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Grassroots Campaign Trail Methods to Recruit for Clinical Trials: Recruitment Lessons Learned from Trail to Trial

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Abstract

Background: Literature reviews have identified recruitment as the single most challenging obstacle in conducting pediatric trials. This paper describes a paradigm shift in recruitment design, developed from experience with grassroots campaigns through the *DRINK* study (Decreasing the Rates of Illness in Kids). The objective of this study was to explain a new method for recruiting in clinical trials based on lessons learned from grassroots political campaigning.

Methods and findings: The study described is a randomized controlled trial of 638 3–6 year olds from the Washington, DC Area. The design involved a comparison between new recruiting approaches modeled after grassroots campaigns and traditional techniques. Traditional techniques for the purpose of this paper are defined by the use of physician referral, mass media such as radio and television advertisements, along with posters in public places like the subway. Grassroots approaches alternatively developed and utilized community contacts and employed targeted small market media community. The main outcome measures were the percentage of budget used and the number of eligible participants recruited.

Conclusions: The results showed that the grassroots recruitment approach saved 30% of the budget, recruited 638 kids in 4 months and retained over 90% for the 90 day trial. New techniques need further exploration as community studies are stressed.

Keywords: RCT, recruitment, grassroots

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Introduction

Pediatric physiological interactions differ from those of the adult population; there is therefore an inherent danger when utilizing products in children that have only been tested in adults. Policymakers and healthcare professionals recognize the need to increase the number of pediatric Randomized Controlled Trials (RCTs) and have responded by creating policies and incentives for industries and organizations to engage in conducting trials in children. Despite governmental incentives, there is still a dearth of pediatric trials, primarily due to the difficulty in recruitment of participants. An electronic search of RCTs published between 1985–2004 found that only 701 (13%) of all RCTs were pediatric, compared to 3,328 published adult trials.[1] Literature reviews identify recruitment as the single most challenging obstacle in conducting pediatric trials.[2,3]

The *DRINK* study (Decreasing the Rates of Illness in Kids), was a clinical trial examining the role of probiotics in infectious diseases. Consenting parents or caregivers were asked to have their participating child consume a strawberry flavored dairy drink for 90 days. Due to seasonal variation on illness, enrollment was limited to four months during the fall and winter months. This paper describes a paradigm shift in recruitment design, developed from experience with grassroots political campaigns. Importantly, as community research is now being highlighted by the NIH, new techniques for recruiting need to be explored.

This shift allowed the project to successfully enroll 638 participants in four months, while utilizing less than 70% of the original six-figure recruitment budget. Additionally this approach, which reallocated funds from a mass media campaign into grassroots techniques, contributed to a retention rate of 92% throughout the 90-day trial. This technique was largely developed from the experience of the project coordinator who worked on developing coalitions in the 2004 presidential campaign, as well as a statewide gubernatorial race in 2005.

Traditional Approach-Identifying Participants

The original recruitment budget and protocol for this trial utilized costly mass media, primarily radio and newspaper advertisements.[4,5] This method would generally yield several hundred callers to a screening line daily. However, mass media does not target specific populations and generally a large percentage of callers are ineligible.[6] Screening ineligible callers takes study personnel away from other necessary project tasks and more productive means of recruitment.

In conjunction with the media campaign, like most clinical trials *DRINK* intended to emphasize the utilization of a flyer campaign at various physician and health care locations for recruitment. Again, this approach is not targeted and results in poor time management for research personnel.

Grassroots solution

The fundamentals of all grassroots campaigns rely on effective messages being delivered by effective messengers; the 2004 Presidential Campaign further refined and improved upon these message-messenger techniques. In 2004, compiled polling data from the previous twenty years revealed that persuadable swing voters had decreased from 20% to 7% of the voting population. This information dramatically changed the strategy for campaigns. The focus for campaigns became one of voter turn out rather than voter conversion. To accomplish this, both Democrats and Republicans had to 1) identify their voters, and 2) mobilize them to the polls. The parties did this based on voting behaviors, groups and association assumptions. Thus, the 2004 elections were about mobilizing specific voters on specific issues through the use of coalition and community leaders. Slogans and spokespersons for these specific voter groups like "Veterans for Kerry", "W stands for Women", "Catholics for Kerry" and YPW (Young Professionals for W) emerged.

On the ground, grassroots representatives were commissioned among different demographics, coalitions and communities focused on mobilizing the "within reach fruit" voters to the polls; these voters identified voters among the networks and associations of the grassroots leaders and representatives. Under this grassroots campaign technique, most successful campaign staffs were not comprised of political analysts or persons with in-depth understanding of political science; but rather, persons who could identify, talk with, and were trusted among specific voter groups.

Like a grassroots campaign, *DRINK's* recruitment strategy relied on tailored messaging. Believing that families would be more receptive to participating in

the study and motivated to call the recruitment line if 1) they received flyers and information about the study from a known contact or 2) received study information designed to inspire trust and comfort, the goal was to have known persons in the community, daycare providers, physicians from our Practice Based Research Network (PBRN) and community leaders from religious groups and other community institutions deliver hand tailored—and Institutional Review Board (IRB)-approved—information directly to families. Information with tailored images outlining clear concise study details yields more eligible callers to recruitment lines, rather than flyers received in the mail or posted on the wall. This direct method reduced the risk of a high proportion of ineligible families being solicited for the study, and allowed for more personnel time in the field. There were a total of only 872 calls to the screening line, of which 741 candidates were screened and 681 met eligibility criteria (91%).

Traditional Approach-Limited to Research Institution

Traditionally clinical trials primarily identify study candidates by recruiting patients already receiving care through the institution conducting the trial. Research institutions send recruitment mailings to patients that believe may fit study criteria. An alternate traditional method places study personnel in sites like clinics, ambulatory care, and emergency rooms, to enroll potential participants in person. Typically data is collected at one site, requiring participants to travel to the research study. Trials often are budgeted to reimburse the travel costs of the participant, but despite these provisions recruiting from a University primarily results in a biased participant population.[7] Additionally, data collected in a laboratory or that of a medical center, often varies from data collected in the community. Thus, results from hospital or university-based settings have limited generalizabilty.

Grassroots solution

Less than 10% of *DRINK* population identified themselves as learning about the study through a physician or healthcare center, but eighty-four percent of participants indicated that they learned about the study through their daycare/school or other grassroots methods (ie, from another participant, community centers, church, website or listserv). An efficient, grassroots solution identifies study candidates in targeted communities. We provided cars and cell phones to research personnel, allowing more face time in the community. We believe this approach is a paradigm shift in recruitment because most sponsors and institutions are willing to spend several thousand dollars on printing and media, but have more reservations when investing in community time of personnel. By providing the staff with tools such as cell phones and cars, they have much greater access to the community and can spend more time in the community. The benefit of this approach is multifold, as research collected in the field—over a laboratory—increased the external validity of the study and by providing Research Assistants (RAs) with cell phones; participants could more easily get in contact with the RAs, limiting missed follow-ups. Thus, more study personnel time in the community lead to greater trust, increasing recruitment and retention. However, the NIH has strict rules on expenses like travel and food for offices, often making this approach difficult when using government funds. However, we have successfully worked with NIH project officers, explained the grassroots approach and have subsequently been granted permission to spend funds for these types of expenses.

DRINK study personnel promoted the study by presenting at various meetings and gatherings and by meeting with community leaders while enrolling participants in their home or community. To identify points of contacts within the communities, the research team networked with churches, synagogues and community groups—scheduling opportunities to go out and present to these different groups increased face time among potential recruitment sites—thus, getting different communities comfortable with the project while continuing to network for contacts within the schools and daycare centers.

Traditional Approach-Cost

Based on extensive personal research the PI (Daniel Merenstein) has assessed the typical clinical trial will cost $10–50,000 per patient. A substantial part of these costs is recruitment and retention of subjects. The original protocol for *DRINK* created by the PI and Sponsor set aside 10% of the entire budget for recruitment, of which 80% was allocated for the utilization of a mass media campaign.

Grassroots solution

The original budget was reconfigured (Table 1) to emphasize grassroots techniques, establishing relationships within the community. This reconfiguration began with providing staff with more appropriate tools and functional support to increase their availability and access to the community; over-time pay, project cell phones, and two additional cars were included. These additional items cost 57% less than the total original budget and 37% less than the media budget alone. *DRINK* saved 30% of the total recruitment budget, only utilizing 16% toward media instead of the original 80% by engaging in a focused and specifically targeted media campaign.

Traditional Approach-Diversity and Establishing Trust

Recruiting minorities and overcoming issues of mistrust for research is a common costly challenge for all clinical trials.[8] Utilizing mass media and Practice Based Research Networks (PBRN) for recruitment present challenges to overcoming these obstacles. Talk radio and major newspapers only reach a selected population. Additionally, utilizing a PBRN requires physicians to refer candidates to trials. There is a strong body of evidence suggesting a general mistrust of the medical/scientific community among minorities and healthcare providers do not always have the time to explain clinical trials to patients, and help them overcome this mistrust.[9] Minorities are more likely to enroll in studies when approached by a trusted known healthcare professional than a faceless flyer.[10] Overcoming barriers for families to enroll their children due to concern and mistrust was equally challenging for *DRINK* as in other pediatric clinical trials.

Grassroots Solution-Diversity

Like a grassroots campaign, *DRINK* recruitment messages were delivered by a trusted messenger and relationships were established throughout several different communities. *DRINK* staff members were not hired for their in-depth understanding of probiotics or clinical trials but rather for their personal experience and professional work histories that pointed to excellent interpersonal skills and an interest in community health. In addition to networking in schools and daycares, *DRINK* staff established relationships with communities like Head Start and religious organizations. The experiences of *DRINK* team members indicated competence in effectively communicating with communities of potential research populations, as well as ease and ability to move within these communities with comfort. Often staff members were culturally matched with the communities they were recruiting, eg, 30% of the staff members were native Spanish speakers. If staff members had intimate knowledge of certain communities based on prior experience, they were assigned these areas. Again, this technique was developed from lessons from the 2004 campaign trail, which implored different community leaders to deliver political campaign messages within their respective communities and associates; for example, the evangelical Christian leaders speaking out at mega-churches and gatherings of Christian communities throughout the country.

Table 1. Associated trial costs.

Original budget plan		Actual grassroot expenses	
Newspaper print ads (5 weeks)	50%	Newspaper print ads (5 weeks)	0%
Radio ads (5 weeks)	35%	Radio ads (2 weeks spanish only)	5.5%
Small market media	2%	Small market media	4%
Food for physicians/daycares	10%	Food for physicians/daycares	6%
6 recruitment phone lines	2%	10 cell phones and 5 recruitment lines	14%
Flyers (printed in house)	1%	Flyers	6%
		Overtime for RAs	28%
		Two extra cars	3%
		Books for daycare	0.5%
Total	100%	Total	70%

Traditional trials are designed top-down with the Principal Investigator and Sponsor making decisions on how to allocate the budget for recruitment. Alternatively, *DRINK* sought input from the community as well as the staff members who were most intimately connected with different communities. Those recruiting in the field are the representatives of the study, and much of the recruitment success or failure is determined by how confidently they represent the project among different groups. Evidence in other pediatric trials confirms the critical contribution of staff in the field to recruitment success. Smith and colleagues, recruiting families with asthmatic children between 2–12 years old from the Emergency Department to partake in a two-week study, report that their high rate of enrollment was primarily due to two dedicated enrollers. The enrollers interacted with the families and Emergency Department staff with ease and competence, yielding successful enrollment of 527 families in sixteen months.[11] The backgrounds of the *DRINK* RAs were essential in the recruitment success for this project.

Table 2 demonstrates the demographic characteristics of the control group and placebo group. As Table 2 indicates, the grassroots approach was a success; families represented diverse demographics, social economic status, race and ethnicity. Additionally 19% of the study population identified themselves as Hispanic or Latino, and conducted interviews in Spanish. Efforts and resources were aimed at developing a trusted brand identity for the study within the community. Every participant received a t-shirt with the *DRINK* logo, as well as magnets to keep study papers together and easily accessible. All research personnel used a canvas bag with the logo when they went on recruitment site visits or home visits. All correspondence within the community or to participants carried the *DRINK* logo. This technique created interest and established name recognition among families within the communities.

Effective campaign messages must be authentic and representative of the messenger. Although socially conservative evangelical Christians may be interested in the same issues and essentially the same message as socially conservative Catholics, it would not benefit a campaign to use a message with Catholic imagery for a group of evangelicals; in fact utilizing similar imagery among both groups would most likely result in deterring voters to the polls, rather than motivating them. Similarly for *DRINK*, the flyer distributed by physicians' offices needed a professional look and feel, congruent to the environment of a physician office, while flyers distributed by daycares and schools needed to represent the nurturing environment caring for primary-aged children. The phrase clinical trial or word probiotic could appear intimidating to parents; recruitment information had to be presented in a manner that would set caregivers' concerns at ease and with an appearance that would avoid the impression that they were unwillingly being solicited, while at the same time adhering to strict but important IRB regulations. Potential participants needed to trust the source of the flyer and avoid questioning the legitimacy or integrity of those conducting the project; it was believed that developing specific flyers for specific groups would help promote confidence in those conducting the trial, and motivate potential participants to call screening lines. Working closely with the IRB and identifying points of contact from the community, a grassroots website was developed and versions of the flyer were tailored specific to the organization

Table 2. Demographic characteristics.

Race (biological mother)	Active	Control
Asian(M)	26 (8.3%)	18 (5.6%)
American Indian or Alaska Native(M)	8 (2.5%)	15 (4.6%)
Black or African American(M)	70 (22.3%)	71 (21.9%)
Native Hawaiian or other Pacific Islander(M)	1 (0.3%)	2 (0.6%)
White(M)	192 (61.1%)	195 (60.2%)
Other(M)	16 (5.1%)	20 (6.2%)
Race (biological father)		
Asian(F)	26 (8.3%)	11 (3.4%)
American Indian or Alaska Native(F)	6 (1.9%)	18 (5.6%)
Black or African American(F)	67 (21.3%)	70 (21.6%)
Native Hawaiian or other Pacific Islander(F)	3 (1.0%)	2 (0.6%)
White(F)	174 (55.4%)	194 (59.9%)
Other(F)	30 (9.6%)	27 (8.3%)
Ethnicity(M)		
Hispanic or Latino	52 (17.1%)	51 (15.8%)
Not Hispanic or Latino	252 (82.9%)	272 (84.2%)
Ethnicity(F)		
Hispanic or Latino	55 (18.3%)	59 (18.3%)
Not Hispanic or Latino	245 (81.7%)	263 (81.7%)
Overall	300	322

or recruitment site type. The website color scheme reflected our logo and although different versions of flyers utilized different and specific colors, every flyer carried the logo in the lower right corner.

Traditional Approach-Internet

The internet is looked upon by many as a new and exciting means of recruitment. Often studies will be advertised at sites that investigators feel may attract the desired population. However even with this targeted population, web advertising may lead to many individuals contacting recruitment lines that are far beyond the catchment area. Clinical trial websites often utilize a "contact form" which allows interested candidates to submit their contact information to learn more about the study. Although this is a useful tool, many individuals are hesitant to supply personal contact information over the internet. Websites must be created sensitively and mindful of public suspicion.

Grassroots solution

We used the internet in *DRINK* but as a tool, rather than a substitute, to provide more face time in the community for research personnel and to increase trust while branding the study identity. We developed a website, www.thedrinkstudy.com, which contained pictures and short biographies of the *DRINK* staff, allowing screened participants to view the pictures of staff who would be meeting them in-person to obtain written consent and gather baseline data. Additionally, the website contained the general data collection forms for the project, allowing interested families to review in advance the nature of the study and eligibility and criteria for participation. Most importantly, a website link is a fast and inexpensive way for recruitment information to be circulated to several different networks. This allowed participating parents the ability to notify their friends and family effortlessly by forwarding in an email the study's website address or post the site link on networks and listservs frequented by parents.

Limitations

Although our recruitment goals were met efficiently in the short time allowed and at a reduced budget, this approach requires time and resources to establish rapport with communities and develop trust. Most importantly, this approach is only successful with staff members who are competent at networking in the community. Safety concerns also must be considered when placing staff in the field, particularly when entering foreign and possibly high violence neighborhoods. Sponsors must be willing to allow researchers the freedom to use funds in the community. Fortunately, we had a sponsor that trusted University guidelines and the research team but current NIH guidelines make much of this approach nearly impossible to accomplish.

There is an additional risk of potential participants feeling coerced to participate, just as historically belonging to certain groups required a vote for a certain candidate or participation in group activities. In our study, this was avoided as community members or leaders were not involved beyond their sharing of enrollment flyers and general information regarding the purpose and nature of the study. Only the team of ten research assistants could conduct screening and enrolling, and as in all IRB-approved studies, participant information was kept confidential. It was never reported back to Head-Start, daycare centers, churches or pediatric offices which families had enrolled.

Our study was limited to healthy children, which made recruiting in the community ideal. This approach may prove to be more difficult when recruiting children for specific diseases. However, the pediatric epidemics under increased investigation such as asthma, obesity, type II diabetes have environmental and social correlations allowing for targeted community recruitment. Additionally, many of these conditions have community groups and resources for family participation. This targeted approach is worthy of further development for use among these disease states.

Conclusion

As recent public policies and literature suggest, there is a shortage of pediatric trials being conducted. Many pediatric trials fail to recruit an adequate sample size for clinical significance and conducting clinical trials is costly. Through the utilization of a grassroots approach and targeting potential populations, projects can meet demanding recruitment goals more efficiently and effectively, while retaining their study population and simultaneously reducing recruitment costs.

A grassroots approach requires a paradigm shift for research departments and sponsors. They have to be willing to invest in personnel and communities, adequately for time and experience working within communities. In addition, research departments and

sponsors must allow for funds to support human resources with the tools necessary to work in the field, such as cell phones, cars and fuel for transportation. We believe this investment ultimately saves money, produces studies with greater validity and respectfully involves communities. Additionally, investment in establishing community contacts may provide future recruitment benefits. Many of daycares centers, schools and the coalition of Head Start centers have been eager to work with us on future projects. Three subsequent studies have utilized some of the connections made from this original project.

Disclosures

This manuscript has been read and approved by all authors. This paper is unique and not under consideration by any other publication and has not been published elsewhere. The authors and peer reviewers report no conflicts of interest. The authors confirm that they have permission to reproduce any copyrighted material.

Author Contributions: Roles and Contributions

Role of the funding source: This original RCT study was an investigator-initiated industry funded study by The Dannon Company, Inc. The non-industry authors developed the initial protocol, gathered, supervised double data entry and analyzed the data, and vouch for the completeness and accuracy of the data and analysis. All research personnel and statisticians were blinded throughout the study, including initial review of all data.

Dr. Merenstein had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Dr. Merenstein had final responsibility for the decision to submit publication.

Study concept and design: Merenstein, Murphy
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Analysis and interpretation of data: Merenstein, Murphy
Initial Drafting of the manuscript: Merenstein, Murphy
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Study supervision: Merenstein

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