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Engagement, Recruitment, and Retention in a Trans-Community, Randomized Controlled Trial for the Prevention of Obesity in Rural American Indian and Hispanic Children

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Abstract

Engagement, recruitment and retention of participants are critical to the success of research studies but specific strategies are rarely elucidated in the literature. The purpose of this paper is to describe the engagement, recruitment and retention process and outcomes in the Child Health Initiative for Lifelong Eating and Exercise (CHILE) study, and to describe lessons learned in the process. CHILE is a multi-level, group randomized controlled trial of a childhood obesity prevention intervention in rural American Indian and predominantly Hispanic Head Start (HS) centers in New Mexico. Barriers to engagement, recruitment and retention included distrust of researchers, long travel distances, and different HS and community structures. CHILE employed multiple strategies from the onset including the use of formative assessment, building on previous relationships, developing Memoranda of Agreement, using a community engagement specialist, and gaining support of a community champion. As a result of lessons learned, additional strategies were employed, including more frequent feedback to intervention sites, revised permission forms, telephone reminders, increased site visits and over-scheduling of interviews. These strategies

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resulted in the recruitment of 16 HS centers, 1,879 children, 655 parents, 7 grocery stores and 14 healthcare providers, meeting or exceeding recruitment goals. By combining principles of community engagement, a variety of recruitment strategies, and lessons learned, this study obtained a high level of recruitment and retention.

Keywords

Obesity prevention; Preschool; RCT; Recruitment; American Indian; Hispanic; Rural

Introduction

Engagement, recruitment and retention are interrelated concepts that influence the involvement of participants in research studies. Community engagement is defined as "the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people" (US Department of Health and Human Services, 1997). Recruitment in randomized controlled trials (RCT) has two main goals: to obtain a representative sample of the target population and to recruit a sufficient number of participants to meet the sample size requirements of the study (Hulley, Cummings, Browner, Grady, & Newman, 2007). Retention involves keeping recruited participants for the duration of the study. General engagement strategies for recruitment and retention are similar (Yancey, Ortega, & Kumanyika, 2006).

The engagement, recruitment and retention of study participants is critical to RCTs but can be difficult, particularly in communities with a history of under-representation in research studies and where mistrust of researchers is commonplace (Davis & Reid, 1999; Katz et al., 2006). Multi-site RCTs (Campbell et al., 2007; Watson & Torgerson, 2006), studies that include minority participants (Fouad et al., 2004; Greenwald & Davis, 2000; Haskins & Kirk-Sanchez, 2006; Hodge, Weinmann, & Roubideaux, 2000; Horowitz, Brenner, Lachapelle, Amara, & Arniella, 2009; Mhurchu et al., 2009; Paskett et al., 2008), studies requiring active parental consent for child participation (Esbensen, Melde, Taylor, & Peterson, 2008; Johnson et al., 1999; McCormick et al., 1999), and studies in rural communities (Wages, Jackson, Bradshaw, Chang, & Estabrooks, 2010) all pose unique recruitment and retention challenges. These challenges can be magnified in trans-community RCTs which require substantial community engagement, relationship building, and focused effort at multiple levels (US Department of Health and Human Services, 2011).

Previous research has identified several elements that can positively influence engagement, recruitment and retention. Rogers (2003) emphasized the importance of having a community champion who occupies a key linking position in the community, has good interpersonal skills, and can serve as a broker on behalf of the health initiative within the community. A study of recruitment to 114 trials found that less than one-third recruited their target number of participants within the time originally specified (Campbell et al., 2007). Factors observed in the trials that successfully met recruitment goals included having a dedicated trial manager and a valued intervention available only within the trial. Campbell et al. (2007) also

found that successful trial recruitment addressed important questions at a timely point and had excellent communication across many levels. King et al. (2005), in a systematic review of studies across all medical specialties, found that individual participant preferences also affect trial recruitment. In addition to the participant's perspective and communication, Patel et al. (2003) identified early consideration of the impact of study design on the recruitment process, close collaboration with colleagues, and feedback to collaborators, associated clinicians and participants as important factors.

The Child Health Initiative for Lifelong Eating and Exercise (CHILE) was a grouprandomized RCT with the goal of preventing obesity among preschool-aged children through increased physical activity and healthier eating. The intervention, described in detail elsewhere (Davis et al., 2013), required engagement, recruitment and retention at multiple levels, including study sites, parents and caregivers, children, grocery stores, and healthcare providers. This article describes the engagement and recruitment process used for CHILE, examines our success in recruitment and retention at each level, and concludes with lessons learned and implications for future research.

Methods

Engagement for Trans-Community Research

Using the social ecological model (Simons-Morton, 2013) as a framework for conducting community research necessitates the effective engagement of the community at multiple levels. For this study, we included individuals, organizations, and environments that influence the physical activity and nutrition behaviors of preschool children. The research team used lessons learned from the Pathways Study (Gittelsohn et al., 2003), and principles of community-engaged research (US Department of Health and Human Services, 2011) to guide their work. Recommendations from Pathways include developing and maintaining long-term relationships and promoting the benefits of the project to the school and community. The principles of community-engaged research include establishing trust, treating participants with respect, ensuring equitable relationships, building clear communication mechanisms, and following through on commitments. Following formative assessment to understand local context and build partnerships (A. Sussman & Davis, 2010), researchers worked with key community members, including Head Start (HS) management, teaching staff and foodservice employees, children, families, grocery store management, and healthcare providers. In the six tribal communities, tribal officials were also involved in the process. A summary of the overlapping engagement, recruitment and retention strategies employed in this study are described in Table 1.

The research team included a community engagement specialist (CES), who was a social worker whose primary responsibility was communication between the study sites and the team. The responsibilities of the CES included specific activities, such as coordinating recruitment efforts, and scheduling intervention and measurement activities. Activities also included relationship-building between the communities and the researchers, such as conveying the needs of the communities to the team and vice versa, and eliciting feedback from the communities about research activities and challenges. In this intermediary role, the

CES helped establish and build trust between researchers and communities and ensure equity in the partnership.

Researchers enlisted members of the local community, CHILE champions (champions), to serve as the primary contact for each HS center. Champions were paid a stipend of \$1,000 per school year to advocate for CHILE at the HS center and within the community, assist with logistics for child recruitment, assist with the coordination of height and weight measurements, and schedule and coordinate semi-structured interviews with parents or primary caregivers. Champions were recruited following recommendations by HS administrators at each site and often were either parents of HS children or HS staff members. All champions received an orientation and manual of procedures detailing their responsibilities and signed a confidentiality agreement.

Recruitment of Head Start Centers

HS centers were selected as the main setting for the CHILE research study because they provide access to very young children from low income families (Gittelsohn et al., 2003), prioritize health and nutrition, and incorporate family involvement (Office of Head Start). HS centers that: (a) served under-resourced communities; (b) enrolled predominantly Hispanic or American Indian children; (c) had at least 20 three-year-old children enrolled; and (d) retained at least 80 % of their students for two years were eligible for the study. HS centers in metropolitan areas were not eligible for inclusion as the focus was on rural communities and small towns, reflecting much of the state of New Mexico. Centers within 150 miles of Albuquerque were prioritized to minimize travel expense. The recruitment process began with initial contact by telephone to screen HS centers for inclusion criteria. Based on a power analysis, our goal was to recruit 16 HS centers.

The engagement and recruitment process took place over 17 months due to several challenges. The first was the lack of a central HS administration. Most programs were administered at the local level by a single entity and had to be contacted and recruited separately. Several of the predominantly Hispanic HS centers were part of umbrella organizations that presented benefits as well as challenges. Recruitment of a single umbrella organization allowed for multiple HS centers under the umbrella organization to participate in the study. In one case, however, two centers from the same umbrella organization that were geographically proximate could not be separately randomized as their administrative structure and management were the same. Therefore one was removed from eligibility. Outreach and engagement to eligible centers involved frequent communications by research team members in person, by telephone, and electronically. Some sites were in communities that had long-standing relationships with the research university, or with specific researchers, facilitating the process. In all cases, gaining support of an individual stakeholder (champion) who advocated for the project at each HS center, community, or oversight organization was integral to the recruitment and engagement process (Rogers, 2003).

In American Indian communities, written project summaries were submitted for review and either a CHILE or local HS representative or both presented the study for approval to tribal administrators, tribal councils, or tribal governor's office personnel. The study was also presented to HS parent and policy councils and to health advisory committees.

Following presentations to requisite decision makers, the recruitment phase for centers ended, and each partnership was formally established with the signing of a Memorandum of Agreement (MOA). The development of the MOAs was instrumental in building trust. These MOAs outlined the commitments of the research team and each participating site, as well as potential benefits of participation. These included in-kind contributions, training and curricula addressing HS performance standards, height and weight measurement of all HS students, and \$1,000 for comparison sites during each year of the intervention phase of the study. MOAs were developed jointly with community partners to ensure equity and a common understanding of roles and responsibilities. Additionally, the MOAs assured participating HS centers that, even if randomized to the comparison group, that they would receive the full CHILE intervention following completion of data collection. All study protocols, including signed MOAs, tribal resolutions, and letters of support from tribal HS programs, were approved by our Institutional Review Board.

Parental Permission for Recruitment of Children

Children were enrolled through active parental permission at intervention and comparison sites. The term 'permission' was used as opposed to 'consent' to be consistent with terminology used in the school environment. The initial goal was to recruit two cohorts of children, one each in Years 1 and 2 of the intervention. Each cohort would consist of 20 three-year-old children from each HS center, for a total of 640 children (16 sites times 20 children times 2 years). Following formative assessment, the team used rolling enrollment of all children attending HS centers for 2 years of intervention after determining that most participating HS sites (n = 13) did not separate children by age (e.g., 3 and 4 year olds were in combined classes). The recruitment goal was revised to 70 % of the total HS enrollment.

To maximize child enrollment through active parental permission, the recruitment process involved both direct recruitment by research staff, bilingual as needed, and follow-up by HS teaching and administrative staff. To build support for the project among HS staff, researchers conducted staff orientation sessions in which they engaged teachers in the development of the HS-based intervention components. Participating HS centers then invited research staff to parent orientation sessions at the beginning of each school year (i.e., Fall of 2008 and 2009). The majority of HS families attended. Research staff presented the CHILE study to families and informed them that all children attending the HS centers that were selected for the intervention would be measured for height and weight, but only those children with parental permission would have their measurement data collected and analyzed by the study team. Research staff then explained the enrollment and informed consent process by which parents could provide permission for their children to participate and answered questions. The CHILE permission form was read aloud to families to facilitate understanding, and parents were then invited to review and sign the form. Parents were permitted to take permission forms home and return them at a later date. Families who were unable to attend the parent orientation at their respective HS centers received the permission form from HS staff and were provided with contact information for research staff. Champions assisted with collection of permission forms. No incentives were given for parental permission, nor were incentives provided to teachers or champions for collecting permission forms. Following a delay in receiving some of the permission forms, we

modified them to permit retroactive access to and use of height and weight measurements. HS centers retained data in their health records, and we had access to data pertinent to those children who were enrolled in CHILE.

Recruitment and Consent of Parents

Parent Interviews were conducted with the adult "who spends the most time with the child." Most frequently the child's mother was recruited and invited to provide consent to participate in the study. Parent Interviews were conducted at the HS centers, lasted approximately 1–2 h, and were conducted in English or Spanish based on interviewee preference. Interview participants from the tribal communities were proficient in English, as were the majority of participants in Hispanic communities.

CHILE champions coordinated and scheduled interviews with a convenience sample of parents. Champions were equipped with a blank schedule, a script explaining the study, and contact information for parents of enrolled children at their HS center. Each site scheduled a minimum of 30 interviewees in order to reach the goal of at least 20 interviews per site. Champions contacted potential interviewees by telephone 2 weeks prior to the interview date. Champions prioritized parents who were interviewed previously to obtain repeated measures data on individual children where possible. When parents arrived at their appointment, the CHILE interviewer read the consent form aloud and gave participants time to read it themselves and ask any questions. Following consent, the interview was conducted and interviewees were compensated \$20 for their time.

Recruitment of Grocery Store Owners and Managers

Grocery store owners and managers were recruited to increase access to and highlight foods promoted in the CHILE intervention. Researchers generated a list of potential partner grocery stores using Reference USA, an online marketing database of U.S. businesses. The grocery store owner and manager recruitment process was based on two factors: location in or near the community, and teacher reports of where HS families shopped for food. Most HS centers only had one grocery store in their community, limiting the choice of stores.

CHILE research staff contacted store owners and managers to explain the project and the requirements for participation. CHILE provided the necessary promotional materials (e.g., brochures, recipe cards) to carry out this component of the larger intervention. In exchange for a grocery store's owner/manager participation, the research team highlighted the store as a CHILE partner to the local HS center in newsletters sent home with HS families and at family events, and encouraged HS teaching and foodservice staff to purchase foods for the CHILE intervention from their local CHILE-participating stores.

During the recruitment process, grocery store owners and managers were asked to commit to participate for the duration of the intervention period, to provide access to the store for CHILE staff to implement the intervention, to maintain the CHILE materials in a tidy fashion, and to notify CHILE staff of changes that could affect project implementation, such as the opening of a competing store.

Stores were included in CHILE based on proximity to a HS center, willingness to participate, and ability to support the nutrition-related goals of CHILE, including the ability to provide fresh fruits and vegetables (in addition to canned and frozen), whole grain foods and low-fat dairy products. Specific details of the CHILE grocery store component are reported elsewhere (Davis et al., 2013).

To keep store owners and managers engaged, a nutrition scientist on the research team maintained regular communication with grocery store management. Research staff visits helped foster the relationship, and provided time to restock recipes and assure that labels were correctly placed. In Year 2, the CHILE nutrition scientist implemented a system of providing grocery store managers with a letter updating them on the intervention, and reminding them they had been designated as a CHILE partner and that HS families were being encouraged to shop at their stores.

Recruitment of Healthcare Providers

To address another level of the social ecological model, and to provide a consistent message, CHILE included community healthcare providers as an intervention component. Providers were recruited to serve as role models, support CHILE goals in their practices, and participate in family events at local HS centers. Healthcare providers were recruited from each of the communities and included nurse practitioners and physicians.

Participating healthcare providers were identified through an established physician research network (Mold & Peterson, 2005) that provided the CHILE team with a list of 21 providers from 8 practices, including 15 physicians and 6 nurse practitioners, who agreed to support the program. The administrator of the physician network communicated with the healthcare providers and arranged orientation meetings in their offices to introduce it. Meetings ranged from presentations at staff meetings to one-on-one encounters at which researchers provided lunch. Each provider received materials informing him or her of the CHILE intervention, along with a letter from the principal investigator thanking him or her for participating in CHILE and detailing his or her role as a resource and role model for the community. Materials outlined specific messages for the providers to promote with their patients and included obesity prevention guidelines from the American Academy of Pediatrics (Barlow, 2007). Providers also received a detailed explanation of the CHILE curriculum, samples of materials distributed to families, and examples of the grocery store materials. CHILE provided pamphlets that presented the CHILE project and a book for clinic waiting rooms (Berenstain & Berenstain, 1984). A physician member of the CHILE research team visited the providers at the beginning of the second year of the intervention to keep them engaged. The CHILE physician gave each participating practice a guide for providers to follow when informing parents of best practices for the health of their children (Hagan, Shaw, & Duncan, 2008).

Discussion

Engagement, recruitment and retention are especially complex in a multi-level, multi-site RCT with under-represented populations. While this research did not include an experimental study of the strategies used, recruitment and retention were high for all

components. This research provides insights into the successful strategies used and adopted as a result of lessons learned (Table 2).

Research Sites

Several factors promoted successful engagement and recruitment at the HS center level. Previous established relationships with the research university, and specific researchers, facilitated the process. A history of equitable, respectful collaboration led to trust for the new study. It was also helpful to designate one individual on the research team to be the primary person responsible for community outreach. Identifying another individual within the community to support the project on behalf of researchers was also critical to success. While initially time-consuming, it was worthwhile to build a relationship with someone in a leadership position within the community who had both the time to dedicate and an interest in pursuing the project.

The HS site recruitment process was facilitated by the development of MOAs specifying the responsibilities and benefits of participation. In some tribal communities, a MOA is required to conduct research. Even when not required, a collaboratively developed MOA is an essential tool to ensure that both the research team and the HS centers understand their respective roles within the research process. Benefits listed in the MOA should meet organizational requirements of the partner organization. For example, the CHILE study provided in-kind contributions, conducted measurements on all children for the HS centers, and designed the intervention curriculum to meet HS performance standards. HS centers assigned to the comparison arm of the study also received a \$1,000 stipend and were assured through the MOA that they would receive the intervention materials following completion of data collection.

Only one site declined participation and all recruited sites were retained throughout the study despite several challenges that required flexibility, creativity, and persistence while maintaining a standardized protocol. These included separate HS administrative structures, staff turnover, one center that divided into two, and the incorporation of Pre-K programs into some centers. The different tribal protocols at each American Indian site also added to the complexity of the recruitment process. As each tribe is a sovereign nation with its own governmental structure and processes, researchers relied on community champions to help navigate the appropriate channels. Tribal communities differed in who could authorize the research (e.g., tribal council, governor's office personnel), who should present the research (i.e., researcher, community champion), and the timeline for approval (e.g., getting on the tribal council calendar could take several months). Because of these differences, it took an average of 23 days longer to obtain signed MOAs from tribal than non-tribal communities. Differing HS infrastructures and tribal protocols were addressed through intensive partnership building, regular communication, and respect for the process. Staff turnover was addressed through orientation and training sessions and regular communication. Communication was maintained throughout the summer months. This included a summit between Years 1 and 2 that facilitated communication between researchers and HS staff, interaction among HS staff, and avenue for the exchange of ideas and feedback on the intervention. This communication served to foster relationships and maintain engagement.

Additional summer planning meetings assisted HS administrators with the integration of the CHILE project into food service and classroom curricula during the coming school year. It also allowed research staff to plan recruitment efforts and measurement strategies for each school year. Children from the HS center that split into two centers were all followed forward. Lastly, the incorporation of Pre-K programs at some of the HS centers was dealt with by excluding children from the study after they entered these programs. This exclusion was necessary as HS and Pre-K have different program requirements. Despite the ineligibility of Pre-K students to remain in the study for analysis, Pre-K programs located within HS centers were provided with the CHILE curriculum and children were still measured for HS records. This continued involvement increased trust and equity between the communities involved and the research team. Moreover, all of these challenges were minimized by maintaining regular communication with all sites—including delayedintervention sites-throughout the study, remaining flexible, and by assigning one primary point of contact (i.e., the CES). In addition, providing an annual \$1,000 stipend to delayedintervention sites likely helped to keep those sites engaged during the 2 years they waited to receive the intervention.

Children

Our initial goal of recruiting and consenting 640 children into CHILE was surpassed by 200 %. This higher-than-expected enrollment resulted in an IRB-required protocol revision. In total, nearly three-quarters of eligible students were enrolled, despite requiring active parental permission and not providing any incentive to families for enrolling. The use of champions from the community, bilingual/bicultural facilitators, a convenient location (HS center), convenient times (orientation or open enrollment throughout the year), and face-toface recruitment were strategies that we used that have been shown to enhance recruitment (Dumka, Garza, Roosa, & Stoerzinger, 1997; Lee, August, Bloomquist, Mathy, & Realmuto, 2006; Marin & Marin, 1991; Reidy, Orpinas, & Davis, 2012). The recruitment process also provided lessons learned. Formative assessment indicated that targeting recruitment efforts at all HS students rather than a specific age group would be less confusing and would therefore lead to greater participation. Other challenges included parents who failed to attend the 'mandatory' (per HS requirements) orientation meeting; parents who forgot to return permission slips; and parents that did not have adequate information to make an informed decision after missing the opportunity to talk directly to a research staff person. To address these challenges, we sent a letter to parents at the beginning of each school year that was also used for rolling recruitment as new students joined the HS center during the school year. In addition to the recruitment letter, parents received project staff contact information and a permission form. Language in the permission form allowed for access to retrospectively collected height and weight data that HS centers maintained on all children as part of their center requirements, and was an effective way to deal with permission forms that were turned in late.

Recruitment of children was complicated by a small number of parents concerned about their children being "used" in research, and one teacher at a HS center that actively dissuaded parents from signing consent forms and participating in the research. The CES actively addressed these issues by working with HS administrators to determine the best

course of action. Responses included increasing outreach efforts to the parents and community and emphasizing during teacher training that the purpose of the research was to improve the health of children in the community.

Parents

The low participation rate in Parent Interviews during the first year was likely due to an inadequate recruitment strategy. It was not uncommon for individuals who agreed to an appointment to not show up for the interview. Changes made to the recruitment strategy to increase participation during Year 2 included the use of reminder calls the day before and the morning of the interviews. A Cochrane review found telephone reminders to be an effective method for increasing recruitment in clinical trials (Treweek et al., 2010). Other lessons learned, and employed in Year 2, included spending more days at smaller sites to recruit from a smaller pool of potential participants; over-recruiting in anticipation of participants failing to come to an appointment; setting and actively pursuing a goal of at least 20 interviews per site; and changing CHILE champion pay from a single payment at the start of the project, to two payments, one at the end of each measurement period. These changes approximately doubled participation rates during Year 2.

Grocery Store Owners and Managers

While all grocery store owners and managers in the intervention communities were successfully retained, there were some challenges. Store owners were willing to participate, provided that there was no requirement to supply staff labor to the project. They were also incentivized to participate by the multiple opportunities for increasing customers (e.g., families, HS teaching and foodservice staff) and purchases from existing customers through the larger study. The literature is limited regarding recruitment of grocery store owners and managers for community interventions. A study with Korean-American store owners in Baltimore showed that owners were successfully recruited when the researcher was of the same ethnicity, and the intention of the research was viewed as positive (Song et al., 2011). However, the role of the store owner was larger in that study, and unlike CHILE, required extensive time and attention.

Research staff learned the importance of respect for the business impact of the intervention. A challenge to consider during the recruitment process for grocery store owners and managers is the cost of food loss due to spoilage, which impacts smaller independent stores more than larger chain stores. Participating store owners and managers were asked to stock specific produce and whole grain foods. These foods often spoil faster than their canned, frozen or refined grain counterparts. If demand is not sufficient for the supply and spoilage occurs, store owners may hesitate to participate, or may terminate their involvement in studies early. Research staff should understand that the goal of the store is to make a profit, that foods that promote health (e.g., fresh produce and whole wheat pasta) may be more prone to spoilage, and that stores may not participate in studies if they are unable to identify ways to minimize losses.

Another lesson learned was that many people in small rural communities do not shop for the majority of their groceries locally. While participating stores were located as close to HS

centers as possible, and were often the only store in that community, data from the formative assessment (A. Sussman & Davis, 2010) and post-intervention Parent Interview data indicated that many families traveled greater distances to large, national chain stores for their primary food shopping, where prices may be lower and there may be a larger variety, resulting in infrequent visits to their smaller community grocery stores. The research team chose to recruit small, local stores within participating communities in order to build relationships in the community, but large chain stores may be in a better position to influence buying behavior.

Healthcare Providers

Healthcare providers were successfully recruited into the study through an established physician research network and were retained throughout the study period. Active participation of these providers in the community, however, was difficult to achieve. First, contacting healthcare providers over the phone is very challenging (Herber, Schnepp, & Rieger, 2009). We learned during the course of the study that the use of a physician member of the research team to contact healthcare providers directly increased participation. The literature confirms that physicians recruiting physicians has greater success (Asch, Connor, Hamilton, & Fox, 2000; Herber et al., 2009; Hudson, Harris-Haywood, Stange, Orzano, & Crabtree, 2006). Scheduling recruitment meetings over lunch and providing lunch was an efficient use of time and also proved to increase participation rates.

Once healthcare providers were recruited and engaged, another challenge was overcoming time constraints. As with previous research (Sussman, Williams, Leverence, Gloyd, & Crabtree, 2008), the providers recruited for CHILE were interested in being part of a community-based obesity prevention program. They often found it challenging to participate, however, due to their work schedules and obligations, as well as the timing of CHILE family events. Providers are so involved in clinical care that they do not have much time left to work with the community (Boyle, Lawrence, Schwarte, Samuels, & McCarthy, 2009; Herber et al., 2009). This problem was exacerbated when HS centers rescheduled or failed to schedule family events with sufficient lead-time for providers to fit them into their schedules.

Funding constraints have also hampered provider involvement in the community. The nurse practitioners and health educator recruited to the project had difficulty getting supervisor permission to participate in family events outside their clinics. Efforts were made to engage and to maintain regular communication with providers, but researchers were again constrained by the time providers could devote to the project. Although the literature indicates that large incentives increase healthcare providers' participation (Rosemann & Szecsenyi, 2004), in this case incentives were not considered a viable solution, as they did not address the primary issue, which was time shortage. Future efforts should focus on recruiting providers who already have a working relationship with HS centers through health councils, as these individuals are already committed to incorporating community health events into their schedules.

Model Development

We developed a model to illustrate the engagement, recruitment and retention process, emphasizing the multiple levels of relationship building required (Table 3). The first level of relationship building is conducted by two individuals, one from the research team and one from the community organization. The research team member may be the principal investigator, the CES, or another member of the team with ties to the community. The community member (champion) should be an individual with sufficient knowledge of the community and the community organization involved, and sufficient power and influence in the community organization to speak on behalf of the organization and the research project. The second level of relationship building focuses on obtaining commitment and adopting a formal agreement. The interactions in these stages take place between the individuals in Level 1 and those with the power to authorize participation in the research. These stages may be time intensive but are critical to successful recruitment and retention. The third level of relationship building focuses on the relationships between all of the research team members and community members involved in the project. Here the emphasis is on fostering the partnership and building trust through listening, shared learning, bi-directional communication and mutual respect. The model provides a practical guide for implementing multi-site, multi-level intervention research in communities with an emphasis on relationship building at multiple levels.

Conclusion

Engagement, recruitment and retention in multi-level community intervention studies are critical to successful research, especially in historically under-represented populations. Contributors to success include building on previous relationships, working with community leaders, forming partnerships with mutual benefits specified in a MOA, and having a CES on the research team who serves as the primary point of contact with the community. It is also critical to be flexible and to respond to changes in the community as the study evolves, while still maintaining fidelity to the study protocol.

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Table 1

Initial strategies for engagement, recruitment and retention in a multilevel, community-based research study

Strategy	Description of the process	Principles addressed
Head Start (HS) Centers		
1. Build on previous relationships	Engaged communities with existing or previous relationships with our research center or members of the research team	Expand trust Maintain long-term relationships
2. Identify an individual in each community to advocate for the study	Identified and worked with a stakeholder in each community who believed in the study and was willing to advocate for it within the community	Find a community champion Build partnership Promote project benefits
3. Jointly develop a Memorandum of Agreement (MOA)	Collaborated with community partners to develop an MOA outlining the roles and responsibilities of both the research team and the community partners, and explicitly stating benefits for both the intervention and comparison sites	Provide for an equitable partnership Establish trust Communicate clearly Promote project benefits
4. Incorporate the partner organization's goals	Designed an intervention that helped community partners meet or exceed their own performance standards and other regulations or requirements	Build partnership Demonstrate respect
5. Assign one dedicated person to maintain contact	Assigned a single point of contact for community partners to use when communicating with the research team	Build trust Communicate clearly Provide for an equitable partnership
Children		
1. Communicate in person with families	Presented the study in-person to family members, reviewed materials and provided an opportunity for questions	Build trust Demonstrate respect Promote project benefits
2. Use appropriate language	Conducted presentations and provided materials in Spanish when appropriate and at the appropriate education level to enhance understanding	Communicate clearly Demonstrate respect
Parents		
1. Employ local champions to assist with the project	Hired local champions to assist with contacting potential participants and scheduling interviews	Find a community champion Demonstrate respect Communicate clearly
2. Conduct interviews at a location convenient to participants	Made interviews as convenient and comfortable as possible for the participants	Demonstrate respect
3. Use bilingual interviewers	Used bilingual interviewers to address participants in the language in which they were most comfortable	Build trust Demonstrate respect
Provide incentives	Provided incentives commensurate with participant commitment	Demonstrate respect
Grocery Stores		

Strategy	Description of the process	Principles addressed
1. Involve a nutrition scientist	Employed a nutrition scientist familiar with the health and nutritional aspects of products and the intervention as well as an understanding of the business impact of the intervention	Build partnership Demonstrate respect
2. Have research team members maintain intervention materials	Had research team members go to the grocery stores at regular intervals to maintain intervention materials (e.g., recipes, project brochures, and signage)	Build partnership Demonstrate respect
Healthcare Providers		
1. Work through an established network of healthcare providers	Recruited community healthcare providers from an established network	Build relationships Focus on participant preferences
2. Make minimal requests on healthcare provider time	Integrated interventions into regular healthcare provider practice	Demonstrate respect Build relationships
3. Use professional recommendations	Used the American Academy of Pediatrics recommendations and built the intervention with those recommendations in mind	Demonstrate respect
4. Offer an intervention-related incentive	Provided an incentive that contributed to the intervention and met professional standards for healthcare providers	Build partnership Demonstrate respect

Table 2

Challenges, strategies and lessons learned during engagement, recruitment and retention in a multi-level, community research study

Challenge	Strategy	Lessons learned
Head Start (HS) Centers		
1. High staff turnover	Increased number of site visits to intervention communities	HS staff turnover necessitated frequent site visits for planning and training and to ensure fidelity
2. Reduced engagement among comparison sites	Increased number of site visits to comparison communities	Extra visits to comparison sites were necessary to maintain their engagement in the research.
3. Inconsistent implementation	Provided process data to intervention sites on a quarterly basis instead of annually	More frequent feedback to sites increased engagement and participation at the HS intervention sites HS administrators used process data to evaluate their site's performance and make changes
4. Barriers to implementation	Integrated participant feedback into the intervention on an on- going basis where possible without sacrificing fidelity	Incorporating HS staff suggestions throughout the study improved implementation Participants should be encouraged to make recommendations even when it was not feasible to incorporate all of them
Children		
1. Confusion around eligibility limited recruitment	Used formative assessment results to determine target populations for recruitment	Formative assessment was invaluable in determining the recruitment strategy
2. Permission forms turned in after baseline data collection	Changed permission forms to allow for retro-active abstraction and use of data	Using permission forms that allowed for retro-active abstraction and use of data increased the amount of data available for analysis
3. Participants could be lost to follow-up	Created permission forms that remained in effect for the duration of the study	Obtaining permission for children to participate for the duration of the study negated the need to re-enroll each year
4. History of distrust of researchers	Provided and participated in community events in addition to orientation/recruitment activities	Actively engaging children and families at events that were not strictly for recruitment or research demonstrated respect and built trust
5. Low enrollment	Developed additional strategies for enrolling participants	Using multiple recruitment strategies increased enrollment and participation.
Parents		
1. Participants failed to show for interviews	Over-scheduled participant interviews	Over-scheduling by 50 % increased participation and made effective use of research staff time when traveling long distances to a research site
2. Participants failed to show for interviews	Changed interview process to include reminder calls	Reminder calls to participants the day before their interviews reduced the number of parents

Challenge	Strategy	Lessons learned
		that failed to show
3. Schedulers and interviewers were not proactively contacting a sufficient number of participants	Revised protocol to emphasize the need to actively pursue an interview goal for each site	Protocols for schedulers and interviewers needed to focus on the importance of contacting and following-up with a specific number of participants
4. Participation by CHILE champions ^{<i>a</i>} waned over the course of the school year	Revised payment schedule for CHILE champions	Stipends paid in two installments (one at the beginning of the school year and one at the end) encouraged more active participation throughout the year
5. Lack of repeated measures for Parent Interviews	Offer greater incentives for follow-up interviews (not done during this study)	Increasing incentives for parents returning for follow-up interviews would reflect the importance of repeat interviews and may have increased the number of return visits
Grocery Stores		
Grocery store personnel had limited time to devote to the project	Project staff ensured that intervention materials were properly stocked and displayed	Stores vary in the amount of support for an intervention. Projects need to be flexible, and not expect stores to dedicate employee time to intervention efforts
Lack of understanding of the intervention by employees led to removal of intervention materials	Increased frequency of store visits and engagement with employees	Information about the intervention was not necessarily transmitted from the store owners and managers to other employees. Project staff needed to do this.
Healthcare Providers		
1. Limited response by healthcare providers	Recruited physician to physician	Using an enthusiastic physician to contact and interact with healthcare providers improved access and engagement
2. Limited healthcare provider time	Met over lunch and provided lunch	With limited time, the most effective strategy for respecting healthcare provider time constraints was to meet over lunch and provide the food
3. Limited healthcare provider engagement	Maintain regular contact and provide reminders	While healthcare providers are interested in participating, time constraints make it difficult. Building a relationship with participating providers over time helped retain their interest and keep them involved

^aCHILE champions were community members that served as the primary contact for each Head Start center, advocated for CHILE at the Head Start center and within the community, and assisted with logistics for recruitment and data collection

Table 3

Stages of community engagement, recruitment and retention for community-based intervention research

1st Relationship individual to individual

Identify a Champion The champion should have sufficient influence and power in the community organization. The champion will speak on behalf of the health initiative to decision-makers in the community. The process is easier if there is already an established relationship between researchers and the community

Create a Shared Agenda This stage incorporates listening, shared learning and negotiation in order to identify whether and how partnership on the project will benefit the community/organization and the research team. It is important to know the community/organization and their needs and priorities

2nd Relationship individual to community

Obtain Commitment Respecting community/organizational procedures, a representative from the research project (e.g., the Community Engagement Specialist) and the community (e.g., champion) advocate for the project with appropriate decision-making groups or individuals

Adopt Formal Agreement Depending on the project and the individuals or organizations involved, this may take the form of a Memorandum of Agreement (MOA), other written or verbal agreement, or signed consent form. This will provide a foundation for the research project and should outline expectations and benefits for both parties. Researchers should allow several months to get to this stage

3rd Relationship research team to community

Foster Partnership After a formal agreement has been signed, listening, shared learning and negotiation will take place between the research team and multiple members of the communities and organizations involved. This is a trust-building period for partners. During this stage formative assessment is conducted to determine how to best implement the intervention in the specific partner environments

Nurture Relationships While Implementing Research Activities This stage is focused on the continued cultivation of relationships through mutual respect, bi-directional communications, and regular contact. New relationships may need to be developed (e.g., in cases of staff turnover or program growth). Researchers need to balance flexibility to accommodate community needs with fidelity to intervention research protocols. Research staff should also provide results to the community when available and in a manner suitable to the community