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Effectiveness of strategies to recruit underrepresented populations into cancer clinical trials

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Background Certain populations, including racial and ethnic minorities and older persons, have had a history of low participation in cancer-related trials, yet there has been little information reported on recruitment strategies tailored to improve their enrollment.

Methods We conducted a systematic literature review to examine the methods used to study recruitment of underrepresented populations into cancer prevention and treatment trials and examined the studies that compared the efficacy and/or effectiveness of different recruitment strategies. We performed an electronic search through multiple databases including PubMed and a hand search of 34 journals. Potential studies were pulled and underwent title, abstract, and article review by at least two investigators.

Results Fourteen articles examined recruitment of underrepresented populations into cancer trials and, of these, five compared efficacy or effectiveness of different strategies for recruitment of underrepresented populations into randomized or concurrent controlled trials. These five studies used various strategies but only three reported that specific recruitment strategies, such as media campaigns and church-based project sessions, resulted in improvement in accrual to cancer trials.

Conclusion There is limited evidence for efficacious or effective strategies to recruit underrepresented populations in cancer-related trials. The available evidence cannot be generalized to these heterogeneous groups. Further study is needed on efficacious strategies for recruitment of underrepresented populations into cancer-related trials. *Clinical Trials* 2006: **3**: 133–141. www.SCTjournal.com

Introduction

In 1993, the National Institutes of Health (NIH) disseminated guidelines for the inclusion of women and minorities in all sponsored research, including cancer-related trials [1]. Randomized trials are considered to be the gold standard when assessing the effects of therapeutic or preventive interventions [2]. However, only 2.5% of adult cancer patients enroll into cancer-related trials, indicating the need for strategies to increase enrollment [3]. In particular, racial and ethnic minorities, older

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persons, those residing in rural areas, and persons of low socioeconomic status are underrepresented in these trials [3–5].

These underrepresented populations experience disparities in cancer incidence, cancer mortality, survival and other cancer care [6–11]. Authoritative bodies have suggested that inclusion of underrepresented populations in cancer clinical trials may be an important component of addressing cancer health disparities and may contribute to the improvement of healthcare services to these populations [12]. To accomplish this, efficacious strategies are crucial to adequately recruit underrepresented populations and ensure the improvement of cancer health among all populations. Yet, there is limited information on the proven methods used to recruit underrepresented populations into cancer clinical trials and no established guidelines exist regarding strategies used to enhance trial participation among these underrepresented populations. We performed a systematic review of the literature to 1) examine the methods used to study recruitment of underrepresented populations into cancer prevention and treatment trials and 2) examine the controlled trials that compared the efficacy and/or effectiveness of different recruitment strategies in underrepresented populations.

Methods

Our methods, including the search strategy and literature review, have been reported in detail elsewhere [13]. In brief, the literature search examined the following electronic databases: MEDLINE®, the Cochrane CENTRAL Register of Controlled Trials, the Cochrane Database of Methodology Reviews (CDMR), the Cumulative Index of Nursing and Allied Health Literature (CINAHL®), the Psychological Abstracts (PsycINFO), and The Campbell Collaboration's Social, Psychological, Educational, and Criminological Trials Register (C2-SPECTR). In addition to the electronic searches, we examined tables of content of 34 journals considered likely to contain relevant articles. The reference lists of eligible articles were also reviewed to identify potentially relevant studies. Articles published in or before July 2004 were included in the review.

Several levels of review were conducted by two reviewers to determine eligibility of the articles identified through our search strategy. First, a title review was conducted to eliminate titles that were irrelevant. At abstract reviews, the exclusion criteria were: not written in English, no original data, no human data, not addressing cancer treatment or prevention, not reporting a controlled trial or recruitment to a controlled trial, reporting a meeting abstract only (no full article was available for review), and not relevant to describing methods for studying recruitment approaches, including efficacious and/or effective strategies. When both reviewers assessed that an abstract contained original data pertinent to the research questions, the complete article was pulled for review. Disagreements at the abstract review level were adjudicated either by consensus or, if necessary, by a third senior reviewer. Full articles underwent a serial review process where one reviewer completed data abstraction forms, and a second reviewer checked for completeness and errors. Quality forms were used to grade studies that compared efficacy or effectiveness of different recruitment strategies. We graded quality of the articles based on the representativeness of study sample, methods used to address bias and confounding, degree of recruitment strategy description, outcomes and follow-up, the quality of the approach to statistical analysis and interpretation, and whether there were apparent conflicts of interest.

Results

Description of study characteristics

Out of 4431 citations yielded by our search strategy, only 14 articles examined strategies for recruitment of underrepresented populations into cancer prevention and treatment trials [14–27] (Table 1). The studies took place in a community setting ($n = 10$), in a hospital-related setting ($n = 2$) or in both ($n = 2$). Three of the four hospital-based studies occurred in an outpatient setting. Eleven studies included patients or persons in the community as the target population. Two of these 11 studies also included physicians [18] and researchers in the target population [21]. Three studies specifically targeted physicians only [22,23,27]. Most studies examined recruitment strategies for specific cancers including breast cancer [20,23,25,27], colorectal cancer [17,20,22,23], and lung cancer [17,19,20,26].

Study designs varied among the eligible articles. Among five studies that were descriptive [14,18,22,26,27], two examined and described the results of a recruitment strategy [22,27], two described aggregate data results from multiple studies or sources of data [18,26] and one study reported potential recruitment strategies tailored around factors influencing patients' willingness to participate into cancer clinical trials [14]. Other study designs included quasi-experimental [15], case series [20], and a qualitative design that used focus groups [24]. The quasi-experimental study was used to examine the gender and racial/ethnic differences in enrollment patterns of

Table 1 Study and population characteristics of studies that examine strategies to recruit underrepresented populations into cancer prevention and treatment trials (n = 14)

Author, year	Study design	Study setting	Target population	Sample size	Underserved group	% Male	Mean age/age range	Recruitment	Cancer studied or cancer prevention
Advani, 2003 [14]	Descriptive	Hospital outpatient	Participants	218	33% AA	NR	22–97	NR	Solid or hematologic malignancy (excluding melanoma)
Berman, 1998 [15]	Quasi-experimental	Community	Participants	437	15% AA; 85% LH	49	37	1990–1992	Smoking cessation
Brewster, 2002 [16]	CCT	Community, hospital outpatient	Participants	940	79% LH	0	43	1999–2000	Cervical
Ford, 2004 [17]	RCT	Community	Participants	NR	100% AA	100	NR	1996–2001	Prostate, lung, colorectal
Kaluzny, 1993 [18]	Descriptive	Community, hospital outpatient, group practice	Participants; physicians	NR	NR	NR	NR	1990–1992	Any
Linnan, 2002 [19]	RCT	Community	Participants	1906	3% LH; 27% LI	53	43	NR	Lung
Maurer, 2001 [20]	Case series	Hospital inpatient	Participants	1134	100% R	NR	NR	1993–1997	Breast, lung, colon, rectum, prostate
Moinpour, 2000 [21]	RCT	Community	Participants; researchers	NR	AA, LH	100	NR	1993–1997	Prostate
Paskett, 1995 [22]	Descriptive	Community	Physicians	NR	NR	NR	NR	1993	Colorectal
Paskett, 2002 [23]	CCT	Community	Physicians	360	100% R	87	47	1992–1996	Breast, colorectal
Randall-David, 2001 [24]	Qualitative	Community	Participants	37	31% AA; 6% AIAN; 3% LH; 73% R	8	55, 18–72	NR	Any
Sears, 2003 [25]	RCT	Community	Participants	558	6% AA; 9% API/LH/other	0	57	1999–2000	Breast
Thornquist, 1991 [26]	Descriptive	Community	Participants	1284	23% OP	53	45–74	1985–1988	Lung cancer prevention
Zhu, 2000 [27]	Descriptive	Community	Physicians	325	100% AA, OP; 91% LI	0	65–85	NR	Breast

AA = African-American; LH = Latino/Hispanic; AIAN = American Indian/Alaska Native; LI = low income; OP = older persons; R = rural; RCT = randomized controlled trial; CCT = concurrent controlled trial; NR = not reported.

Latino/Hispanics and African-American participants into a smoking cessation trial [15]. In the case series study design, enrollment of cancer patients into clinical trials was examined to determine whether participation had an effect on the patterns of care after implementation of the intervention [20]. Five of the 14 studies examined the efficacy and/or effectiveness of different recruitment strategies through the use of randomized or non-randomized controlled trials [16,17,19,21,23].

Half of the 14 studies specifically included African-Americans ($n = 7$) and five studies included Latino/Hispanics in the study population. Some articles provided relevant data for other under-represented populations, including American Indian/Alaska Native populations ($n = 1$), those living in a rural setting ($n = 3$), older persons ($n = 2$) or those who had low incomes ($n = 2$). Although one study reported Asian/Pacific Islanders and Latino/Hispanics within their "Other" category of study participants, the lack of further reference or subanalysis of these groups did not permit examination of these populations in the context of this study [25].

The studies reported a variety of methods for enhancing recruitment of underrepresented populations to cancer-related trials. Recruitment letters, flyers and telephone calls were used in most of the studies. Monetary and material incentives were reported for one study [27]. Additionally, in several studies, organizations or third-party insurers [26], businessmen [17] and physicians [18,22,23,26] were used to facilitate recruitment.

Description of controlled trials that evaluated efficacy or effectiveness

For the five studies that compared efficacy and/or effectiveness of different recruitment strategies [16,17,19,21,23], the recruitment strategies and settings varied (Table 2). The study participants involved those living within a rural setting, blue-collared manufacturing employees, and either African-Americans, Latino/Hispanics, or both. Four of the five studies targeted patients or participants within the community as the target study population [16,17,19,21]. Additionally, researchers [21] and physicians [23] were included as part of study populations. Four of the five studies evaluated participation in cancer prevention trials [16,17,19,21] and only one study examined participation in a cancer treatment trial [23]. The results of the interventions also varied from no observed improvement [21,23] to an increase in recruitment into cancer-related trials [16,17,19] (Table 3). Each of the five studies is described in detail below.

Brewster *et al.* reported differences in recruitment into cancer prevention trials between a clinic registry method and a media campaign targeting Latina/Hispanic women [16]. Among the women screened by telephone and consented to present to the clinic, recruitment was nearly three times more successful via the media campaign than via the clinic registry (odds ratio [OR] = 2.97; 95% confidence interval [CI] 2.52–3.51). In addition, the odds of presenting to the clinic were three times higher for women recruited by the media campaign than for those recruited via the clinic registry (OR = 3.00; 95% CI 2.38–3.78). The researchers concluded that the media campaign method was more beneficial than the clinic registry in recruiting women. In addition, they reported that the media campaign recruited a larger number of uninsured and Latina/Hispanic women into the study.

Ford *et al.* examined recruitment differences in PLCO (prostate, lung, colorectal, ovarian) cancer screening trials among African-Americans who were randomized into one of three increasingly intensive intervention arms or a control group [17]. The control group used a standard method of recruitment such as a standard recruitment letter, African-American or Caucasian interviewers for eligibility screening, baseline information collection via mailed packets, and reminder phone calls and mailings for completion of the mailed packets (Arm D). Each intervention arm (Arms A, B and C) used various intervention strategies such as enhanced recruitment letters and telephone calls from African Americans. The most intensive, intervention arm (Arm C) implemented a church-based project session in addition to the enhanced recruitment letter and telephone calls. The authors reported significantly higher enrollment yield (3.9%) in the most intensive church-based intervention arm (Arm C), compared to the other two intervention arms (2.5% [Arm A] and 2.8% [Arm B]) or the control group (2.9% [Arm D]) ($P < 0.01$).

Linnan *et al.* reported differences in enrollment, reach, and attrition of a home-based, cancer prevention intervention program between two employee recruitment arms, passive and active [19]. Passive recruitment indicated that worksites provided employee information to the research team. Active recruitment indicated that worksites did not provide any employee information to the research team, and that employees actively signed up and provided contact information. Compared to the active recruitment arm, the passive recruitment arm reached a higher proportion of employees (74.5% versus 24.4%, 50.1% difference, $P < 0.0001$) but had lower enrollment (40.9% versus 77.5%, 36.6% difference, $P < 0.0001$) and higher attrition rate (46.0% versus 29.9%, 16.1% difference, $P < 0.0001$). The authors concluded that the results provided insight into the

Table 2 Characteristics of recruitment strategies in studies on the efficacy and/or effectiveness of strategies for increasing participation of underrepresented populations in cancer prevention and treatment trials

Author, year	Target population	Intervention group description	Timing/duration/frequency of Intervention (qualitative description)	Elapsed duration of interventions	Underserved recruitment primary outcome (Y/N)
Brewster, 2002 [16]	Clinic registry	Identified from clinic registry and contacted to participate	Clinic registry recruitment occurred in first six months	1 year	Yes: objective was to review recruitment strategies associated with recruiting Latinas into prevention trials
	Media campaign	Newspaper advertisements in English and Spanish; study fliers	Media campaign recruitment occurred in the latter six months		
Ford, 2004 [17]	African-Americans, Arm A	Enhanced mailing process; eligibility screening conducted by African-American interviewers; baseline information gathered via mailed packet	NA	NA	Yes; enrollment of African-American men to cancer screening trial
	African-Americans, Arm B	Enhanced mailing process; eligibility screening conducted by African-American interviewers; baseline information gathered via telephone interviews			
	African-Americans, Arm C	Enhanced mailing process; eligibility screening and church project sessions conducted by African-Americans; baseline information gathered at church sessions; letters and telephone call reminders for church session			
	African-Americans, Arm D	Control group	NA	NA	
Linnan, 2002 [19]	Passive employee contact	Companies provided list of employee names and home phone numbers to facilitate recruitment	Baseline	NA	No
	Active employee contact	Employees actively signed up to participate	Baseline	NA	
Moinpour, 2000 [21]	African-Americans, Site A	No specific details of intervention for each of the five sites were given	October 1994–March 1997	~2.5 years	No, but the successes and failures in increasing minority participation in cancer prevention trial were presented
	African-Americans, Site B African-Americans, Site C African-Americans, Site D Latino/Hispanics, Site E				
Paskett, 2002 [23]	Physicians in North Carolina	Tumor-reporting system, nurse facilitator, quarterly newspapers, and health educator	Intervention was conducted from 1993 through 1996	~4 years	Yes: enrollment of rural patients to controlled trials
	Physicians in South Carolina	Control group	NA	NA	

RCT = randomized controlled trial; CCT = concurrent controlled trial; NR = not reported; NA = not available.

Table 3 Outcome point estimates for the efficacy and/or effectiveness of recruitment strategies for increasing participation of underrepresented populations in cancer prevention and treatment trials

Author, year	Descriptor of point estimate (percentages, OR, difference)	Point estimate (value) significance	CI, *P* value	Author conclusion
Brewster , 2002 [16]	Odds ratio of consent by telephone (comparing women recruited by media campaign to the cohort recruited from the clinic registry reference group)	2.97	2.52–3.51	Media campaign recruitment yielded better recruitment results compared to the clinic registry recruitment strategy
	Odds ratio of actually presenting to clinic (comparing women recruited by media campaign to the cohort recruited from the clinic registry group)	3.00	2.38–3.78	
Ford, 2004 [17]	Difference of enrollment between Arm C versus Arm D	1.0%	$P < 0.01$	Arm C, the most intensive of the arm interventions, yielded higher enrollment compared to the control (Arm D) and other intervention arms (Arms A and B)
Linnan, 2002 [19]	Difference of enrollment between passive versus active recruitment strategies (percentage)	36.6%	$P < 0.0001$	Active recruitment had lesser reach, higher enrollment, and smaller attrition rate. Passive recruitment had wider ethnic and financial diversity. No significant differences on organizational factors comparing active and passive recruitment
Moinpour, 2000 [21]	Change in Site A enrollment from 1995 to 1996 (percentage)	−0.3%	NR	NR
	Change in Site B enrollment from 1995 to 1996 (percentage)	−0.5%	NR	
	Change in Site C enrollment from 1995 to 1996 (percentage)	−1.8%	NR	
	Change in Site D enrollment from 1995 to 1996 (percentage)	−0.6%	NR	
	Change in Site E enrollment from 1995 to 1996 (percentage)	+0.5%	NR	
Paskett, 2002 [23]	Change in clinical trial enrollmentof breast cancer patients from 1991 to 1996, North Carolina (percentage)	−9%	NR	No improvement in enrollment of cancer patients into cancer clinical trials was observed after intervention
	Change in clinical trial enrollment of colorectal cancer patients from 1991 to 1996, North Carolina (percentage)	+1%	NR	
	Change in clinical trial enrollment of breast cancer patients from 1991 to 1996, South Carolina (percentage)	+44%	NR	
	Change in clinical trial enrollment of colorectal cancer patients from 1991 to 1996, South Carolina (percentage)	−5%	NR	

NR = not reported.

advantages and disadvantages that researchers may encounter when designing and implementing recruitment strategies. However, they also noted that these different recruitment methods might not be applicable to all types of work sites.

Moinpour *et al.* reported the use of minority recruiters as part of the recruitment strategies into cancer prevention trials at five different sites but did not give any specific details of the interventions [21]. The overall impact between the five sites appeared to be minimal, according to the percentage of people recruited among the five sites before and after the implementation of the recruitment strategies. Four of the sites reported a decrease in percent enrolled (−0.3%, −0.5%, −1.8%, −0.6%) in contrast to only one site reporting an increase in percent enrolled (+0.5%). No statistical significance of these results was reported. Since these recruitment interventions occurred near the end of the recruitment period of the reported clinical trial, the authors concluded that evaluation of the effectiveness of these strategies was difficult.

Paskett *et al.* investigated the effect of an intervention program–consisting of a nurse facilitator, tumor-reporting system and other aspects–aimed at physicians and the community in rural counties of North Carolina. They compared the change in enrollment of breast cancer and colorectal cancer patients into cancer treatment trials from 1991 to 1996 from rural counties of North Carolina to rural counties of South Carolina [23]. The change in enrollment varied both positively and negatively by cancer type and between the counties in North and South Carolina. In particular, the intervention program in North Carolina resulted in a minimal increase in enrollment of colorectal cancer patients and a decrease in enrollment of breast cancer patients. The varying results led the authors to conclude that no appreciable improvement in recruitment of cancer patients into clinical trials was observed with the intervention.

Details of the quality of the five studies have been reported elsewhere [13]. The quality of the studies that examined efficacy or effectiveness generally varied on a number of aspects. (results not shown.) Though studies portrayed a few strengths, including adequately addressing representativeness in the studies, each study had weaknesses in other aspects. These weaknesses included the lack of definition of successful recruitment, failure to use methods to minimize bias or confounding (such as randomization of study participants or blinding of researchers/participants) inadequate discussion of the statistical analyses (including dealing with withdrawals) or minimal reporting of the justification for the recruitment strategies.

Discussion

The enactment of NIH policy for including women and minorities in research has pushed researchers to make more of an effort in recruiting these populations. Given the evidence that these and other groups are underrepresented in cancer clinical trials, it is critical that effective recruitment strategies be designed to increase their participation. A number of strategies have been used in attempts to enhance recruitment and participation of underrepresented populations, but the available evidence on these strategies remains limited.

Overall, the literature shows that 14 studies examined recruitment strategies for underrepresented groups, and only five evaluated the efficacy or effectiveness of these recruitment strategies. Three of the five studies reported some effectiveness with strategies such as media campaigns and church-based project sessions [16,17,19].

However, the results from the studies warrant cautious interpretation. Few studies evaluated recruitment strategies of African-Americans and Latino/Hispanics, and even fewer evaluated other populations including older persons, persons from rural and/or low-income settings, and other racial and ethnic minorities. This limits the ability for researchers to construct evidence-based strategies tailored for different populations. In addition, the quality of studies brings doubts to the strength of the evidence and validity of the results. The small number of studies, their heterogeneity, the lack of consistency in the results and the quality of the evidence suggest that further studies are needed to evaluate the efficacy and/or effectiveness of strategies to increase enrollment into cancer-related trials. A study published after our review period examined an educational intervention to improve accrual for older persons to cancer treatment trials but found no improvement in accrual between intervention and control arms [28]. This study further acknowledges the importance and need for continuing research on increasing cancer-related trial enrollment among underrepresented populations.

The systematic examination of the literature carried both strengths and limitations. The possibility of reporting or publication bias may exist particularly due to the lack of coverage of unpublished literature. However, to our knowledge, no other review exists regarding this specific topic, indicating that our assessment of the literature is critical. Our systematic review of the literature was comprehensive and encompassed electronic searches through six databases, with strategies specific for each database, and hand searches of 34 journals. In addition, our review process went through a number of levels (title, abstract, and article review) with each involving a minimum of two reviewers.

These factors contributed to the validity of the review.

The lack of representation of certain populations in cancer clinical trials indicates a significant barrier to improvement of cancer-related outcomes. Considering the lack of evidence-based procedures for recruitment of underrepresented populations, we recommend that researchers design and evaluate the efficacy and/or effectiveness of recruitment strategies tailored to specific underrepresented groups. From the available evidence thus far, few strategies, such as media campaigns and intensive interventions that incorporate multiple methods of contacting participants, may enhance participation into cancer clinical trials. We also suggest that researchers examine the reasons why certain recruitment strategies did not show any significant increase in cancer trial accrual; these methods may still yield fruitful results should they be specifically modified and/or improved. By promoting the ongoing research and implementation of proven intervention strategies, this knowledge will eventually improve the ability for researchers, clinicians and policymakers to address disparities in recruitment to cancer-related trials.

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