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Strategies to enhance participant recruitment and retention in research involving a community-based population

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Abstract

Challenges associated with recruiting and retaining community-based populations in research studies have been recognized yet remain of major concern for researchers. There is a need for exchange of recruitment and retention techniques that inform recruitment and retention strategies. Here, the authors discuss a variety of methods that were successful in exceeding target recruitment and retention goals in a randomized clinical trial of hearing protector use among farm operators. Recruitment and retention strategies were 1) based on a philosophy of mutually beneficial engagement in the research process, 2) culturally appropriate, 3) tailored to the unique needs of partnering agencies, and 4) developed and refined in a cyclical and iterative process. Sponsoring organizations are interested in cost-effective recruitment and retention strategies, particularly relating to culturally and ethnically diverse groups. These approaches may result in enhanced subject recruitment and retention, concomitant containment of study costs, and timely accomplishment of study aims.

Keywords

Recruitment; Retention; Clinical trials; Farmers; Noise induced hearing loss

1. Introduction

An estimated 1.5 million farmers are exposed to farm hazards as farm residents, farm family workers, or hired workers (Tak, Davis, & Calvert, 2009). Farmers experience frequent exposure to high noise and have among the highest prevalence rates of hearing loss among all categories of workers (Tak & Calvert, 2008). Despite their risks, farmers are rarely

served by an Occupational Safety and Health Administration (OSHA)-mandated hearing conservation program (OSHA, 1997; Pryor, Carruth, & LaCour, 2005). Farmers are commonly exposed to hazardous farm noise from an early age, and have frequent exposure to recreational noise, such as ATVs and firearms (Marlenga et al., 2012).

Noise exposure is a leading cause of noise-induced hearing loss and tinnitus, negatively impacting the physical, emotional, social, and employment life of affected persons. Hearing loss has also been associated with increased risk for injury among farmers (Choi et al., 2005; Sprince et al., 2003). Hearing conservation has been identified as a high priority agenda item by agriculture- and non-agriculture-related agencies (DHHS, 2010). Use of hearing protectors is an effective method of preventing noise-induced hearing loss when engineering or administrative controls are not feasible or economical (National Institute for Occupational Safety & Health (NIOSH), 2009). However, use of hearing protectors among farm operators is low (McCullagh, Ronis, & Lusk, 2010). Epidemiological studies show a need for interventions to increase hearing protector use among farmers (Gates & Jones, 2007; McCullagh, Lusk, & Ronis, 2002; McCullagh et al., 2010). Here, the authors report on their experiences with recruitment and retention challenges and solutions in an intervention effectiveness study with farm operators.

2. Background: Recruitment of farm operators

Similar to other clinical trials, recruitment and retention of study subjects was critical to accomplish the study aims and advance the health status of the farming population. Unsuccessful recruitment and retention of participants in clinical trials threaten the depletion of study financial resources; this often forces the investigators to extend the period of enrollment, add incentives and recruitment personnel, and otherwise struggle to meet enrollment targets (Treweek et al., 2013). Studies that are not successful in overcoming these challenges are likely to be under-powered, or fail to achieve statistical significance due to inadequate enrollment or retention. In a recent study by Oregon Health Sciences University researchers, one third of all studies terminated between 2005 and 2009 at OHSU had low enrollment (zero to one participant), costing the institution nearly \$1 million annually (Kitterman, Cheng, Dilts, & Orwoll, 2011). Similarly, a study of oncology clinical trials revealed that over half of the studies reviewed closed prematurely due to low enrollment (Schroen & Petroni, 2010).

Only a few studies have focused on issues of recruitment and retention of farm operators as study subjects. Horsburgh and Langley (Horsburgh & Langley, 2011) were successful in recruiting 24% of a population of farm owners to a New Zealand study using advertisements, mailed letters, local research assistants, cash incentives, and telephone contacts. They reported the largest number of participants dropping out at the written consent stage, primarily due to time pressures. Stoecklin and colleagues (Stoecklin-Marois, Hennessy-Burt, & Schenker, 2011) recruited a population-based sample of Hispanic farm workers for interviews using home visits. Only 1% of eligible households refused to participate, primarily due to distrust of researchers or lack of time. Neither of these reports included details of recruitment or retention methods. No studies were located that systematically tested recruitment or retention strategies in a sample of farm operators.

Previous investigators have noted challenges associated with recruitment and retention of non-farming, underrepresented, hard-to-reach, and minority populations. Barriers in these groups include but are not limited to mistrust of government and research institutions, transportation issues, economic and time constraints, high disease burden, personal biases, lack of clarity on the risks and benefits of participating in the study, lack of access to computers and telephone, and language and cultural differences (Ejiogu et al., 2011; Griffin, O'Connor, Rooney, & Steinbeck, 2013; Harrigan et al., 2013; Nagler, Ramanadhan, Minsky, & Viswanath, 2013; Taylor-Piliae, Boros, & Coull, 2013; Tramm, Daws, & Schadewaldt, 2013). Although these studies have focused on diverse populations such as African Americans, individuals of low socioeconomic status, and older adults, several of the barriers and approaches to recruitment and retention are similar to those of other groups.

3. Methods

The HEAR on the Farm study was designed to compare the effectiveness of several approaches to promote hearing protector use among farm operators. One goal of this study was to compare the effectiveness of various interventions in influencing hearing protection device use behavior. The project involved a partnership between the authors' affiliated university and a major farmer organization. Results of this study are expected to be used to inform future research-to-practice studies to increase hearing protector use among farm operators. Increased use of hearing protection devices is expected to reduce rates of noise-induced hearing loss and other damaging effects of high noise exposure, and improve quality of life in this high-risk and underserved worker group.

Study procedures were reviewed and approved by the authors' institutional review board. Participants logged on to a designated Web site where baseline data were collected and participants were randomly assigned to one of five intervention groups. Participants were offered a variety of strategies (e.g., online information, or mailed hearing protectors, or both); participants returned (with reminders) to the Web site at 6 and 12 months for monitoring of their use of hearing protection and related attitudes and beliefs.

3.1. Recruitment and retention strategies were based on a philosophy of mutual benefits, knowledge building, and translation

In a systematic review of community-based participatory research, De Las Nueces and colleagues (De Las Nueces, Hacker, DiGiralamo, & Hicks, 2012) reported that community-based participatory research approaches were effective in increasing participation in research of hard-to-reach populations such as racial and ethnic minorities. Community-based participatory research involves mutual benefits, partnership, knowledge building, and translation (Horowitz, Robinson, & Seifer, 2009).

The HEAR on the Farm study focused on noise-induced hearing loss, a public health problem that is of concern to farmers. The study incorporated an ecological perspective in that it addressed the multiple determinants of hearing protector use behavior previously identified in research, i.e., hearing protector-specific attitudes and beliefs, as well as gender (McCullagh et al., 2010).

While the study team gained valuable research data from participation of farm operators, the study design also incorporated benefits for farm organizations. For example, some farm organizations were attracted to the opportunity to offer free programming for their members. Benefits to the research team included access to members through organization newsletters, Web sites, and field representatives. Study team members facilitated communication with members by educating farmer organization staff about the study aims and mechanics in individual conversations, presentations at farm organization staff meetings and webinars, and preparing sample newsletter and Web items. Consequently, farmer organizations had increased capacity to provide member services, while researchers obtained access to persons who were eligible to participate in the study.

In the planning stages of the study, we identified several factors that favored the feasibility of a successful recruitment program. First, the project was based on a long-standing partnership between the principal investigator and a large farmer advocacy organization. Second, the investigator had developed recruitment strategies with similar groups that proved successful in previous studies. Third, the investigator sought support early in the planning stage for the project from representatives of a large national farmer organization.

The study built on existing strengths and resources within the farming community. All partnering state affiliates had a safety program in place, and one or more staff members assigned to that program. The state organization had large numbers of members, an organizational hierarchy, and established media for communication with members. Safety program officers became the organizational gatekeepers to, liaisons with, and cultural brokers between, the study team and farm operators. Farm operators had already demonstrated their altruism toward health and safety research in previous studies with this investigator. However, like previous study populations, the prospective subjects in this study were quite unfamiliar with clinical trials. This necessitated some explanation to organization representatives, their communication department staff, and prospective study participants.

Members from the farming community were invited to participate in the project from the earliest phases of project development, and invitations were also extended to members of expert panels and in vanguard tests. Prior to launching of subject recruitment, the study team worked individually with each local affiliate to develop a marketing plan specific to that organization. A variety of resources were developed and made available to the safety program officers, including strategies for introducing the study to farm organization members, motivating them to participate, and connecting with enrollment mechanisms. The study team developed a variety of electronic, print, and visual messages that were designed to appeal to an array of farm operators, and a logo branding the project was included on recruitment and retention messages. Finally, the study team created a variety of incentives to motivate participants to enroll and complete the study, and designed recruitment messages to appeal to potential participants' diverse motivations for enrolling. These motivations included interest in the cash incentive to individual enrollees, opportunity to learn hearing protection strategies, and interest in advancing the goals of the collaborating farm organization through monetary award programs for meeting study completion quotas. Study personnel primarily used personal contacts (rather than electronic methods) to communicate with farm organization representatives. Furthermore, the study team negotiated individually

with each farm organization representative to develop strategies for working with the organization.

A four-part system of incentives was developed to address a variety of influences on study participation. First, individual participants were eligible to receive a cash award at completion of each of three data collection points (baseline, 6 months, and 12 months). Disbursement of each portion was semi-automated and processed upon completion of each phase. Individual participant incentives were graduated at \$10 (baseline), \$10 (6 months), and \$20 (12 months). Although small at each interval, dividing the incentive was designed to aid in the return of participants to ensure that they receive the remainder of their participation reward. The second incentive category was delivered to the participating organization. The study team contracted with farm organizations to award organizations that successfully met participant study completion goals. Individual study participants were informed that, through their participation, the farmer organization of which they were a member would earn credits for their completion of study activities. Third, study participants were informed that study participation involved resources that could help them to better understand hearing hazards on their farm, and to take measures to protect their hearing. Finally, study participants were reminded that results of the study would be used to develop programs to help other farm operators. Consequently, farm operators had four potential motivators for engaging in the study: personal financial, organizational financial, personal safety, and altruism. In addition, participating farm organizations had the opportunity to earn rewards for their successful support of study recruitment and retention.

3.2. Recruitment and retention strategies were designed to be culturally appropriate

The study was designed to fit the unique identities and cultures of farmer groups and organizations. Farm work requires seasonal variations in work hours, and often-extended workdays (United States Department of Labor, 2005). Most U.S. farms are family-owned, small, and exempt from the Occupational Safety and Health Act (Anonymous, 1997; Liebman et al., 2013). Unlike other industries, farm work has no associated surveillance system to address work-related injuries (Linder, 2013), and farm operators are characteristically independent and resistant to external influences. These factors presented potential obstacles to recruitment and retention, but were addressed through a variety of communication and other methods.

At all times, interactions with farm organization representatives and farm operators were characterized by respect for their privacy and time. The study coordinator was fastidious in promptly delivering incentives and study materials to enrollees. Study team members contacted non-respondents using email, telephone, and postal reminder messages, but limited contacts in number and time of day.

3.3. Recruitment and retention strategies were tailored to the unique needs of partnering agencies

The study team sought endorsement from a variety of farm organizations, resulting in multiple partnerships. Each partnership was characterized by a distinct marketing plan that

accommodated the uniqueness of the organization's mission, membership, and organizational structure.

The team was often invited to attend farmer group meetings, either as attendees or as vendors. However, attending farm shows as vendors was sometimes confusing for attendees, as they often assumed that the study team represented a commercial interest seeking a purchase from the farm operators. Study team members took special efforts to distinguish themselves from commercial vendors who sell products and/or services. Rather, the team was careful to identify themselves as researchers who had a farmer health research interest, rather than financial interest, in participating. Study personnel approached attendees at these meetings and explained the study purpose and procedures to producers. Since the meeting organizers were often insistent that their members not be harassed or “bothered,” team members employed sensitivity and discretion in soliciting attendees to enroll in our study. Conversely, maintaining a passive presence generally limited attendee interest in our study. Success in pursuing enrollment targets at these meetings required study team members to strike a balance between a persuasive marketing approach and a hasty retreat when confronted with disinterest.

The study team made every effort to identify themselves as a university-affiliated group endorsed by the farm organization, and working on behalf of farmer health and safety. A professionally designed and produced large-scale portable color banner was displayed at each recruitment event. The poster included the study title, logo, color image of a farm operator in a farm setting, brief description of the study, and contact information. Similarly, professionally designed and produced color flyers were distributed to farm organization meeting attendees. In addition to information included on the poster, flyers also described the cash incentive that participants would receive upon study completion. Business cards with the study name, logo, and individual team members' contact information were also distributed to attendees. The study name and logo were also included in email messages. Attendees were requested to tell associates about the study and share study information with friends and/or family members who might be interested.

Because on-site study enrollment was not used in this study (interested farm operators visited a Web site for screening and enrollment), we found that offering a sign-up sheet to interested attendees gave the study coordinator an opportunity to e-mail study invitations to attendees. We repeated solicitations to the same candidate no more than twice. We used similar recruitment strategies at farmers' markets, although in this venue, farm operators were the exhibitors rather than the attendees. We were respectful of farmer-vendors' sales goals, restricting our contact to intervals between customers.

3.4. Recruitment and retention methods were developed and refined in a cyclical and iterative process

Recruitment and retention methods were continually reassessed for effectiveness by tracking subjects' follow-up status and frequent assessment of completion rates. These data informed recruitment and retention plans. For example, advice from an experienced research colleague included reassurance in the early stages of the subject recruitment process that similar studies are commonly slow to begin recruitment and often gain speed over time.

While the study team took solace in this remark, it encouraged passivity and false confidence. Valuable time passed before the team realized that the slow enrollment was not a problem that would solve itself, and a more aggressive plan was sought.

At a time when enrollment was lagging, the team sought consultation with external sources. One of these was a commercial email list service; we trialed this service on a limited basis to gauge its success. After a disappointing result, we did not renew or expand service with this provider, and resumed full responsibility for contacting prospects. A second external consult was with the host university's clinical research recruitment experts. This consultation affirmed the approaches already in use, and therefore did not induce changes in recruitment strategy.

Over time, enrollment rates indicated that recruitment efforts would need to be expanded beyond the major farm organization with which the study team had originally contracted. Study team members actively searched for additional farm organizations that offered a good fit with study aims. Once a target organization was identified, study team members engaged in negotiations with organization representatives to develop a study marketing strategy, often including attending organizational member meetings.

Telephone follow-up of participants became a major and ongoing effort in order to minimize attrition. This was a labor-intensive undertaking during the growing and harvesting seasons because study participants were often engaged in farm tasks throughout daylight hours, and time zone differences between the eastern time zone of the study team, and later more western time zones often required late evening telephone calls. Ultimately, our modified study protocol using multiple follow-up measures was successful in meeting recruitment goals and ensuring that participants completed surveys at all three time points.

The team remained cognizant that meeting enrollment targets was necessary, but not sufficient, for study success. Because the 12-month post-intervention data were used as the major study outcome criterion, completion of 12-month follow-up surveys (rather than enrollment numbers) served as the holy grail for the study team. Completion rates were monitored at frequent intervals, and results were used to inform methods of communicating with study subjects.

Our perspectives regarding subject retention changed over the course of the data collection period. The study protocol called for participants to respond to questionnaires in three waves: at baseline, 6 months, and 12 months. It became apparent early in the study that a substantial number of participants were not responding to the automated 6-month email reminders to submit survey data, and were at risk for termination from the study. A variety of obstacles placed some participants at risk for dropout. First, automated reminder emails from the study were inadvertently diverted to participant junk email boxes. In response, we instituted a procedure of sending additional reminder emails to each (non-responding) participant. These booster emails were helpful in prompting actions and were not shunted to junk email boxes. Second, some participants were slow to access the study Web site because of weak computer skills. Consequently, study participants were contacted by telephone at home by the study coordinator, and offered an opportunity to complete study activities via

telephone. Third, some participants lived in locales with poor Internet access. Finally, some participants moved their residence without notifying the study personnel, and did not provide forwarding street and/or new email addresses. As a last resort, participants received reminders by postal service, and Web-based searches were occasionally used to locate study participants at risk of expiration. Unfortunately, original study protocol approved by the authors' university institutional review board (IRB) provided for limited contact by the study team to recalcitrant participants; our need to more aggressively follow-up with study participants necessitated amendments.

4. Results

The initial recruitment target was 709 subjects, based on an anticipated attrition rate over the 12-month study period of 40%. However, after several months of data collection, farm operator participation records showed that retention of study subjects exceeded that projected in target enrollment development. Consequently, the new lower attrition rates were used to recalculate enrollment targets, reducing the target from 709 to 487 (a 30% reduction). However, after the low attrition experienced in the first several months of follow-up, the study team revised the target to a lower number: 487. Application of methods described here resulted in the recruitment of a somewhat larger number of subjects ($n = 497$). However, the accumulation of study subjects progressed at a somewhat slower rate than projected in the study protocol, taking place over 18, rather than the originally-planned 12, months. Final retention rates are pending study completion.

5. Discussion

The recruitment and retention strategies in a clinical trial with a geographically dispersed and unorganized study population, based on the ideals of community-based participatory research, were highly successful in achieving target enrollment goals and retaining study subjects at a high level. However, these approaches did not result in avoiding challenges. Some challenges were common to other clinical trials, e.g., participant barriers of time and logistical problems. However, unique challenges to this study included recruitment in a community-based (rather than clinical-based) setting, the geographic dispersion, and a high value on independence and self-sufficiency characteristic of the study population.

Farm operators and their farm organization representatives were largely uninformed about clinical trials and how their participation would contribute to the advancement of the research enterprise. This necessitated some explanation to farm organization representatives, their communication department staff, and prospective study participants. While some investigators (e.g., cancer researchers) have organized groups (e.g., Coalition of Cancer Cooperative Groups) to study and promote clinical trials among their patients, no similar organization exists for farm health and safety researchers. The National Institute for Occupational Safety and Health Agricultural Centers and others may benefit from considering forming such groups. One goal of this group might be to develop strategies to raise awareness of clinical research, explain the benefits of clinical trials, and develop methods to help this population make informed decisions about volunteering in clinical trials.

The costs of low study enrollment are significant, including loss of return on investment in routine study procedures (e.g., development of study application and tools, hiring staff, setting up contracts and accounts), competition for limited institutional resources, negative impacts on relationships with partnering agencies, and loss of reputation involved with a failed study. These expenses deplete research resources while failing to contribute to research outcomes. This is a particularly distressing reality in the context of the current financial environment (Kitterman et al., 2011). Given these factors, investigators and their host institutions have much to gain from examining risks of low enrollment and proactively managing these risks.

Retention in this 12-month study was uncommonly high, at 93%. We attribute this success, at least in part, to our participatory approach. Other studies also have documented the important role of partnership building in recruiting and retaining study participants (McFarlane, 2007). While community-based participatory research principles are not new, our experience demonstrated that operationalization of these principles in a study of farm operators is in fact challenging, even when the research team is informed, organized, and well-intentioned. Investigators may want to liberally estimate the time and other resources allowed for planning and implementing the recruitment and retention plan, and assure that study personnel are committed to the partnering process, even when it involves investment of limited study resources.

An activity that involves considerable time on the part of investigators, their staff, and institutional personnel is the amending of study procedures and respective IRB reviews. Investigators may save valuable time by including in the IRB application more comprehensive methods for recruitment and retention than are anticipated. Once the recruitment and retention plan is operationalized, the study team can selectively and conservatively select approved methods, and expand them as necessary, thereby avoiding the costs of later amendments.

The study is limited in that we did not conduct a test of our recruitment and retention strategies. Ideally, the study would have included controlled tests of one or more recruitment and retention strategies. Such trials of various recruitment and retention strategies will improve understanding of the effectiveness of these strategies in this unique population. Consequently, our understanding of approaches used in this study is limited, and not generalizable to other populations.

The development of the project's intervention represents the investment of considerable resources from an experienced, expert scientific team and study partners. The study team is committed to the eventual dissemination and translation of study results to target diverse and appropriate audiences. The intervention materials represent a resource that may be of potential value to farm operators beyond the life of the proposed study. Should the intervention be effective and satisfactory to users, the study team will explore opportunities to make the intervention available to a larger audience, to the potential benefit of a much larger audience of farm operators. Accomplishment of these dissemination and translational goals are dependent upon adequate recruitment and retention.

There is a need for further research to develop methods to assess the feasibility and effectiveness of subject accrual methods. Additional studies are also needed to examine factors that limit and enhance subject participation in clinical trials, and their impact. This information can be used to identify studies at risk for failure to accrue subjects, and to develop strategies to enhance recruitment and retention. These measures are expected to contribute to the effectiveness of clinical trials research.

6. Conclusion

Researchers have reported various challenges associated with recruiting and retaining study participants in research studies. These challenges are further intensified with hard-to-reach and vulnerable populations such as farm operators. Our study, which aimed to test the effectiveness of several approaches to promote hearing protector use among farm operators, exemplifies how recruitment and retention challenges can be anticipated and addressed. The use of community-based participatory approaches as the basis for recruitment and retention of study participants was shown to be very effective. This approach facilitated clear communications, participant–researcher relationship building, and community-based invested inputs and outcomes.

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