



Published in final edited form as:

Contemp Clin Trials. 2007 July ; 28(4): 423. doi:10.1016/j.cct.2006.11.006.

Costs of Recruiting Couples to a Clinical Trial

Georgia Robins Sadler, BSN, MBA, PhD,

Clinical Professor of Surgery, UCSD School of Medicine, Associate Director for Community Outreach, Rebecca and John Moores UCSD Cancer Center, SDSU/UCSD Joint Doctoral Program in Clinical Psychology, San Diego, CA USA

Celine M. Ko, MA, MS, PhD,

Doctoral Candidate, SDSU/UCSD Joint Doctoral Program in Clinical Psychology, Rebecca and John Moores UCSD Cancer Center, San Diego, CA USA

Vanessa L. Malcarne, PhD,

Professor of Psychology, San Diego State University, SDSU/UCSD Joint Doctoral Program in Clinical Psychology, Rebecca and John Moores UCSD Cancer Center, San Diego, CA USA

Rajni Banthia, PhD,

SDSU/UCSD Joint Doctoral Program in Clinical Psychology, Rebecca and John Moores UCSD Cancer Center, San Diego, CA USA

Ivan Gutierrez, BS, and

Academic Intern, Rebecca and John Moores UCSD Cancer Center, San Diego, CA USA

James W. Varni, PhD

Professor, Department of Landscape Architecture and Urban Planning, Vice Chair for Research, Department of Pediatrics, College of Medicine, Texas A&M University, College Station, TX USA

Abstract

Multiple barriers contribute to the slow recruitment of participants to research studies, which in turn extends the time required to translate promising scientific discoveries into proven therapeutic interventions. A small but growing literature is developing on the extraordinary costs of recruiting participants to studies, and thereby demonstrating that underestimating the cost of participant recruitment can contribute to these recruitment problems. These recruitment challenges and costs are exacerbated when the participants' study eligibility is determined by relatively narrowly defined illness parameters. Recruitment challenges are further compounded when dyads (two individuals engaged in a sociologically significant relationship, such as husbands and wives, siblings or extended families) must be recruited to an illness-focused study. For these latter groups, there are no data to guide researchers in how to anticipate those participant recruitment costs.

This paper describes the staff costs for a variety of strategies used to recruit participants to a randomized supportive care study for couples who were within 18 months of a prostate cancer diagnosis. Pegged to the value of the U.S. dollar for the period, the average cost of staff time was \$288 per recruited and enrolled dyad, plus a promised additional \$100 incentive for study retention. Within the strategies used, the staff costs per recruited dyad ranged from \$ 152 to \$1,688. Accrual

© 2006 Elsevier Inc. All rights reserved.

Corresponding Author: Georgia Robins Sadler, MBA, PhD, Associate Director, Moores UCSD Cancer Center, 9500 Gilman Drive, La Jolla, California 92093-0658, Phone: (858) 534-7611, Fax: (858) 534-7628, Email: gsadler@ucsd.edu.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

per strategy ranged from zero to 107 enrolled couples. When asked for secondary sources of information about the study, many participants reported more than one source of study referral, reflective of the multifaceted recruitment strategies deployed. In spite of innovative, culturally competent, and broad based recruitment methods, attainment of a diverse sample was difficult to accomplish in this study. Having estimates of the actual cost of recruiting dyads to research studies can help investigators prepare realistic study budgets.

Keywords

Clinical trials; Cost; Couples; Diversity; Dyads; Prostate Cancer; Recruitment; Recruitment strategies

Introduction

The difficulty in recruiting participants to clinical trials poses an ongoing obstacle for researchers, as well as for patients who await medical advances [1,2]. Slow rates of participant accrual to clinical trials are compounded by the difficulty of attracting a sample that is representative of the nation's women, elders, children, and minorities [1–9]. Accurately anticipating the cost of recruiting subjects to clinical trials is difficult and frequently underestimated because so little data have been reported in the literature.

In recognition of the importance of recruiting subjects to studies quickly and the value of a diverse sample of participants, investigators have begun to focus on monitoring the costs of recruiting subjects to clinical trials. A small but growing literature has recently evolved that systematically evaluates the efficacy and cost of various recruitment strategies, including the incentives likely to be associated with subjects' accrual to clinical trials [10–30].

Some studies have estimated costs related to recruiting healthy participants. For example, a 1989 clinical trial by Borhani et al. reported a cost of \$798,000 to recruit 880 normotensive participants between the ages of 25 to 49 (\$907/recruited participant), while a 1993 study by Bjornson-Benson et al. analyzed the cost of five recruitment strategies, reporting a range from \$54 (media) to \$670 (neighborhood canvassing) per participant recruited to the Portland Lung Health clinical trial [12,24].

A few studies have reported costs of recruiting at-risk persons to clinical trials, generally focusing on the elderly. Combined personnel and supply costs of \$515 per enrolled participant were reported by Gismondi et al. for recruitment to their clinical trial examining Vitamin E supplementation in nursing home residents aged 65 and older [26]. Ory et al. recruited frailer older adults to randomized clinical trials at seven sites, using various methods suitable to each site. Recruitment cost estimates included labor costs (including fringe benefits) plus non-labor expenses. Estimated costs per randomized participant ranged from \$100 to \$900, with most sites averaging more than \$300 [27]. Recruitment costs varied with eligibility criteria – the site with the least restrictive eligibility criteria had the lowest recruitment costs per enrolled participant; the sites with the most frail participants had the highest recruitment costs per person.

Davey et al. recruited elderly people with osteoarthritis to a randomized clinical trial of water therapy [28]. They studied both the cost of recruitment and enrollment. Direct costs were 27.66 pounds per patient if recruited through general practitioners, versus a very low cost of 2.72 pounds per patient for those recruited via a free local newspaper article. However, the newspaper article yielded very few recruits who ultimately enrolled in the trial (66, versus 242 through the general practitioners).

Tarlow et al. present a very detailed examination of recruitment costs associated with their randomized feasibility trial for caregivers of persons with Alzheimer's disease [29]. Average cost per enrolled participant was \$101. The most efficient strategy (\$86 per enrolled participant), and the one that yielded the most participants, was termed "formal recruitment," and referred to a recruitment process in which participants were referred by personnel at the participating health care sites. Costs for this approach were reduced in part because some of the professionals involved declined or were not allowed to accept reimbursement. The most expensive approach per participant was community-directed; this also produced few enrolled participants. This approach was based on social marketing theory and incorporated such strategies as paid advertisements targeting minority communities, web pages, and email announcements.

The reported costs of recruiting subjects with serious diseases to studies are particularly high. Folmar et al. reported estimates of recruitment costs for a controlled clinical trial involving postmenopausal women with coronary disease; costs ranged from \$1,152 to \$1,715 per randomized participant [25]. Gill et al. reported recruitment costs ranging from \$764 to \$868 per randomized participant for a controlled clinical trial involving frail community elders [13]. The Diabetes Prevention Program research group reported costs of \$1,075 per randomized participant for a large study involving persons with impaired glucose tolerance [30]. No studies were identified that had examined costs for recruiting dyads or groups in relation to a specific illness.

Many of these studies were initiated or accomplished prior to the changes included in the United States National Institutes of Health's Revitalization Act of 1993 guidelines which mandated a greater emphasis on recruiting clinical trial samples that are representative of the nation's women, elders, children, and diverse ethnic and cultural groups. Recruiting these diverse samples requires culturally sensitive, customized recruitment strategies. Such customization will likely contribute to escalating recruitment costs.

Also, many of these cost studies were completed before the Health Insurance Portability and Accountability Act of 1996 (HIPAA) guidelines were implemented to provide greater protection of patients' privacy. As Erlen notes, many of the strategies that were previously successfully used are less within the acceptable interpretations of maintaining patients' privacy, and hence investigators' prior experience estimating the costs associated with those recruitment strategies are no longer useful for developing budgets that accurately predict future study recruitment costs [31]. These changes designed to increase patients' privacy have added new challenges and, potentially, additional costs to the already difficult task of identifying and recruiting participants who fall within narrowly defined eligibility criteria. physicians' recommendations to enroll in a study are known to be highly effective for patient recruitment. For this study, for example, the original plan was to have the research staff circulate among the clinicians' offices to review patient charts and the clinics' electronic databases to help participating clinicians identify study-eligible patients. Then, in collaboration with the clinicians, the research staff was going to prepare letters that introduced the study to these patients. This strategy was no longer viable under the new mandates.

The current study sought to recruit couples to participate in a randomized prostate cancer supportive care study in which both members of the spousal dyad needed to consent and participate. The man had to be within 18 months of his pathologically confirmed diagnosis for prostate cancer. In addition, both members of the dyad had to be proficient in English, be married or permanently co-habiting with their "significant other," and live within or near the County of San Diego, a 5,000 square mile region of nearly three million residents. As a result, there was a much more narrowly defined pool of potentially eligible participants for this study than for a study recruiting individual normotensive participants of all ages, for example.

The authors anticipated that the current study would experience significant recruitment challenges, given the subject recruitment cost data from the studies cited above combined with the federal mandates, the narrow eligibility criteria, and the need to consent dyads. To accommodate the current study's relatively small recruitment budget, cost effective and guideline-compliant recruitment strategies were needed.

A small group of physicians were willing to volunteer some of their personal and staff time to identify their study eligible patients and recruit them to the study. This very narrowly focused strategy was anticipated to be a highly effective and efficient way of identifying and recruiting patients. However, since the clinicians were volunteering their time, this strategy could not be relied upon to produce an adequate stream of study participants. Hence, other efficient, and narrowly focused, subject recruitment strategies would also be needed. Levinson coined the term "guerrilla marketing strategies" to encompass highly focused, low cost grass roots product promotion, e.g. hanging coupons on doorknobs of homes located within a one mile radius of a business. Also, Silverman has described word-of-mouth strategies as a method of even more narrowly focusing the dissemination of a message or "narrowcasting" messages for dissemination, e.g. offering current customers something in exchange for bringing a new customer to a business [32,33]. The research team used these two grounding strategies as the foundation for developing the project's other recruitment strategies.

In this paper, the authors report on the success and associated cost of each successful enrollment by strategy. We hypothesized that physicians and their staff would generate more successful recruitments (i.e., dyads that actually enrolled in the study) than any other source because of the established relationships between these healthcare professionals and the patients they treat and the resultant weight that a recommendation to participate in the study would have. We also hypothesized that certain community-specific recruitment strategies (e.g., churches or salons with a predominant ethnic constituency) would generate a disproportionate number of successfully recruited minority dyads. We hypothesized that the costs for recruiting dyads from ethnic minority groups would be higher than White/Caucasian dyads.

Methods

Description of the Clinical Trial

Between the years 2000 and 2004, dyads were recruited to participate in a study that examined whether a problem-solving therapy (PST) intervention for wives of men diagnosed with prostate cancer, could improve health-related quality of life for both members of the dyad. The experimental arm's 8-session PST intervention was delivered individually to the wife in her home. Both the wife and husband consented to participate in assessments at baseline, posttreatment, and six-month follow-up. The control arm's participants completed the same survey instruments at the same three evaluation points without the intervention. Couples in both study groups received \$100 at the completion of the six-month follow-up.

Procedures

All paid project staff members who engaged in recruitment activities maintained a detailed diary of their time spent developing and implementing various participant recruitment strategies. To evaluate the effectiveness of the recruitment strategies, the enrolled couples were asked how they had learned about the trial. While some couples could list more than one way in which they had learned about the trial, they had no difficulty identifying what triggered their enrollment in the trial, so this response was used for the analysis.

To determine the personnel costs of recruitment and the efficacy of each strategy, the time each staff member spent performing recruitment activities was multiplied by the cost of their hourly

salary plus benefits. This analysis was done primarily to help researchers anticipate the relatively large cost associated with staff time for recruitment, rather than the comparatively incidental expenses associated with supplies (inkjets, pens, etc), copying, postage, and mileage costs. In addition, the cost (\$0) of the non-compensated time invested by referring physicians, their allied medical staff, support group leaders, indigenous community leaders, volunteer student research assistants, and other volunteers was excluded.

Due to IRB and HIPAA compliance guidelines, it was not possible to collect accurate data on the total number of individuals who were contacted or exposed to recruitment materials. To protect patients' privacy, no one other than physicians, their staff, or support group leaders was allowed to identify and contact study-eligible patients. Under IRB's direction to further protect patients' privacy, letters sent by physicians to their study-eligible patients were sent as a general, rather than as a personal, solicitation, encouraging the recipient to share information about the study with any couples they felt might be eligible. The additional IRB-approved recruitment strategies selected to narrowcast information about the study followed the guidelines set forth by Levinson [32] and Silverman [33]. Recruitment strategies were classified into 11 primary clusters (see Table 1). The foci of the information dissemination were patients and their loved ones, older couples where the age risk factor put them and their social circle at greater risk of prostate cancer, and African American men for whom the risk of prostate cancer was greatest.

Sample Description

Power analysis calculations, based on the main study hypothesis that assignment to treatment (versus control) would result in a better quality of life outcome, dictated enrollment of 170 dyads. One hundred seventy-two men diagnosed with prostate cancer and their cohabitating female spouses/partners were enrolled in the PST clinical trial. The men ranged in age from 41 to 89 ($M = 65.5$; $SD = 9.96$); spouses ranged in age from 32 to 86 ($M = 61.23$, $SD = 10.67$). Months since diagnosis ranged from 0.5 to 23 months ($M = 5.37$; $SD = 4.69$). Table 2 displays additional medical and socio-demographic information about the patients and their spouses.

Results

Table 3 shows the number of randomized dyads resulting from each reported referral source. Dyads were most likely (62%) to report the patient's physician or physicians' staff as their source of study information while the remainder reported one of the alternate strategies deployed (See Table 1). Dyads were not only significantly more likely to identify physicians/staff as their source of recruitment versus any other recruitment strategy ($\chi^2 = 226.241, p < .0001$), they were significantly more likely to identify physicians/staff than all other recruitment strategies combined ($\chi^2 = 18.456, p < .0001$). Interestingly, physicians/staff were more likely, when compared with all other recruitment sources, to refer dyads in which the patient's cancer was diagnosed as Stage 1 ($\chi^2 = 8.604, p < .05$). Of patients referred by physicians, 62% were diagnosed as Stage 1, 23% as Stage 2, 10% as Stage 3, and 5% as Stage 4. Of patients who came to the study from all other sources, 36% were Stage 1, 43% were Stage 2, 15% were Stage 3, and 6% were Stage 4. There were no differences for age or latency since diagnosis between patients referred by physicians/staff and those coming to the study from other sources. Finally, comparison of source of recruitment for self-identified White/Caucasian versus ethnic minority dyads revealed no significant differences ($\chi^2 = 5.345, p = .254$).

Table 3 also reports: 1) the direct cost of staff time devoted to recruitment activities and 2) the indirect cost associated with weekly planning and strategy sessions. Costs are reported in U.S. dollars for the period 2000 to 2004. Both cost estimates were calculated by multiplying the number of hours each staff member invested in each strategy by the specific hourly rates for each staff member. Hourly rates ranged from the PI's to doctoral research assistants'. There were cases in which the PI's involvement was critical; for example, the introductory sessions

explaining the study to physicians and community leaders. In contrast, once the PI had established a collaboration with, for example, a community pastor, then the Sunday morning outreach session could be accomplished by a doctoral research assistant at a much lower rate of pay.

Total (direct and indirect) staff time devoted to recruitment was 2,654 hours, totaling \$49,394 for the 172 couples recruited to the study. It took an average of 16 hours of staff time to recruit each couple to the study (2,654 hours/172 couples) and cost an average of \$288 per couple (\$49,394/172 couples). Couples were also paid a \$100 incentive fee after participating in the study for an average of \$388 in total cost per recruited dyad. Table 3 also shows a breakdown of these costs by each direct referral source. An analysis of the hour and dollar costs divided by the number of couples recruited via each strategy is also shown in Table 3. The cost associated with each referral source varied widely. The most expensive sources of referral were the cancer organizations and African American beauty salons and barbershops, while the least expensive were the physicians/physicians' staff. It is of note that some of the strategies employed resulted in no couples recruited, such as recruitment efforts at the Senior Citizen Center. There were no significant differences when cost of couples' recruitment was compared across ethnic groups,

Discussion

The average cost for enrolling and retaining a dyad to this study was \$388 (\$288 for staff time plus \$100 retention incentive), far below that reported by many previous studies in which clinically diagnosed or at-risk individual adults were recruited. However, it is important to emphasize that the costs reported in this paper represent only the salaried staff time for the research team. They, therefore, potentially under represent the full cost of subject recruitment because they do not include the salary costs of the referring physicians, their staff members, support group leaders, organizations' staff members, or other community members who volunteered their time to help recruit patients to this study. Had these individuals required compensation for their time overall, recruitment costs would have been much higher, and this strategy would have been the most expensive rather than the least expensive. Also not included are: 1) the costs of the physicians' time at the community hospitals to prepare and submit the study's IRB application proposal to permit recruitment within their facilities; 2) the costs of developing the network of partnering churches, beauty salons, and cancer organizations; and 3) the costs of the undergraduate and graduate students who helped with subject recruitment. Hence, creatively using volunteers to recruit participants was vital to keeping the recruitment costs as low as possible and also was vital to the narrowcasting of the recruitment messages. Cost estimates also do not include the research institution's nor the partnering community institutions' recruitment-associated costs of mileage/toll, copying, postage, and stationary. Researchers will need to account for these additional costs as appropriate when developing their study recruitment budgets.

The results reported from this cost-benefit analysis also underscore the importance of on-going evaluation of recruitment strategies' effectiveness. Strategies that are found to be effective can be repeated while less effective strategies can be discontinued. For this study, the narrowcast recruitment messages from physicians and their staff were the most frequent and efficient referral sources. The literature offers multiple examples of the importance of physicians' recommendations to patients' decision to take a health action [34–36].

However, this high rate of physician referrals may also be a reflection of some of the specific characteristics of this study. Unlike many therapeutic clinical trials, for this study the patients remained under the medical care of their referring physicians throughout their participation in this trial, removing a critical barrier to physicians' referral of their patients. Thus while the

concern was raised that their patients would be lost to the study's sponsoring institution, the physicians were reassured that it was highly unlikely, thereby overcoming a frequently reported barrier to referral [37]. Second, in referring patients to this supportive care study, the physicians also recognized that a referral might provide some degree of psychosocial support for patients randomized to the supportive care intervention or to the control arm, where they received added attention during the data collection process. For studies where referring physicians will transfer their patients' care to the clinical research team, it is even more critical that researchers be able to spell out the potential long term benefits to future patients.

While providers were an exceptional source of participant referral, researchers must consider the possibility that the referring physicians will unintentionally or intentionally introduce selection bias in their referrals. Physicians in this study, for example, referred a significantly large number of patients in the early stages of this disease. For other studies, physicians may find it easier to refer their healthiest patients feeling that they would be most receptive to participation. Alternately, they may be more inclined to refer their most difficult or sickest patients. There may be cultural and language barriers to clinicians' referral of patients of diverse ethnic characteristics. Patients coping with an illness without insurance may have more limited access to physicians or be dependent upon public clinics where a series of residents rotate under the supervisions of a credentialed physician. Davey, et al. described the possible selection bias when a substantial proportion of physicians chose not to participate in the trial or where staffing was inadequate to help recruit participants [28]. Geraets, et al. raised the possibility that physician recruitment is not systematic, but rather is influenced by factors such as motivation, available time, degree of study involvement, forgetfulness, and financial reimbursement [38].

Providing other investigators with data about the actual costs of recruiting subjects to studies, will help them prepare and substantiate budgets that more realistically address the true cost of subject recruitment. With IRBs becoming more protective of patients' privacy, physicians will be in ever greater demand to help researchers with the patient identification, information, and recruitment process. To retain their cooperation in the face of ever narrowing patient care reimbursement rates, researchers and funding agencies should anticipate that an additional future cost of subject recruitment will likely be providing physicians and partnering organizations with salary compensation to allow time for physicians and staff to cull eligible patients, prepare and distribute study information, and handle patients' inquiries. These are no longer tasks that can be accomplished by the study's research staff, nor is it realistic to expect the practicing clinicians to do so under current reimbursement rates.

Inadequate budget allocations for recruitment can contribute to the slow accrual of subjects to trials by leaving researchers with limited recruitment options. However, lack of adequate budgeting for staffing and materials is only part of the problem, as was demonstrated when a pastor personally led a meeting to encourage six eligible minority couples to learn about this study, and none opted to enroll in it, citing lack of time or a desire to not get involved. To address barriers to clinical trial participation and the disparities that could be involved from underrepresentation in research studies, on-going public education is needed. Raising the community's awareness of the role that research plays in advancing scientific knowledge and the role that diverse samples play in producing findings that can be more confidently generalized to the community at-large should help researchers' ability to recruit diverse study samples [39].

Investigators should design a multi-pronged recruitment approach that incorporates strategies shown to be most effective at reaching the desired sample. This may mean considering different approaches to recruitment for multiple constituencies. The need for participation of both members of a couple in the clinical trial described here meant that recruitment plans had to target both husbands (who were also the patients) and their wives. Because either member of

the dyad could serve as point of contact, recruitment efforts expanded beyond the medical setting, where patients are typically recruited, into a variety of community settings where the spouses could be accessed. Such an approach, however, necessitates increased sensitivity in recruitment activities, as members of the dyad may have different needs and possibly conflicting reasons for wanting, or not wanting, to participate in the study. In some cases, patients or spouses contacted us to participate before soliciting agreement from their partners. When this happened, additional personnel time was invested to either provide further information or to, on occasion, mediate disagreements.

As researchers plan the optimal sample characteristics and size for their studies, it is helpful to develop a focused recruitment plan and estimate the costs of each strategy, as well as to have alternate back-up strategies. The first step is to delineate desired characteristics and eligibility requirements for the sample, including such characteristics as the age distribution, gender, ethnic and cultural mix, socio-economic mix, language, acculturation, and other characteristics for the specific study. The second step is to delineate specific outreach strategies that will be deployed to reach people with the defined characteristics, who will do them, and how much staff time will realistically be required per each participant recruited. A third step is to consider what other ancillary expenses will be involved, such as travel and parking, phone expenses, paper supplies, advertising charges, participant incentives, including participants' transportation, parking, childcare, and refreshments. A final consideration is whether there will be any post-recruitment expenses to keep the participants apprised of the study's progress to encourage word-of-mouth dissemination about the study to others.

The recruitment study presented here has several limitations. First, it exclusively focused on personnel costs. Other potential costs, such as those associated with extensive media-based advertising campaigns or use of advanced technology (e.g., streaming video, interactive internet sites), were not considered, primarily because budgetary considerations for the clinical trial being conducted prohibited the use of such expensive approaches. Researchers wanting to use these strategies as part of their overall recruitment effort will need to carefully budget for costs associated with producing as well as maintaining the necessary technology. Further, as discussed above, we were able to rely on a substantial amount of noncompensated effort, ranging from physicians' direct solicitation of their patients support work by undergraduate research assistants. This likely lowered our costs, and may not be generalizable to other settings. In addition, we already had an established recruitment network in the community, a resource others may need to invest time and resources in developing. Finally, we were recruiting couples; more commonly studies recruit individual patients.

Conclusion

Contributing to the significant costs of conducting clinical trials are the costs of recruiting participants to trials, costs that are magnified by the critical need and Federal mandate to accrue diverse samples [40,41], as well as by requirements of HIPAA. The findings of this study provide researchers who conduct controlled clinical trials with one estimate of the actual cost of accruing disease-specific dyads to research studies. The findings also demonstrate the relative efficacy and efficiency of various strategies employed in a focused and interwoven approach to recruitment. This study demonstrated that narrowly focused approaches to recruitment can enhance subject recruitment while helping to control costs. Finally, the findings suggest the importance of identifying and utilizing recruitment resources with reduced or no associated monetary costs, as well as the continued need to develop additional recruitment strategies to recruit diverse samples.

Acknowledgments

We would like to acknowledge the following San Diego area referring health care professionals for their help in accruing patients to this study: Christopher Amling, M.D., Israel Barken, M.D., the late Howard Fuerst, M.D., Jeffrey Gaines, M.D., Richard Hall, M.D., Robert Hathorne, M.D., Peter Johnstone, M.D., Linas Kazlo, M.D., Huathin Khaw, M.D., Robert Langer, M.D., Kenneth Nitahara, M.D., Francisco Pardo, M.D., Jonathon Polikoff, M.D., Marianne Rochester, M.D., Carol Salem, M.D., Marilyn Sanderson, R.N., Kenneth Schimizu, M.D., Stephen Seagren, M.D., John Smiley, M.D., Thomas Szolar, M.D., and Linda Wasserman, M.D. We also wish to thank the following organizations: the American Cancer Society, the Prostate Cancer Research & Education Forum, the Informed Men's Support Group, and The Wellness Community. Special thanks to the San Diego stylists and their salons who contributed to this research study.

Grant Acknowledgements: This study was supported by the: California Cancer Research Program grant 99-00556V-10049, an intramural grant from the Rebecca and John Moores UCSD Cancer Center Foundation, National Cancer Institute grant R25CA65745, National Institutes of Health, Division of National Center on Minority Health and Health Disparities EXPORT Grant P60MD00220, National Cancer Institute Minority Institution/Cancer Center Partnership Program Grants U56 CA92079 and U56 CA92081, and the NCI CORE GRANT P30 CA 23100.

REFERENCES

1. Avorn J. Including elderly people in clinical trials: Better information could improve the effectiveness and safety of drug use. *BMJ* 1997;315(25 October):1033–1034. [PubMed: 9366725]
2. Bugeja G, Kumar A, Banerjee A. Exclusion of elderly people from clinical research: a descriptive study of published reports. *BMJ* 1997;315(25 October):1059. [PubMed: 9366735]
3. Shavers V, Lynch C, Bumeister L. Factors that influence African-Americans' willingness to participate in medical research studies. *Cancer* 2001;91(1 supplement):233–236. [PubMed: 11148585]
4. Mouton C, Harris S, Rovi S, Solorzano P, Johnson M. Barriers to black Women's participation in cancer clinical trials. *J Natl Med Assoc* 1997;89(11):721–727. [PubMed: 9375475]
5. Green B, Partridge E, Fouad M, Kohler C, Crayton E, et al. African-American attitudes regarding cancer clinical trials and research studies: results from focus group methodology. *Ethn Dis* 2000;10(1):76–86. [PubMed: 10764133]
6. Sadler G. A call to action: patients' access to clinical trials. *Health Soc Work* 2001;26(3):196–200. [PubMed: 11531196]
7. Killien M, Bigby J, Champion V, Fernandez-Repollet E, Jackson R, et al. Involving minority and underrepresented women in clinical trials: the National Centers of Excellence in Women's Health. *J Womens Health Gend Based Med* 2000;9(10):1061–1070. [PubMed: 11153102]
8. Shavers-Hornaday V, Lynch C, Burmesiter L, Torner J. Why are African Americans under-represented in medical research studies? Impediments to participation. *Ethn Health* 1997;2(1–2):31–45. [PubMed: 9395587]
9. Tejada H, Green S, Trimble E, Ford L, High J, et al. Representation of African-Americans, Hispanics, and Whites in National Cancer Institute Cancer treatment trials. *J Natl Cancer Inst* 1996;88(12):812–816. [PubMed: 8637047]
10. MacEntee M, Wyatt C, Kiyak H, Hujoel P, Persson R, et al. Response to direct and indirect recruitment for a randomised dental clinical trial in a multicultural population of elders. *Community Dent Oral Epidemiol* 2002;30(5):377–381. [PubMed: 12236829]
11. Martinson B, Lazovich D, Lando H, Perry C, McGovern P, et al. Effectiveness of monetary incentives for recruiting adolescents to an intervention trial to reduce smoking. *Prev Med* 2000;31(6):706–713. [PubMed: 11133338]
12. Bjornson-Benson W, Stibolt T, Manske K, Zavela K, Youtsey D, et al. Monitoring recruitment effectiveness and cost in a clinical trial. *Control Clin Trials* 1993;14(2 Suppl):52S–67S. [PubMed: 8500313]
13. Gill T, McGloin J, Gahbauer E, Shepard D, Bianco L. Two recruitment strategies for a clinical trial of physically frail community-living older persons. *J Am Geriatr Soc* 2001;49(8):1039–1045. [PubMed: 11555064]
14. Valanis B, Blank J, Glass A. Mailing strategies and costs of recruiting heavy smokers in CARET, a large chemoprevention trial. *Control Clin Trials* 1998;19(1):25–38. [PubMed: 9492967]

15. Swanson G, Ward A. Recruiting minorities into clinical trials: Toward a participant-friendly system. *J Natl Cancer Inst* 1995;87(23):1747–1759. [PubMed: 7473831]
16. Bielski R, Lydiard R. Therapeutic trial participants: Where do we find them and what does it cost? *Psychopharmacol Bull* 1997;33(1):75–78. [PubMed: 9133754]
17. Adams J, Silverman M, Musa D, Peele P. Recruiting older adults for clinical trials. *Control Clin Trials* 1997;18(1):14–26. [PubMed: 9055049]
18. Silagy C, Champion K, McNeil J, Worsam B, Donnan G, et al. Comparison of recruitment strategies for a large-scale clinical trial in the elderly. *J Clin Epidemiol* 1991;44(10):1105–1114. [PubMed: 1941003]
19. Brown B, Long H, Gould H, Weitz T, Milliken N. A conceptual model for the recruitment of diverse women into research studies. *J Womens Health Gend Based Med* 2000;9(6):625–632. [PubMed: 10957751]
20. Piantadosi S, Patterson B. a method for predicting accrual, cost, and flow in clinical trials. *Control Clin Trials* 1987;8(3):202–215. [PubMed: 3665522]
21. Kaakko T, Murtomaa H, Milgrom P, Getz T, Ramsay D, et al. Recruiting phobic research subjects: Effectiveness and cost. *Anesth Prog* 2001;48(1):3–8. [PubMed: 11495403]
22. Street A, Strong J, Karp S. Improving patient recruitment to multicentre clinical trials: The case for employing a data manager in a district general hospital-based oncology centre. *Clin Oncol (R Coll Radiol)* 2001;13(1):38–43. [PubMed: 11292134]
23. Garrett S, Thomas A, Cicuttini F, Silagy C, Taylor H, et al. Community-based recruitment strategies for a longitudinal intervention study: the VECAT experience. *J Clin Epidemiol* 2000;53(5):541–548. [PubMed: 10812328]
24. Borhani N, Tonascia J, Schlundt D, Prineas R, Jefferys J. Recruitment in the Hypertension Prevention trial. *Control Clin Trials* 1989;10(3 Suppl):30S–39S. [PubMed: 2680272]
25. Folmar S, Oates-Williams F, Sharp P, Reboussin D, Smith J, et al. Recruitment of participants for the estrogen replacement and atherosclerosis (ERA) Trial: A comparison of costs, yields, and participant characteristics from community- and hospital-based recruitment strategies. *Control Clin Trials* 2001;22:13–25. [PubMed: 11165419]
26. Gismond P, Hamer D, Leka L, Dallal G, Fiatarone Singh M, et al. Strategies, time, and costs associated with the recruitment and enrollment of nursing home residents for a micronutrient supplementation clinical trial. *J Gerontol A Biol Sci Med Sci* 2005;60(11):1469–1474. [PubMed: 16339336]
27. Ory M, Lipman P, Karlen P, Gerety M, Stevens V, et al. Recruitment of older participants in frailty/injury prevention studies. *Prev Sci* 2002;3(1):1–22. [PubMed: 12002555]
28. Davey R, Edwards S, Cochrane T. Randomised controlled trial of the cost-effectiveness of water-based therapy for lower limb osteoarthritis. *Health Technology Assessment* 2005;9(31):1–114.
29. Tarlow B, Mahoney D. The cost of recruiting Alzheimer's disease caregivers for research. *Journal of Aging Health* 2000;12(4):490–510.
30. Rubin R, Fujimoto W, Marrero D, Brenneman T, Charleston J, et al. The Diabetes Prevention Program: recruitment methods and results. *Control Clin Trials* 2002;23(2):157–171. [PubMed: 11943442]
31. Erlen J. HIPAA - Implications for research. *Orthopedic Nursing* 2005;24(2):139–142.
32. Levinson, J. New York: Houghton Mifflin Company; 1993. *Guerrilla marketing: Secrets for making big profits from your small business.*
33. Silverman, G. New York, NY: American Management Association; 2001. *The secrets of word-of-mouth marketing How to trigger exponential sales through runaway word-of-mouth.*
34. Austin L, Ahmad F, McNally M, Stewart D. Breast and cervical cancer screening in Hispanic women: A literature review using the health belief model. *Womens Health Issues* 2002;12(3):122–128. [PubMed: 12015184]
35. Brawarsky P, Brooks D, Mucci L, Wood P. Effect of physician recommendation and patient adherence on rates of colorectal cancer testing. *Cancer Detect Prev* 2004;28(4):260–268. [PubMed: 15350629]
36. Jones L, Courneya K, Fairey A, Mackey J. Effects of an oncologist's recommendation to exercise on self-reported exercise behavior in newly diagnosed breast cancer survivors: a single-blind, randomized controlled trial. *Ann Behav Med* 2004;28(2):105–113. [PubMed: 15454357]

37. Mills E, Seely D, Rachlis B, Griffith L, Wu P, et al. Barriers to participation in clinical trials of cancer: a meta-analysis and systematic review of patient-reported factors. *Lancet Oncology* 2006;7(2):141–148. [PubMed: 16455478]
38. Geraets J, Groot Ide, Goossens M, Bruijn Cde, Bie Rde, et al. Comparison of two recruitment strategies for patients with chronic shoulder complaints. *British Journal of General Practice* 2006;56(523):127–133. [PubMed: 16464327]
39. Sadler G, Peterson M, Wasserman L, Mills P, Malcarne V, et al. Recruiting research participants at community education sites. *Journal of Cancer Education* 2005;20(4):235–239. [PubMed: 16497136]
40. Avent R, Dollman R. Cancer clinical trials in the community setting: A 20 year perspective. *Cancer Biother* 1995;10(2):95–113. [PubMed: 7663578]
41. Bailes JS. Current issues in oncology reimbursement. *Oncology* 1995;9(11 suppl):185–189. [PubMed: 8608051]

Table 1

Recruitment Strategies

Recruitment strategies	Description
Health care providers	Doctors, nurses, receptionists, and social workers were recruited to disseminate clinical trial information and recruitment materials. Project staff provided onsite recruitment assistance (within IRB guidelines) with phone calls, mailings, and in the clinic.
Churches	Clergy promoted the studies with flyers, church bulletins, pulpit announcements, and research team presentations.
Support groups	Prostate cancer support group leaders announced studies and disseminated flyers.
Community cancer organizations	Organizations included study announcements in newsletters, called known prostate cancer patients, and mailed flyers to their constituents.
Salons/Barbershops/ Grocery Stores	Research assistants posted and disseminated flyers. They also encouraged stylists and barbers to discuss the study with clients.
Senior citizen centers	Flyers were posted in senior centers and presentations were made by project staff.
Targeted mailings	Staff sent mailings to people who have previously participated in other studies (with IRB approval) or were listed among the research institution's affinity groups.
Media	Staff distributed press releases to generate electronic and print media coverage and purchased print advertisements.
Health fairs	Staff offered cancer education and study recruitment materials at community health fairs.
Professional association meetings	Staff made presentations at the research institution's Grand Rounds, offered CME sessions about prostate cancer and the study, and made presentations at women's/men's clubs such as the Soroptimists Club.
Word-of-Mouth	Every contact and study participant was encouraged to tell others about the study and given copies of flyers to facilitate this.

Table 2

Participant Demographic Information (N=172 Couples)

Characteristics	Males		Females	
	n	%	n	%
<u>Combined Income</u>				
< \$20,000	12	7	11	6.4
\$20,001 – \$30,000	15	8.7	19	11.1
\$30,001 – \$50,000	40	23.3	45	26.2
\$50,001 – \$75,000	47	27.3	37	21.5
>\$75,000	52	30.3	47	27.3
Unknown	13	7.6	6	3.5
<u>Stage of Cancer</u>				
A	85	49.4		
B	46	26.7		
C	18	10.5		
D	7	4.1		
Unknown	16	9.3		
<u>Education</u>				
High school or less	26	15.1	45	26.2
Some college	50	29.2	57	33.1
College graduate	36	20.9	31	18.1
Grad/professional school	59	34.3	37	21.5
Unknown	1	0.6	2	1.2
<u>Ethnicity</u>				
Caucasian	147	85.5	140	81.4
African American	11	6.4	9	5.2
Latino	3	1.8	9	5.2
Asian	5	2.9	8	4.7
Native American	3	1.8	0	0
Other	2	1.2	4	2.3
Unknown	1	0.6	2	1.2

Table 3

Time and Cost Analysis By Means of Participant Recruitment

Recruitment Strategies That Provided Subjects	Number of Dyads from Each Source N = 172	Staff Hours Spent Recruiting Participants	Costs Incurred Using Staff Member's Hourly Rates	Hours/Couple Recruited	Dollars/Couple Recruited
Direct Recruitment Strategies					
Health Care Providers	106	1089	\$ 16,267	10	\$153
Churches	3	49	\$ 1,578	16	\$526
Support Groups	19	400	\$5,481	21	\$288
Community cancer organizations	2	179	\$ 3,376	90	\$ 1,688
Salons/Barbershops/Grocery stores	2	59	\$2,170	30	\$ 1,085
Senior Citizens Centers	0	30	\$390	None recruited	None recruited
Targeted Mailings	5	189	\$ 2,457	38	\$491
Media	17	219	\$ 5,533	13	\$325
Health Fairs	0	130	\$ 1,690	None recruited	None recruited
Professional association meetings	0	40	\$1,444	None recruited	None recruited
Word-of-Mouth	4	0	0	Unknown	Unknown
Indirect Recruitment Effort Expended					
Planning and Strategy Sessions	172 ^a	270 ^b	\$ 9,008 ^b	1.6	\$ 52.37
Other Recruitment					
No Recall of How Recruited	14	Unknown	Unknown	Unknown	Unknown
Total	172	2,654	\$ 49,394		

^a not included in column total^b divided across all 172 participants and added to direct costs