

Challenges Faced in Recruiting Patients from Primary Care Practices into a Physical Activity Intervention Trial¹

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Background. Special challenges are encountered when clinical trial recruitment targets a physician practice-based population, as opposed to recruiting from the community. Since most published information about recruitment has focused on the latter group, summation of successful primary-care-based recruitment strategies could prove useful for future trials recruiting from this population.

Methods. The Activity Counseling Trial (ACT) is a multicenter, randomized clinical trial that evaluated approaches to primary care-based interventions to increase physical activity in sedentary adults 35-75 years of age. Fifty-four clinicians from eight practices recruited 874 participants from three U.S. sites. Recruitment challenges that related, in great part, to the primary care setting included: (1) focusing on patients from ACT physician practices who had regularly scheduled or intend-to-schedule appointments within the next year; (2) placing trial staff in the clinical offices for recruitment purposes; and (3) placing trial interventionists in the physicians' offices. Other challenges were related to recruitment of minorities and men.

Results. Patient mailing yielded 43.4% of all randomized participants, followed by office-based questionnaires (32.5%) and direct telephone contact (21.6%). Based on a retrospective cost-effective analysis (indirect costs excluded), the self-administered office-based questionnaire was the least costly strategy for one site

(\$14/randomized participant), followed by patient mailing at another site (\$58). The direct telephone contact method utilized at one site serving primarily a minority population yielded a per randomized participant cost of \$80.

Conclusions. Recruitment of clinical trial participants from practice-based populations requires modification of the strategies used to recruit from the community. Multiple strategies should be employed, followed closely for their respective yields, and adapted as needed. © 1999 American Health Foundation and Academic Press

Key Words: behavioral intervention; clinical trial; clinical trial recruitment; cost-effective analysis; general practice; physical activity; primary care; recruitment.

INTRODUCTION

Despite increasing trends toward conducting clinical trials in primary care practices [1,2], there is little information in the literature that describes specific strategies and logistics involved in enrolling primary care patients into practice-based clinical trials [3-7]. Although recruitment of patients from a primary care setting has been compared to more traditional methods of community-oriented recruitment such as use of public data bases, mass media advertising, community health screening, and patient referral [5], to our knowledge no published studies have compared multiple recruitment approaches used within the general practice environment or described how these approaches differ in terms of their cost-effectiveness.

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National Institutes of Health, is a multicenter, randomized controlled clinical trial designed to evaluate the efficacy of two primary care, practice-based physical activity behavioral interventions compared with a standard-care control over a 24-month intervention period [8, 9]. Sedentary but healthy participants were randomized to one of three arms, all of which involved the same level of physician advice about increasing physical activity. Each arm had differing levels of behavioral counseling, which was administered by a health educator when enrolled ACT participants visited their primary care physicians for nonacute medical visits. Although ACT encountered some challenges unique to this patient population, the study exceeded its target recruitment goal within the requisite time allotted for recruitment.

Because ACT recruited from the primary care practices of cooperating ACT physicians, the trial could not adopt the community-oriented recruitment methods utilized in many clinical trials. This report describes the strategies that were developed to recruit healthy but sedentary patients from this setting and compares these approaches in terms of their overall yields and cost-effectiveness.

METHODS

ACT was designed to enroll 810 community dwelling, sedentary individuals (417 men and 393 women) 35 to 75 years of age and in stable health. The planned recruitment, screening, and enrollment phase of 18 months began in late 1995, after central and local measurement training and certification of key ACT staff and investigators. The Recruitment Subcommittee, in conjunction with the Steering Committee, developed the study eligibility criteria and recruitment strategies for ACT.

Three sites (Cooper Institute for Aerobics Research/University of Texas Southwestern Medical Center in Dallas, University of Tennessee at Memphis, and Stanford University School of Medicine in Palo Alto) recruited participants from the cooperating ACT physician practices (see list of ACT investigators and practices at end of paper).

Some of the factors considered in the selection of ACT physician practices included (1) a prior positive working relationship between the ACT study investigators and the physicians; (2) clinical practice proximity to the ACT measurement clinic (locale for baseline and follow-up measurements); (3) interest in the study among physician candidates and their staff; (4) availability of computerized patient databases (for purposes of contacting patients to inform them about ACT); (5) representation of a broad range of practice types (e.g., private, academic, HMO, public); and (6) a high percentage of African American or Hispanic patients within some clinical practices.

During the recruitment period, the ACT study coordinators worked with their staff to gain access to patient records in the ACT clinical practices. Two to three health educator interventionists met with patients at the clinical practice offices or, for one site, at the ACT research office near the clinical practice, where they (1) randomized eligible study participants when the participants came in for their next scheduled physician visit and (2) implemented the three trial interventions (two experimental and one control).

Study Population

Patients qualifying for ACT had to be sedentary and in stable health. Table 1 summarizes the study eligibility criteria [8]. Those taking medications for certain chronic conditions (e.g., hypertension) were required to be on stable therapeutic doses for a minimum of 3 months before being considered for screening.

Since the primary focus of ACT was to evaluate interventions that could be implemented routinely in general clinical practice, only those patients planning or scheduled to visit their ACT physicians within the next year were eligible for screening. Thus, patients who might have visited their physicians solely for the purpose of receiving the ACT intervention were not eligible to participate.

Recruitment Strategies

ACT physicians did not participate directly in recruitment activities (except at one site, where initial efforts in direct physician recruitment of participants were soon discontinued). Rather, physicians offered their support by agreeing to make their patients available for recruitment and by allowing their office staff to work with ACT personnel to identify potentially eligible study subjects. Although recruitment strategies varied by site, four primary approaches emerged.

Patient mailing (Memphis and Stanford). Patient names and addresses were obtained from clinic appointment/address lists or databases. These were sorted by age and some medical exclusions. Personalized letters about the study, printed on clinic letterhead and signed by patients' physicians or the clinic medical director, were mailed to patients, regardless of whether they had a scheduled appointment. Patients could either call the ACT measurement staff or send in an attached mail-back card. Each site performed repeat patient mailings.

Office-based questionnaire (Dallas and Stanford). The office-based questionnaires, which consisted of a number of questions that addressed eligibility criteria, were completed under varying conditions: (1) interviewer-administered in the waiting room, after preliminary chart review for a number of exclusions such as age or specified medical conditions; (2) self-administered

TABLE 1
ACT Eligibility Criteria

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> • Community-dwelling men and women • 35–75 years of age • Receiving primary care from a participating ACT physician • Scheduled to see an ACT physician • Exhibiting a sedentary lifestyle, defined as energy expenditure of $\leq 35 \text{ kcal}\cdot\text{kg}^{-1}\cdot\text{day}^{-1}$ measured by 7-day physical activity recall • Willing and able to participate in all aspects of the trial • In stable health • Independent in activities of daily living • Able to alter physical activity in accordance with the intervention program • If on medication for chronic disease, on a stable dose for the past 3 months • Willing and able to give informed consent 	<p><i>Medical conditions</i></p> <ul style="list-style-type: none"> • History or evidence of coronary heart disease • Cerebrovascular disease • Peripheral vascular disease • Arrhythmias • Valvular heart disease • Cancer (other than skin cancer) in past 5 years • Diabetes mellitus • Pulmonary disease • Severe psychiatric illness • Severe systemic illness • Blood pressure: resting diastolic $>100 \text{ mm Hg}$ or resting systolic $>180 \text{ mm Hg}$ • Discomfort at any level of exercise • Abnormal treadmill test • Pregnancy, lactation, or not practicing contraception (women only) <p><i>Inability to comply with study protocol</i></p> <ul style="list-style-type: none"> • Hearing or sight impairments resulting in inability to use the telephone or read forms • Impaired cognitive function • Anticipated move or distance from clinic • Participation in other trials • Participation of another household member in ACT • Alcohol intake >21 drinks per week • Functional limitations • English illiteracy • Judgment of clinical center staff

by patients in the waiting or exam rooms who were preliminarily screened for some exclusions; and (3) self-administered by “unselected” patients (i.e., those who were not prescreened for any exclusions) in the waiting or exam rooms.

Direct telephone contact (Dallas, Memphis, and Stanford). Names and phone numbers were obtained from appointment schedules (computerized or not). Patients were prescreened by age and by several medical exclusions. The majority of calls made across the three sites were “cold” calls, i.e., without letters about ACT being sent to patients first. If ACT staff were able to reach a patient by phone and the patient was interested in the study, a study-wide telephone prescreen form was administered during the call.

Physician recruited (Stanford). Physicians actively recruited their patients into the study by previewing the charts/medical records of those patients whom they saw in the clinic and by discussing ACT with those who were potentially eligible.

Cost-Effectiveness of Site-Specific Recruitment Strategies

Clinical sites participating in ACT did not collect consistent study-wide information regarding the resources

required for recruitment, nor were all sites able to track the resources invested in particular recruitment strategies. Thus, a *post hoc* estimate of the cost of the three principal recruitment strategies—expressed as cost per randomized participant—was performed at two of the three sites.

The numerator of each cost-effectiveness ratio was the sum value of labor effort, postage, materials, and mileage, where applicable. The denominator was the number of individuals successfully recruited from the site that was using a specific recruitment strategy. With regard to the numerator, because regional variation in the cost of overhead and wages/fringes could confound the cost estimates, these were held constant in the analysis using the following assumptions: (1) fixed costs such as use of office space, telephones, and utilities were the same for each site and for each recruitment strategy; consequently, these costs were not included in the numerator, since adding a constant to each numerator would not change the rank order of the cost-effectiveness ratios; (2) the cost of recruitment was based on an estimate of the variable costs or direct materials and labor resources needed to complete recruitment; for the purpose of this analysis, all labor effort directed toward recruitment is defined as a variable cost (i.e., none of the labor effort is designated

as “fixed” or using existing resources at no additional expense to the study); (3) estimated labor costs were based on a constant wage and fringe rate across sites using a wage of \$20/h with a 32.5% fringe, or \$26.00/h.

Screening Visits

Preliminary recruitment efforts took place at the physician practices, while screening measurements were conducted at separate measurement sites (which also served as the locations for participant follow-up measurements). The separation of the measurement site from the intervention sites (i.e., the physicians’ offices) minimized the amount of interference in the clinical practices and facilitated efforts to keep all measurement staff blinded to participants’ treatment assignments.

A total of three face-to-face screening visits (SV0, SV1, and SV2) were preceded by a telephone prescreen interview, during which patients were informed about ACT and then queried about basic demographic information and preliminary information on levels of physical activity and possible medical exclusions.

Randomization Visit

Measurement clinic staff informed the health educator that an eligible patient was scheduled to see the ACT physician and was to be randomized. During the clinical practice visit, the physician (who remained blinded to patient treatment assignment) offered to all ACT participants the same standardized information about the benefits of increasing physical activity, after which the health educator randomized the participant and then initiated the first phase of the assigned intervention. Randomization was achieved by direct touch-tone dialing by the health educator into the computerized randomization system, located at the Coordinating Center [10].

RESULTS

The recruitment of physician practices into ACT yielded a study-wide total of eight primary care practices that specialized in internal medicine and family practice. These included four at Stanford, two at Dallas, and two at Memphis. (One of the Memphis practices consisted of a group of clinics affiliated with a local hospital.) The clinics represented a broad spectrum of practices (public, private, academic, and HMO). A total of 51 physicians, 2 physician assistants, and 1 nurse practitioner agreed to allow their patients to be recruited into ACT. Of the 3908 patients undergoing prescreen telephone interviews, 22.4% were randomized into the study. The study-wide yields of patients from one screening contact to the next were high, with 43% of all patients contacted at the telephone screen attending

SV0, 61% of SV0 screenees attending SV1, 87% of those screened at SV1 attending SV2, and 97% of all SV2 patients being randomized. Of those not attending subsequent screening visits, approximately 80% were ineligible at the previous visit and 20% did not continue for other reasons. By the end of the recruitment period, the study-wide recruitment goal of 810 had been exceeded, with the study achieving 108% of its target goal by randomizing 874 participants. Memphis, Dallas, and Stanford enrolled 93, 112, and 117% of their target recruitment goals, respectively.

The primary medical reason for patient exclusion from ACT was insulin-dependent diabetes—4.3% of all patients screened for the study were excluded for this condition. Three and one-half percent of all exclusions were due to stroke. Less than 1% of all screenees were excluded for depression or for being too active.

The study did very well in achieving its minority and gender recruitment goals. African Americans represented 25% of all ACT participants (original goal was 20%), 4% of the ACT cohort was Hispanic (original goal was 10%), and 4% was represented by other minorities (original goal was 3%). Recruitment goals for both men and women were exceeded (101% for women, 115% for men).

ACT experienced an initial lag time for recruitment (Fig. 1), which lasted for about 14 weeks, after which the enrollment curve began to steepen. By week 36, the recruitment rate had approached the projected rate. This rate remained fairly constant throughout the remainder of the recruitment phase.

In terms of how comparable ACT participants were relative to those screened for ACT but not randomized, ACT participants were younger (51 versus 54 years),

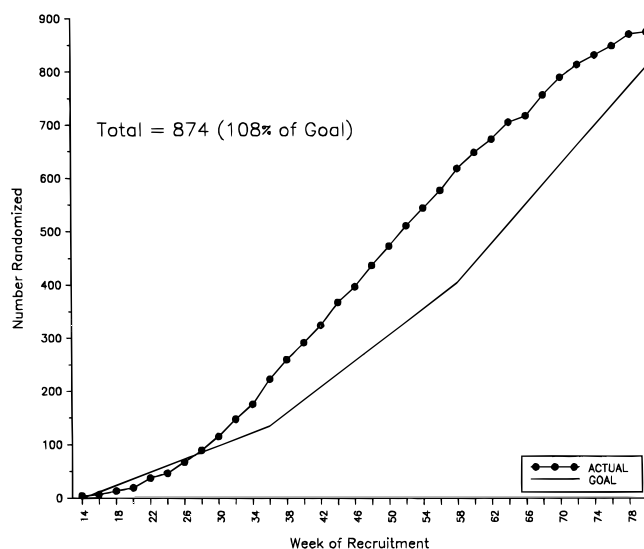


FIG. 1. Cumulative number of randomized participants vs recruitment goal.

better educated, more frequently employed and married, had a higher household income, and smoked less. Although the study did achieve most of its racial target goals, it does include a significantly higher percentage of Caucasians (i.e., non-Hispanic whites) and less than half as many African Americans (i.e., non-Hispanic blacks) as the sample that was screened but not randomized.

Effectiveness of Primary Recruitment Strategies

There was no central tracking of the progress of the various recruitment strategies at the three sites. Although each site tracked and monitored locally the yields from the different recruitment strategies, this was not done uniformly across the sites for all strategies. For example, not all sites were able to continually monitor and document (1) the differing yields from the telephone contact strategy, based on calls that were preceded by a letter vs cold calls (the majority of calls were cold); (2) the number of office-based questionnaires distributed versus the number completed; (3) the number of phone vs mailback card responses to the patient mailings; or (4) patient response yields from first vs second mailings. For these reasons we are not able to offer a prospective summary of site-specific yields from the primary recruitment methods utilized. Since all three sites were able to determine retrospectively the number of randomizations by recruitment source, this information is provided. The retrospective cost-effective analysis presented later in this paper does capture and analyze some site-specific recruitment yields that could prove useful toward better evaluating the cost/time effort vs recruitment benefit.

Patient mailing (Memphis and Stanford). This source yielded a total of 379 study participants or 43.4% of all patients enrolled in ACT (Table 2). For one site, an indeterminate but small number of phone/mailback card responses may have been attributed to an additional source, a flyer about ACT that was placed in the waiting and exam rooms.

Office-based questionnaire (Dallas and Stanford). Despite the varying approaches used to administer the office-based questionnaires in Dallas and Stanford (see Methods), the yields from this general strategy were combined across the two sites, since one site was unable to track the yields from its different approaches. A total of 284 randomized participants, or 32.5% of all 874 ACT study subjects, were recruited into the study through this strategy.

Direct telephone contact (Dallas, Memphis, and Stanford). A total of 189 patients were randomized into ACT from this source. This represents nearly one-fourth (21.6%) of the 874 ACT subjects. This source, although productive in terms of number of participants

TABLE 2
Source Contribution to Study-Wide Recruitment

Recruitment source	Number randomized from source	% Contribution to recruitment of 874 randomized participants
Patient mailing		
Memphis	167	
Stanford	212	
Total	379	43.4
Office-based questionnaires		
Dallas	205	
Stanford	79	
Total	284	32.5
Direct telephone contact		
Dallas	97	
Memphis	86	
Stanford	6	
Total	189	21.6
Physician-recruited		
Stanford	12	1.4
Unaccounted sources	10	1.1
	874 participants	100%

randomized, proved to be too labor intensive and was abandoned at two of the sites.

Physician recruited (Stanford). Twelve patients were recruited into the study through this approach (a total of 1.4% of all enrolled participants). This method was discontinued early in the study.

Recruitment sources for 10 patients enrolled in the study could not be determined.

Cost-Effectiveness of Site-Specific Recruitment Strategies

Patient mailing (Stanford). The Stanford site tracked expenses associated with patient mailings. The cost components included stationery (\$1126), mailback cards (\$295), postage for mailing (\$1126), postage for mailback cards (\$281), photocopying, envelopes, and labels (\$224), address lists (\$1380), and labor (300 h at a wage and fringe rate of \$26/h or \$7800). Stanford contacted 3868 individuals by mail, resulting in 212 individuals being randomized. The total cost for patient mailings was \$12,232 or \$58 per randomized participant.

Office-based questionnaires (Stanford and Dallas). Stanford—ACT staff interviewed potentially eligible patients who were waiting in the clinic to see their ACT physicians. According to staff logs, staff invested 760 h at the clinic administering the questionnaires. At a wage and fringe rate of \$26/h, this translates into \$19,760. Factoring in \$0.05 per page, the cost of the two-page screening form administered to 1085 potential

subjects was \$109. Flowers and food (\$115) were occasionally provided to demonstrate appreciation for inconveniences associated with ACT staff recruitment efforts in the clinic. The total cost of this approach was \$19,984 to recruit 79 participants or \$253 per randomized participant. This strategy was abandoned early in the study as it was extremely labor intensive and did not yield the number of expected participants.

Dallas—Patients completed the one-page office-based questionnaires themselves. Office nursing staff did a preliminary prescreen for eligibility and then gave the questionnaires to patients who appeared to be appropriate for the study. Two ACT staff members conducted a 30-minute training session for the clinical practice nurses, during which the nurses were informed about the screening criteria and procedures used to recruit participants into the study. At a wage and fringe rate of \$26/h, this totaled \$26. A total of 2100 office-based questionnaires cost \$0.05 per page or \$105. Over the 54-week period during which the office-based questionnaire was used at this site, study staff traveled 5 miles roundtrip to the clinic on a weekly basis to obtain the completed questionnaires. Using rates of \$0.32 per mile for 270 miles traveled (\$86), parking at \$1.00 per trip (\$54), and the labor effort of approximately 20 minutes per trip (wage and fringe rate of \$26/h) yielded a cost of \$468.

Since clinic nursing staff were not compensated for their time on this study, the cost of nursing staff is not included in this analysis. Also, study staff estimated that the effort required by nursing staff to distribute questionnaires as part of their office routine was minimal, further justifying their exclusion from the total cost estimate.

A total of 881 office-based questionnaires was completed and reviewed for interest and eligibility. Study staff estimated that each form required approximately 1 minute to review. At a wage and fringe rate of \$26/h, this translates into \$382.

Five hundred twenty-five of the 881 patients completing the questionnaire (60%) were deemed eligible to receive a follow-up prescreen phone call. It was estimated that 167 unsuccessful 1-minute phone calls were made to reach the 525 eligible subjects. At a wage and fringe rate of \$26, these costs amounted to \$72. All 525 subjects were contacted and screened, with each prescreening call requiring 5 minutes. At the standard wage and fringe rate assumed for this study, this translates into \$1138.

The estimated cost of providing staff incentives (sweatshirts and free health club memberships for distributing and collecting the questionnaires) was \$523. Summing in the above-noted expenses, the cost of recruiting 205 participants was \$2854 or \$14 per randomized participant.

Direct telephone contact (Dallas). The Dallas site tracked the number of phone calls made to patients who were scheduled to visit their primary care physicians. Study staff attempted to contact 4091 of these individuals. About 10% of these call attempts represented disconnected phone lines. Of the remaining 3682, staff were successful in reaching 2438 (66%) but were unable to make contact with the remaining 1244 patients (34%).

Successful phone contacts—For the 2438 patients who were successfully contacted, study staff estimated that the average amount of time required to introduce the study and to prescreen the participant was 5 minutes. Based on a wage and fringe rate of \$26/h, the cost of making the 2438 successful contact calls was \$5282.

Successful phone contacts requiring repeat calls—Over 90% of the 2438 successfully contacted patients were reached on the first phone call attempt (2239 patients). For the remaining 199 patients, 161 were reached on the second try, 22 on the third try, 9 were reached on the fourth call, and 7 on the fifth attempt. Thus, 260 unsuccessful calls were placed to patients who were eventually reached (161 + 44 + 27 + 28).

Unsuccessful phone contacts—Of the 409 patients with disconnected telephones, one phone call was made for each disconnected line. For the other 1244 individuals who were never reached, it was estimated that three phone call attempts per subject were made.

Overall cost-effective estimate—For the 4401 unsuccessful calls made to subjects who were and were not successfully contacted [260 calls to patients eventually reached + 409 calls to patients with disconnected telephones + (1244 × 3) calls to individuals with telephones who were not reached], recruitment staff estimated a labor effort of 1 minute for each of these calls. At a wage and fringe rate of \$26/h, the cost of these unsuccessful calls was \$1907. Adding to this the cost of making the 2438 successful contact calls (\$5282), the cost of staff effort required to recruit by telephone was \$7189. Of the 4091 attempted patient contacts, 1400 were preceded by an introductory letter during the early stages of recruitment (see Discussion for further explanation). The cost of postage, materials, and printing for these letters was \$560. The total cost of phone recruitment was \$7749 for the 97 enrolled participants or \$80 per randomized participant.

Table 3 compares the findings of the cost-effective analysis to site-specific yields of randomized participants for the three primary strategies. For Dallas, the office-based questionnaire approach gave the best yield (68% of the 302 enrolled participants at this site) and the lowest cost per randomized participant (\$14). The remainder of the Dallas enrolled population (32%) was recruited via the telephone contact method at a cost

TABLE 3

Yield vs Cost-Effectiveness of Three Main Recruitment Strategies by Site

Strategy/site	% Contribution to site-specific randomized population	Cost per randomized participant
Direct telephone contact		
Dallas	32	\$80
Patient mailing		
Stanford	66	\$58
Office-based questionnaires		
Dallas	68	\$14
Stanford	25	\$253

of \$80/randomized participant. At Stanford, the office-based questionnaire gave both a relatively low yield (25% of its 319 ACT participants) and an extremely high dollar value per study subject (\$253). Patient mailing proved to be the best approach at Stanford, both in terms of yield (66% of all enrolled participants) and cost (\$58/randomized participant).

DISCUSSION

Despite the many challenges encountered in recruiting patients into ACT, the study completed recruitment (and exceeded its goal) within the allotted 18-month period. This is especially gratifying, given the unusual conditions of the study and the fact that many clinical trials have had to extend their enrollment periods because of slower-than-anticipated recruitment [11–13]. The lag time for recruitment in ACT was projected (Fig. 1), as recruitment for clinical trials often starts out slowly and increases over time [14,15].

Caution must be exercised in interpreting the recruitment source data. Since no study-wide data were prospectively collected, overall recruitment source information included in this report provides some insight into only the relative yield of each approach. The *post hoc* cost-effective analyses do offer some estimates concerning site-specific efficiency of the primary recruitment strategies.

Given the fact that each site was able to determine retrospectively the number of randomizations by recruitment source, the following comments can be made. The direct telephone contact method was abandoned at Memphis and Stanford, as it proved to be too labor intensive. However, this strategy was maintained at Dallas throughout the entire recruitment period, since this site was able to take advantage of a preexisting computerized database at one of the clinical practices serving a minority population. This enabled recruitment staff to have easy access to patient data, including the ability to screen electronically by age and a number of medical exclusions.

Patient mailing yielded the greatest percentage of randomized participants (43.4%). A number of primary prevention studies have made similar observations [16–18], while other studies have found mass mailing to be the least efficient method [19]. In an annotated bibliography of recruitment in clinical trials [13], Lovato *et al.* attribute the success of mass mailing to its “relatively low-cost . . . for contacting large numbers of potential participants.” This explanation very likely accounts for the fact that the Memphis and Stanford sites eventually invested much effort and many resources into this strategy.

Despite the heterogeneity within the office-based questionnaire strategy (see Methods), data from this approach were collapsed into a single category, since one site was unable to monitor the yields from the different strategies. This approach yielded one-third of all enrolled ACT participants. The early strategy of physician recruitment after review of patient charts/medical records was found to be very labor intensive and was soon abandoned.

As summarized in Table 3, Dallas’ self-administered office-based questionnaire produced the lowest cost per study subject (\$14/randomized participant) and contributed the highest percentage (68%) of randomized participants from that site. The direct telephone contact approach at this same site was moderately efficient (\$80/randomized participant) and contributed 32% to the enrolled subjects from that site. The \$80 cost-effectiveness ratio represents the combined results from two separate groups, since nearly one-third of individuals contacted by phone received an introductory letter. Because of the *post hoc* nature of this analysis, we cannot determine whether the yields were better for those receiving letters vs those receiving cold calls. The majority of Stanford’s randomized subjects originated from patient mailings (66%), a strategy that also proved to be moderately cost-effective (\$58/randomized participant). On the other hand, the staff-administered office-based questionnaire used at Stanford rendered a lower yield of study participants (25%) and proved to be very costly (\$253/randomized participant). Not surprisingly, the efficiency of the self-administered office-based questionnaire at Dallas greatly exceeded the efficiency of the staff-administered office-based questionnaire at Stanford.

Although these cost-effectiveness comparisons appear to be both reasonable and informative, they do represent estimates that are based on retrospective analyses. Furthermore, the unique features of the ACT clinical sites and the populations they served limit the generalizability of the findings regarding the relative cost-effectiveness of the approaches studied. For example, because of the racial distribution at the Dallas site, different recruitment methods were used to recruit different subpopulations. The direct telephone contact

method was used at one Dallas clinic with primarily minorities (predominantly African Americans and some Hispanics), while the office-base questionnaire was utilized in a Caucasian population at the other Dallas clinic. Another potential limitation to generalizability is the manner in which other research institutions allocate labor associated with recruitment activities. Existing secretarial staff could assume some recruitment responsibilities (i.e., shifting some of what was treated in our analysis as a variable cost to a fixed cost), thus reducing research staff effort and cost. Finally, the indirect costs associated with recruitment were not taken into consideration.

In terms of demographics of the study sample, the differences between those randomized into ACT and those screened but not randomized is reflected in other trials [19–21]. Agras and Bradford also observed that married, white, working individuals with a higher level of education are most likely to be enrolled in human research trials [22].

A discussion of ACT recruitment would be incomplete without highlighting not only the difficulties involved but also the actions taken to overcome these difficulties. Major challenges were related to the unusual design of the study as well as to more typical difficulties faced in recruiting participants into community-based clinical trials.

Recruitment Challenges Unique to ACT and Primary Care Patient Populations

Patients did not show up for their physician visit/randomization appointments. Once measurement staff determined that a patient was eligible for ACT, the health educator was informed of the date and time that the patient would be visiting the doctor. Unfortunately, it was not uncommon for patients to reschedule, cancel, or simply not show up for their scheduled appointments. This necessitated complicated rescheduling, sometimes resulting in the “loss” of an eligible patient. Subjects were reminded during their three screening visits of the date and time of their physician appointments. They were asked to inform ACT measurement staff if physician appointments had to be canceled or rescheduled. The health educator could then be informed about a patient “no-show.” At the physician clinic, health educators reviewed the appointment schedules to confirm that an eligible participant was still coming in at his/her scheduled date and time.

Clinical practice staff consider presence of ACT staff in their clinic an intrusion. During recruitment, ACT staff were trained to pull charts expeditiously and unobtrusively and to be flexible, considerate, and keenly aware if clinical practice staff appeared to be overburdened, in which cases recruitment efforts were temporarily postponed. To impart a sense of study involvement and to keep them informed about the progress of

the trial, clinic physicians and staff were invited to attend regularly scheduled ACT meetings. Efforts were made to be receptive to physician/staff feedback and suggestions about recruitment. Incentives were offered to demonstrate an appreciation for clinical practice staff involvement in the study (occasional luncheons and complimentary movie tickets, food coupons, coffee mugs, and memberships to a local health club).

Recruitment Challenges Common to Community Populations

Recruitment falling behind targeted goals. To counter this problem, more practices were added, more clinicians within current practices were added, one unproductive practice was dropped, and repeat patient mailings to nonresponders were initiated. At several practices, physician assistants and a nurse practitioner were added. These newly acquired clinicians received training similar to the training conducted for the original ACT physicians.

Minority recruitment falling behind targeted goals. At some clinics serving primarily minority populations, many patients either could not speak English or had medical conditions that excluded them from the study. One minority practice was eventually “dropped” from the study for these reasons. Efforts were made to add African American physicians, and a minority recruitment coordinator was hired at one site. Other measures included compensating minority subjects for their travel expenses to the measurement clinic and continuing to provide encouragement and support to minority clinic physicians and their staff.

Recruitment of men falling behind targeted goals. Although overall recruitment accelerated in response to the strategies described above, recruitment of men initially fell well behind the enrollment rate for women (Figs. 2 and 3). By week 48 of recruitment, it was clear that a sufficient number of women were in the screening “pipeline” to achieve the female recruitment goal, so female recruitment was discontinued at all three sites. Strategies were then aimed at increasing the number of men screened. Figure 2 tracks the plateau effect as female recruitment was discontinued, and Fig. 3 summarizes the accelerated rate of male enrollment as efforts were refocused on recruiting more men into ACT. These efforts included (1) sorting patient databases and mailing/phone lists by gender for preliminary contacts; (2) enlisting the support of female patients/ACT participants, who were encouraged to inform their male relatives and friends about ACT; (3) drafting a recruitment letter targeted toward men (indicating that the study was now enrolling only men and describing the benefits of exercise in reducing heart disease); (4) performing multiple mailings to male patients; (5) sending letters

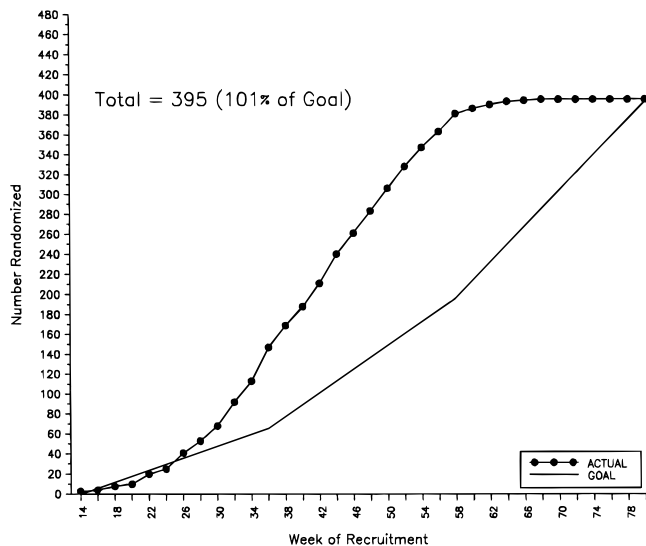


FIG. 2. Cumulative number of randomized women vs recruitment goal.

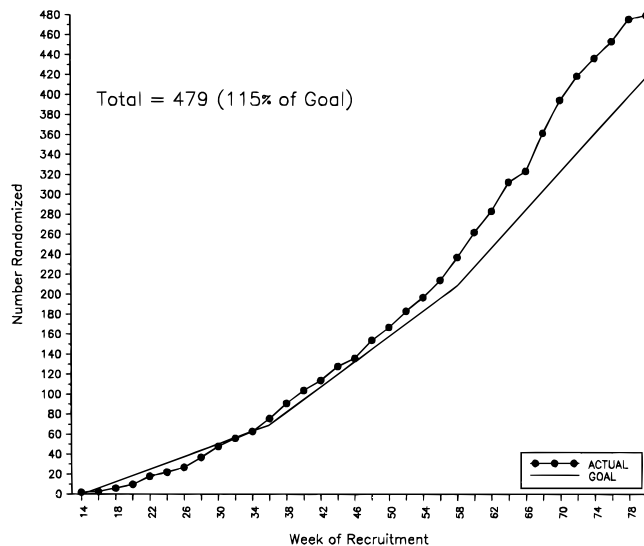


FIG. 3. Cumulative number of randomized men vs recruitment goal.

to male patients before calling them—men appeared more apprehensive of cold calls; (6) recruiting physicians with substantial male patient populations; (7) performing evening and weekend telephone prescreens and screening visits; (8) targeting older men such as retirees; (9) distributing office-based questionnaires to men only; and (10) accommodating special considerations, such as allowing split screening visits for some male subjects who did not have time to stay for one continuous visit.

CONCLUSIONS

Clinical trial recruitment from primary care practices requires some modification of the methods used when recruiting from a community population. Selection of the clinical practices is critical. Efforts must focus on maintaining physician/staff interest during this difficult trial phase. Recruitment strategies should be multifaceted, with close tracking of each approach and capabilities for adapting particular sources to enhance enrollment.

In terms of which recruitment strategies were the best in ACT, the direct phone contact approach was most effective when combined with preexisting patient databases. Two of the three sites eventually redirected their resources to patient mailing, which provided the best yields when factoring in labor efforts and efficiency. The office-based questionnaire was most cost-effective and gave the greatest yield as a self-administered rather than a staff-administered instrument.

Many published recruitment reports detail the effectiveness of specific recruitment strategies in trials that have as their target populations local communities, as opposed to the more restrictive population defined in

ACT. It is hoped that more reports detailing recruitment strategies for primary prevention studies targeting patients from a cluster of primary care practices will appear in the literature.

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