient's schedule or childcare. Families may discourage participation in research [9]. Women may choose not to participate in cervical cancer screening studies because they are embarrassed, fearful of discomfort, and anxious about the severity of the results [7]. The existing literature on barriers to recruitment is largely based on anecdotal evidence, leaving a real need for recommendations based on a quantitative review of recruitment methods [10].

Because cervical cancer screening procedures are very personal and often involve some discomfort, it is necessary to study and utilize the motivations for healthy women to participate in these trials. For example, in a study on the use of *N*-(4-hydroxyphenyl) retinamide (hereafter referred to as 4-HPR) as a medication for cervical dysplasia treatment, patients reported a variety of reasons for participation, including family cancer history, desire to help others, fear of future treatment, hope that future treatment would be unnecessary, and the appeal of less invasive treatment [9]. Many of the potential participants for cervical cancer screening trials may have similar motivations as self-motivating factors such as those listed above are among the most powerful incentives for participation in clinical research in general [11]. The literature reveals that physicians also play an important role in the motivations for participation [12]. The physician influences participation through her role as the patient's source of knowledge about the clinical trial and the procedures that it entails.

The purpose of this report is to identify the most effective recruitment strategies for healthy women from the community for a trial of optical technologies for cervical cancer screening. In addition, we report the most common motivations for participation in the trials.

Methods

The cervical cancer screening trials were conducted at the University of Texas M.D. Anderson Cancer Center (MDACC), the University of Texas Health Science Center (UT HSC), and the Harris County Hospital District's Lyndon B. Johnston Hospital (LBJ) in Houston, Texas, as well as the British Columbia Cancer Agency (BCCA) in Vancouver, Canada. Recruitment began in October 2000 and is expected to end in December 2005. This paper only reports data from the women who were recruited at the Houston facilities.

The trial involves testing a new optical technology, fluorescence and reflectance spectroscopy, for detecting cervical dysplasia. Participants undergo Pap smears and colposcopically directed biopsy, as well as optical spectroscopy. The diagnostic study recruits women with a history of abnormal Pap smears, and the screening study involves females without a history of abnormal Pap smears. Some of the women in the diagnostic study were recruited from colposcopy clinics, while some were recruited from the community. All women in the screening study were recruited from the community. Women had to be non-pregnant and at least 18 years of age to be eligible.

For women recruited from the community, recruitment methods included radio and television advertisements and news stories, newspaper advertisements, newsletters, billboards, up-to-date trial information on the MDACC website, and voluntary distribution of flyers by MDACC employees at a number of different locations. Women were also recruited at fairs and festivals throughout the city. As the study began, family or friends of those who participated in the study or heard about it through the sources mentioned above were also good sources of information for potential participants. Furthermore, MDACC employees transmitted the information to friends, family, and co-workers.

Recruitment information provided prospective participants with the contact information of the research coordinator, who was responsible for an eligibility check, registration, and scheduling. Prospective participants could contact the research coordinator by telephone, e-mail, or pager. Their method of contact depended on how they were recruited. The participants' names, contact information, and how they heard about the study were recorded into a database. An organized, secure Registration and Scheduling database was created using Filemaker Pro 5.0, which was used to register participants and monitor scheduling status throughout the study. Eligibility criteria were checked, and if any uncertainties appeared, the research coordinator consulted a nurse practitioner or a physician. Those who did not meet these requirements were ineligible and were not enrolled in the trial. Participants who cancelled their scheduled appointment and did not want to reschedule, as well as those who refused to participate at the point of care, were also not enrolled. Whether they met eligibility criteria and were scheduled or were ineligible and therefore withdrawn from the study, medical data, socio-demographic information, and their participation or lack thereof in the study were recorded for all prospective participants who contacted study personnel.

Since the majority of participants were scheduled several weeks in advance, the risk of them forgetting the appointment was high. Research coordinators mailed letters that included the time and place of the screening approximately 1 to 2 weeks before a participant's appointment. Included with the letter was a map with directions, a brochure with

information about the study, and the research coordinator's contact information. These were given to reinforce participant confidence in the study, to address any further questions regarding any part of the procedure, or to provide them the means to cancel or reschedule their appointment. The day before trial participation, each participant was called and reminded of her appointment.

All statistical analyses were performed using Microsoft Excel 2000. Data from an official study database that includes participants' information was used in the χ^2 analysis that compares reasons for participation. Data from the Registration and Scheduling database was used in the χ^2 analyses that compare methods of recruitment (Table 2).

Results

Of the 1670 women who contacted the research coordinators to participate in one of the two trials, 432 were excluded from the study because they did not meet eligibility criteria, 238 were scheduled but did not participate, and 1000 remaining women actually participated in the trials.

Reasons for participation

There are a variety of reasons that a woman may or may not consider when she decides to participate in a cervical cancer screening trial. When women attended their appointment, we asked an open-ended question about why they were interested in participating and recorded all their responses. Examples of typical participant responses are shown in Table 1. We found seven common responses: helping others (35.9%), needed a Pap smear or follow up examination (23.3%), general personal health concerns (15.3%), for a more thorough examination than usually provided (11.7%), personal interest (9.2%), could not otherwise afford an examination (6.8%), and family history of cancer (5.3%). The number of participants that gave a reason other than these 7 (4.2%), or that gave no reason (4.0%), were smaller than any of the seven main responses.

To determine whether reasons for participating varied by abnormal Pap smear history, a χ^2 test was performed for each reason for participation. Women who had a history of an abnormal Pap smear were more likely to cite wanting to help others than women with no such history. Women without a history of abnormal Pap smear were more likely to give reasons related to personal health, needing a Pap smear, wanting free health care, personal interest in the trial, and having a family history of cancer. The number of women giving other reasons, or no reason, was similar between the two groups.

Recruitment methods

The recruitment method that resulted in the most contacts about the study (Table 2) was newspaper news coverage and advertising (n = 419), followed by family and friends (n = 374), and television news coverage (n = 253). The fewest contacts were generated by flyers (n = 18) and staffing booths at fairs and festivals (n = 9). However, the most efficient method, as measured by the percentage of contacts that were eligible and participated, were M.D. Anderson employees (80%), newsletters (73%), and family and friends (68%). Those who were ineligible and "no-shows" were more likely to have learned about the trials from billboards and newspapers. Most of those who were recruited at fairs or festivals were ineligible, while those recruited through flyers were more likely to be no-shows. A high proportion of those recruited through the newsletter were no-shows as well. The recruitment method was significantly related to the outcome of the contact (i.e., whether the women were ineligible, eligible but did not attend appointment, or eligible and attended the appointment). Learning of the trials through the website, television, or radio seems to have had no relationship with the result of the recruitment.

We have also collected data on the cost of the recruitment strategies (see Table 3). According to our results, the most

Table 1
Reasons for participation among women with positive and negative history of abnormal Pap smear (percentages add to more than 100 because some participants gave more than one reason)

Protocol	No history of abnormal Pap	History of abnormal Pap	Total	Pearson χ^2 test P value
Total number of participants	690	816	1506	
Reason for participating	N (% of 690)	N (% of 816)	N (% of 1506)	
To help others	131 (19.0)	410 (50.2)	541 (35.9)	<0.001
Personal health	138 (20.0)	92 (11.3)	230 (15.3)	<0.001
Need a Pap or follow up	222 (32.2)	129 (15.8)	351 (23.3)	<0.001
Free/comp/no insurance	70 (10.1)	33 (4.0)	103 (6.8)	<0.001
Family history of cancer	51 (7.4)	29 (3.6)	80 (5.3)	0.001
Personal interest	76 (11.0)	63 (7.7)	139 (9.2)	0.028
Other	36 (5.2)	27 (3.3)	63 (4.2)	0.065
None	22 (3.2)	38 (4.7)	60 (4.0)	0.147
For more thorough examination	72 (10.4)	104 (12.7)	176 (11.7)	0.164

Table 2
Recruitment strategies ranked by total number of contacts, with the number and percentage of women who participated, were ineligible and were eligible but did not attend appointments (Pearson Chi-square significant at $P = 5.71E-27$)

Recruitment strategy	Recruitment strategies			
	Total number of contacts *N*	Participated *N* (%)	Ineligible *N* (%)	No-show *N* (%)
Newspaper	419	224 (54)	122 (29)	73 (17)
Family/friends	374	255 (68)	67 (18)	52 (14)
Television	253	154 (61)	68 (27)	31 (12)
MDA employee	141	113 (80)	18 (12)	10 (7)
Radio	141	89 (63)	35 (25)	17 (12)
Billboard	122	24 (20)	74 (61)	24 (20)
Newsletter	120	88 (73)	17 (14)	15 (13)
Website	73	40 (55)	23 (32)	10 (14)
Flyer	18	11 (61)	1 (6)	6 (33)
Fairs/festivals	9	2 (22)	7 (78)	0 (0)
Total number of women	1670	1000	432	238

efficient and least costly recruitment method, in terms of the costs per eligible participant, was by a word of mouth, with the help of family and friends. This recruitment method involved no cost and was the source of information about the trial for 255 participants. Furthermore, dissemination of information about the cervical screening study by MDACC employees, television and radio news coverage, and the institutional newsletter was responsible for recruiting a large number of participants at no cost to the project. The National Public Radio and different television news channels also asked for interviews with the principal investigator, which were broadcast at no cost to the project.

Costs were incurred for some recruitment methods; of these, newspaper advertising and news coverage were the most cost-effective, with a cost of $25.32 for each eligible participant. Flyers were less cost-effective ($90.90 per eligible participant) due to the low number of participants who learned about the trial through flyers. More effective placement of flyers might make this a more cost-effective strategy in future trials. Website cost was calculated by multiplying the time employees spent building the website by the salary of that employee. The total cost was 5000 USD, $125 for each eligible participant who learned about the study through the website. There were several inefficient recruitment methods. The least cost-effective method was advertising on billboards. There were 30 billboards distributed around the city in high traffic areas for a period of 6 weeks, costing the study 24,000 USD. They brought in only 24 participants, at a cost of $1,000 per participant. Furthermore, 61% of the women who learned about the trial through billboards were ineligible, and 20% did not show up for appointments. Distributing information at the fairs and festivals brought 0.2% of participants and was a volunteer operation completed by employees on their spare time. The only cost encountered in this method was the cost of the brochures: 900 USD.

Conclusions

We succeeded in recruiting participants for the cervical screening clinical trials and found significant differences in the effectiveness of the various recruitment methods ($P < 0.001$). The most cost-effective method for finding eligible women who attend the research appointment is word of mouth from a family member or friend. This result speaks the importance of ensuring that participants' experiences are positive. Being treated well and knowing that their contribution to the research is valued increase the probability that they will refer others to the trial. Although the newspaper and website were successful and fairly cost-effective recruitment methods, slightly under half of the women who contacted the project staff after seeing trial information in these two media channels either were ineligible or did not show up for their study appointment. Women who found out about the study from friends/relatives or MDA employees had a higher participation rate than most other methods. News coverage by television, radio, and print media outlets were also cost-effective ways of recruiting potential participants. However, the news

Table 3
Cost of the participant recruitment strategies, ranked by cost per eligible participant

Recruitment strategy	Cost (USD)	Cost per eligible participant	Additional information
Family/friends	0	$0/255 = $0	Information transmitted voluntarily by word of mouth
MDA employee	0	$0/113 = $0	Information transmitted voluntarily by word of mouth
Television	0	$0/154 = $0	Television news coverage
Radio	0	$0/89 = $0	Public radio news coverage and advertisement
Newsletter	0	$0/88 = $0	Story in local institutional newsletter
Newspaper	$5672	$5672/224 = $25.32	Paid advertisement and news stories in three newspapers
Flyer	$1000	$1000/11 = $90.90	Printed as needed; cost approximated
Website	$5000	$5000/40 = $125	Employee time * employee salary
Fair/festival	$900	$900/2 = $450	Cost of brochures, volunteer operation of employees on their spare time
Billboard	$24,000	$24,000/24 = $1000	30 billboards for a period of 6 weeks

media is most interested in providing coverage of the study in the early phases; later on in the trial, additional mass media efforts, including paid advertising, may be needed. It is also shown that mass media advertising and news coverage have the potential to reach large numbers of people but also result in many calls from people who are not eligible for the study (more than recruitment by family/friends and employees)—this is a hidden cost to these recruitment methods. In addition, certain very costly mass media strategies were very unsuccessful in bringing in participants. Among the least efficient recruitment and most expensive strategies were billboards, which produced only a small number of contacts, the majority of whom were ineligible or did not attend their appointments.

Our group found common motivations for participation, which can be used for the design of future recruitment efforts. Because many women gave similar reasons for participating, advertising could appeal to potential participants by mentioning some of these reasons, such as the opportunity to help others while obtaining needed preventive medical care.

The two trials had an interesting difference: many more women in the diagnostic trial wanted to help others. The higher incidence of each of the other reasons for participation in the screening trial may simply be due to the large number of women that cited helping others in the diagnostic trial. The reason so many cited "helping others" as their motivation is unclear. The diagnostic trial's eligibility requirements included an abnormal Pap smear. This important difference means that these women had already had a Pap smear and therefore probably had insurance and regular health care. They would be getting a follow up examination anyway and may have decided that they could be "helping others" at the same time. Many were already patients in the colposcopy clinic who were recruited by word of mouth. If they chose to participate, helping others was a likely motivation. The screening trial included women who had never had an abnormal Pap smear, some of which had never had a Pap smear at all.

Recommendations

The following recommendations are provided based on our experience designing the cervical screening trials and a literature review, which will hopefully be an aid to future research coordinators. Incorporate multiple recruitment techniques: newspaper advertisements, radio, television, websites, flyers, newsletters, billboards, "word of mouth," and any others as needed. Enhance "word of mouth" techniques by actively engaging participants and staff in the recruitment of friends and family, providing them with pamphlets for distribution. Thoroughly provide information regarding the study to the recruiters. Assign a research coordinator to lead the recruitment process and maintenance. Create a secure registration and scheduling database to help monitor participants; we found Filemaker Pro to be very helpful. Use multiple reminders to increase participation rate, sending letters and calling the prospective participants prior to the appointment. As proposed in previous research, monitor the rate of recruitment to change or improve techniques as needed [11]. These recommendations should significantly improve the quality of screening trials as well as contribute to the achievement of reliable results.

Acknowledgments

The authors gratefully acknowledge the contributions of Deborah Rogers-Barr and Paula Roberts; the clinical research staff (Pamela Bourdeux, Glenda Dickerson, Jessica Lara, Karen Smith, Winda Rodriguez-Toothaker, Patricia Trigo, and Christy Whitmore); nurse-colposcopists (Karla Ballersteros, Latira Chenevert, Alma Sbach, Judy Sandella); behavioral team (Deshaunda Bostic, Nicole Craft, Jessica Gallegos, Andrea Hansis-Diarte, and Tao Le); protocol director Karen Rabel; editors Stacy and Brian Crain; and co-principal investigators of program project Dr. Rebecca Richards-Kortum of the UT-Austin and Dr. Calum MacAulay of BCCA and all other collaborating physicians and researchers. Financial support from the National Cancer Institute (PO1-CA82710) is gratefully acknowledged.

References

[1] Halpern SD, Karlawish JH, Casarett D, Berlin JA, Townsend RR, Asch DA. Hypertensive patients' willingness to participate in placebo-controlled trials: implications for recruitment efficiency. Am Heart J 2003;146:985–92.

[2] Jordhoy MS, Kaasa S, Fayers P, Ovreness T, Underland G, Ahlner-Elmqvist M. Challenges in palliative care research; recruitment, attrition and compliance: experience from a randomized controlled trial. Palliat Med 1999;13(4):299–310.

[3] Lewis CE, George V, Fouad M, Porter V, Bowen D, Urban N. Recruitment strategies in the women's health trial: feasibility study in minority populations. Control Clin Trials 1998;19:461–76.

[4] Bailey JM, Bieniasz ME, Kmak D, Brenner DE, Ruffin MT. Recruitment and retention of economically underserved women to a cervical cancer prevention trial. Appl Nurs Res 2004;17(1):55–60.

[5] Adams-Campbell LL, Ahaghotu C, Gaskins M, Dawkins FW, Smoot D, Polk OD, et al. Enrollment of African Americans onto clinical treatment trials: study design barriers. J Clin Oncol 2004; 22(4):730–4.

[6] Parra-Medina D, D'Antonio A, Smith SM, Levin S, Kirkner G, Mayer-Davis E. Power study. Successful recruitment and retention strategies for a randomized weight management trial for people with diabetes living in rural, medically underserved counties of South Carolina: the POWER study. J Am Diet Assoc 2004;104:70–5.

[7] Brown DR, Found MN, Basen-Engquist K, Tortolero-Luna G. Recruitment and retention of minority women in cancer screening, prevention, and treatment trials. Ann Epidemiol 2000;10:513–21.

[8] Ford JG, Howerton MW, Bolen S, Gary TL, Lai GY, Tilburt J, Gibbons MC, Baffi C, Wilson RF, Feuerstein CJ, Tanpitukpongse P, Powe NR, Bass EB. Knowledge and Access to Information on Recruitment of Underrepresented Populations to Cancer Clinical Trials. Evidence Report/Technology Assessment No. 122 (Prepared

by the Johns Hopkins University Evidence-based Practice Center under Contract No. 290-02-0018.) AHRQ Publication No. 05-E019-2. Rockville, MD. Agency for Healthcare Research and Quality. June 2005.

[9] Follen M, Atkinson EN, Schottenfeld D, Malpica A, West L, Lippman S, et al. A randomized clinical trial of 4-hydroxyphenylretinamide for high-grade squamous intraepithelial lesions of the cervix. Clin Cancer Res 2001;7:3356–65.

[10] Gates S, Brocklehurst P, Campbell M, Elbourne D. Recruitment to multicentre trials. BJOG 2004;111:3–5.

[11] Aitken L, Gallagher R, Madronio C. Principles of recruitment and retention in clinical trials. Int J Nurs Pract 2003;9:338–46.

[12] Mannel RS, Walker JL, Gould N, Scribner Jr DR, Kamelle S, Tillmanns T, et al. Impact of individual physicians on enrollment of patients into clinical trials. Am J Clin Oncol 2003;26:171–3.