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Evaluation of active and passive recruitment methods used in randomized controlled trials targeting pediatric obesity

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Abstract

Objective—Evaluate enrollment numbers, randomization rates, costs, and cost-effectiveness of active versus passive recruitment methods for parent-child dyads into two pediatric obesity intervention trials.

Methods—Recruitment methods were categorized into active (pediatrician referral and targeted mailings, with participants identified by researcher/health care provider) versus passive methods (newspaper, bus, internet, television, and earning statements; fairs/community centers/schools; and word of mouth; with participants self-identified). Numbers of enrolled and randomized families and costs/recruitment method were monitored throughout the 22-month recruitment period. Costs (in USD) per recruitment method included staff time, mileage, and targeted costs of each method.

Results—A total of 940 families were referred or made contact, with 164 families randomized (child: 7.2±1.6 years, 2.27±0.61 standardized body mass index [zBMI], 86.6% obese, 61.7% female, 83.5% white; parent: 38.0±5.8 years, 32.9±8.4 BMI, 55.2% obese, 92.7% female, 89.6% white). Pediatrician referral, followed by targeted mailings, produced the largest number of enrolled and randomized families (both methods combined producing 87.2% of randomized families). Passive recruitment methods yielded better retention from enrollment to randomization ($p < 0.05$), but produced few families (21 in total). Approximately \$91 000 was spent on recruitment, with cost per randomized family at \$554.77. Pediatrician referral was the most cost-effective method, \$145.95/randomized family, but yielded only 91 randomized families over 22-months of continuous recruitment.

Conclusion—Pediatrician referral and targeted mailings, which are active recruitment methods, were the most successful strategies. However, recruitment demanded significant resources. Successful recruitment for pediatric trials should use several strategies.

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Keywords

Pediatric obesity; intervention; recruitment; pediatrician; cost; randomized controlled trial; advertisement

Introduction

Childhood obesity is a serious public health issue and randomized controlled trials (RCTs) testing different treatment options are needed (1). RCTs require cost-effective recruitment methods to generate adequate numbers of participants to randomize to differing interventions within a specified time. Treatment of childhood obesity often involves parent-child dyads (2,3) and frequently RCTs of family-based interventions experience challenges in recruiting adequate numbers of families to randomize (4). It is hypothesized that the time commitment required in these programs (i.e., a parent attends sessions, regular family meetings are encouraged, changes in eating/leisure-time activities in all family members are recommended) is a primary obstacle for participation (4). Despite limited research regarding successful recruitment methods for childhood weight control interventions (5,6), it is unclear what methods of recruitment are optimal and cost-effective.

Previous reports on pediatric obesity intervention trials have described the employment of various recruitment methods (2,5,7–9). Generally, a distinction can be made between active recruitment methods (e.g., recruitment through pediatricians, targeted mailing), in which researchers identify and directly target potential participants, and passive recruitment methods (e.g., flyer and posters, newspaper advertisement), in which participants identify themselves as potential participants (10). As the success of a recruitment method may depend on several factors, (i.e., population and the condition being studied), it is not clear which recruitment method (active or passive) should be recommended for family-based childhood weight control trials. For example, for a condition that is highly recognizable by potential participants, a passive recruitment method may be feasible, as potential participants are able to easily self-identify as having the condition and thereby respond to a newspaper advertisement or television commercial for a trial that targets the condition. For conditions in which potential participants are not able to easily self-identify as having the target condition of the trial, an active recruitment strategy, such as physician identification and referral, may be needed.

Besides being concerned with enrollment numbers (number of participants with signed consents), another important factor for RCTs is the ability of the recruitment method to identify participants who will enroll and also complete the initial screening process so that randomization into the trial can occur. As passive recruitment methods may attract self-identified participants, these enrolled participants may be more committed to completing the screening process so that they may be randomized and receive treatment, as compared with those enrolled participants who did not self-identify and instead were actively recruited into the trial.

Thus, the purpose of the present study was to examine number of families enrolled, proportion of families randomized, costs, and cost-effectiveness of active and passive recruitment methods used over a two-year time period for two family-based childhood weight control RCTs. As parents do not commonly identify their overweight children as being overweight (11,12), we hypothesized that more active forms of recruitment would yield larger numbers of enrolled families (families who had signed consents, but who had not completed baseline assessments). Additionally, as methods of passive recruitment might help identify more committed families, we hypothesized that passive methods of recruitment would yield a higher percentage of randomized from enrolled families (families who had signed consents and completed baseline assessments and thus were randomized into the study) than the active methods of recruitment. Finally, it was hypothesized that participants recruited by passive methods would have a higher zBMI than participants recruited by active methods, as children with a higher zBMI would more likely be identified by their parents.

Methods

Participants

Between November 2005 and September 2007, 940 families were referred or self-initiated contact for two family-based pediatric weight control trials. Child eligibility criteria for the two trials included the following: aged 4 to 9 years; 85th percentile for body mass index (BMI), as determined by the CDC growth charts (13); having no dietary or physical activity restrictions; and not meeting at least one dietary or activity recommendation targeted in one of the trials (one trial focused on increasing physical activity and decreasing sweetened drink intake versus decreasing TV watching and increasing lowfat milk intake [trial 1], with the other trial focused on increasing fruit, vegetables, and low-fat dairy versus decreasing sweet and salty snack foods and sweetened drinks [trial 2]). An additional eligibility criterion was a parent willing to attend eight, 1-hour, parenting group sessions over a 6-month period. Families were ineligible if the participating parent could not read English, had a psychological disorder that would impair ability to participate in the program, or if the family was planning to move out of the area during the program. Of the 940 families who were referred to or self-initiated contact with the study, we were not able to complete the phone screening process on 391 (41.6%) families. This inability to phone screen was due predominantly to two reasons: disconnected or incorrect phone number, or unwillingness to be phone screened (i.e., no adult in the household answered the phone after numerous attempts to contact the family and no adult ever returned messages that were left on voice mail or with other family members). One hundred and sixty-four (17.4%) families were randomized into the trials. See Figure 1 for the number of families completing each stage of the recruitment process. All participating families lived in Rhode Island, Connecticut, and Massachusetts at the time of enrollment. The protocol used in both trials was approved by the Institutional Review Board at Rhode Island Hospital (Providence, RI).

Procedures

For trial 1, we only recruited families through pediatricians as testing the practicality of this recruitment form was a secondary aim of this study. Families for trial 2 were recruited through all described methods. Eligible families were invited to an orientation at which

consent to participate (and assent if the child was 8 years or older) was obtained. Enrolled families were asked to return in the following week for a baseline assessment, which included obtaining child and parent demographic information; height and weight measures; 3-day food records; three previous day physical activity records (PDPAR); and liking and preference ratings for different foods and activities. Following completion of the baseline assessment, families were randomized into the trials.

Measures

Demographics and anthropometrics—Child's and parent's age, gender, and race/ethnicity were obtained by self-report. Weight was measured with participants wearing light clothes and no shoes by an electronic scale to the nearest 0.1 kg and height, without shoes, was measured by a stadiometer to the nearest 0.3 cm, using standard procedures (14). BMI, which is weight in kilograms/height in meters squared, was calculated for parent and child. Children's zBMI was calculated by standardizing the BMI value in relation to the population mean and standard deviation for children's age and gender (13).

Enrollment and randomization numbers/costs—A participant-tracking log was maintained to determine the number of families referred/self-initiated contact, phone-screened, invited to orientation, enrolled, and randomized through the various methods of recruitment. We determined recruitment costs, in USD, by adding up all staff time (assuming an hourly rate plus benefits of \$16.99 for research assistants and \$24.96 for the project coordinator), advertisement, and other recruitment material expenses (i.e., copying, mailing). Phone costs were not included in expenses as length of phone calls were not timed. Cost-effectiveness was determined by taking total cost of a recruitment method and dividing it by the number of enrolled and randomized families obtained by that recruitment method.

Recruitment strategies

Active strategies

Referral from pediatricians: Two-hundred and three pediatricians, nurse practitioners, and family physicians in private practice and in community health centers, as well as pediatricians and residents at two clinics of a local children's hospital, were asked to refer eligible patients. Providers who wanted to refer families were supplied with brochures, referral forms, and BMI calculators. Providers referred participants to the program based solely on the child's age (4 to 9 years) and weight status (< 85th percentile BMI). A staff member maintained monthly phone contact with providers to ensure that providers remembered the trials and to supply additional referral materials. One hundred and thirteen providers referred at least one patient. Pediatrician referral was implemented during the entire recruitment period of the trials (November 2005 to September 2007). Costs associated with pediatrician referral included staff time and mileage for initial visits with interested pediatricians, and staff time and mileage for maintenance of contact with referring pediatricians. Additional costs included material and printing costs for brochures and referral forms, as well as BMI calculators.

Targeted mailings: Between April 2006 and July 2007, targeted mailings (140 368 pieces of mail) were sent to households that had a 4- to 9-year-old child, within a 10- to 15-mile

radius around the research center where the trials were held. Most of the addresses were purchased from Aldata, Apple Valley, MN. In addition, addresses of households with children aged 4–9 years attending public kindergartens and elementary schools in Providence, RI, were obtained from the public school department at no cost in June 2007. The mass mailing reached households in the form of a black and white trifold brochure describing trial 2, providing contact information and a pre-stamped return postcard. Targeted mailing costs included staff time for designing and labeling brochures, printing of brochures, purchasing household addresses, and postage.

Passive strategies

Newspaper advertisements: Print advertisements were approximately 4"×4"-sized advertisements listing the main features of trial 2 and contact information. These advertisements appeared 22 times (placed in Wednesday and Sunday editions) between February 2006 and August 2007 in a local daily metropolitan newspaper, reaching a population of approximately 700 000 adults per week. The advertisement also appeared 545 980 times as banners in the online representation of the local daily newspaper between May and June 2007. The advertisement was linked to the research center's home page and was clicked on 185 times. Print advertisements also appeared seven times in three monthly newspapers specifically geared towards parents of young children and families between June 2006 and August 2007. In addition, advertisements were published in 22 free weekly community newspapers reaching 145 000 households for one week in August 2007. Costs for newspaper advertisements included staff time for designing advertisements (i.e., finding appropriate pictures to include in advertisements and proofing advertisements) and communication with personnel associated with the newspaper. Additional costs included advertisement placement.

Bus advertisements: For six weeks during May and June 2007, 30"×108"-sized advertisements explaining the basic features of trial 2 were attached to 12 public transportation buses' side panels in the greater Providence, RI area. Costs for bus advertisements included staff time for advertisement design and communication with personnel associated with the public transportation system and advertisement placement.

Internet presence: During the entire length of the recruitment period, information on both trials along with contact information was posted on the research center's website. In addition, information on trial 2 was posted on a hospital network affiliated with Alpert Medical School at Brown University in the category "Research" from May 2007 to September 2007, and advertisements were posted on the employee intranet from March to April 2006. Costs for this recruitment method included staff time for advertisement design and communication with personnel associated with the intranet.

Earnings statements: During June 2007, trial 2 was advertised under "Important Notes" on employee earnings statements of hospitals affiliated with Alpert Medical School at Brown University. Staff time for advertisement design and communication with personnel involved with earnings statements were the costs for this recruitment method.

Fairs, community centers, schools: Research staff attended three parent fairs and health fairs with an estimated 1 000 attendees in total between March 2006 and March 2007. A promotional booth was staffed to answer parents' questions about trial 2 and to hand out brochures. Print advertisements about trial 2 appeared in parent and health fair program books. Posters and flyers were also distributed to local community centers, libraries, and schools. Costs for this recruitment method included staff time, mileage, materials, copies, and costs of registrations and advertisements associated with the events.

Television advertisement: A 30-second spot for trial 2 was aired 893 times on varying cable television channels in the greater Providence, RI area for seven weeks in January and February 2007. The estimated number of households receiving the varying channels was 264 390. Costs for television advertisements included staff time for designing advertisements and communication with personnel associated with the local cable company. Additional costs included advertisement placement.

Word of mouth: Other sources included recruitment of participants through word of mouth. For example, in addition to study participants referring other families, a local newspaper once printed information about trial 2 without the study staff's initiative.

Statistical analysis—Differences between baseline characteristics in the participating children and parents in the two trials were analyzed using independent t-tests and Chi-Square tests. Differences in recruitment methods (active versus passive) in proportions of families that were enrolled only versus enrolled and randomized by active versus passive recruitment methods were examined using Chi-Square tests. Differences in zBMI in randomized families by active versus passive recruitment methods were examined by independent t-tests. Significance was set at $p = 0.05$. All data were analyzed using SPSS, version 15 (15).

Results

The baseline characteristics of the 164 randomized children and parents are shown in Table I. There were no significant differences in baseline characteristics of the children or parents in the two trials, thus all data from the two trials were combined. Overall, the sample was predominantly female (61.7% and 92.7% for children and parents, respectively) and Caucasian (83.5% and 89.6% for children and parents, respectively). Additionally the majority of the sample was obese (86.6% and 55.2% for children and parents, respectively).

Enrollment and randomization

The recruitment method that produced the greatest number of enrolled and randomized families was pediatrician referral, followed by targeted mailings, which are both active recruitment methods (see Table II). Pediatrician referral produced slightly more than half of the families enrolled and randomized (56.4% and 55.5%, respectively) in the trials. When number of enrolled and randomized families were determined per month of use of recruitment method, again, pediatrician referral and targeted mailings produced the largest numbers (4.5 and 3.5 randomized families per month per use of pediatrician referral and targeted mailings, respectively). Two passive methods of recruitment, bus and television

advertisements, yielded no families and thus produced the lowest number of enrolled or randomized families in the trials.

For ability to maintain enrolled families through the baseline assessment process so that they may be randomized into the trials, of the seven recruitment methods that produced enrolled families, all of these methods also produced randomized families. For the passive methods of recruitment, rates of being able to maintain families from enrollment to randomization ranged from 50% (internet presence) to 100% (earnings statements and fairs/community centers/schools), with 4 out of the 5 passive recruitment methods producing a randomization rate from enrollment of 83.3% or higher. Of the two active recruitment strategies used, similar percentages of conversion from enrollment to randomization occurred (66.4% referral and 63.4% mailing). When the enrollment to randomization numbers were compared, a significant difference between active and passive methods was found (65.3% vs. 87.5%, $p < 0.05$). When the zBMI of families randomized through active and passive methods of recruitment were compared, no differences were found ($p = 0.49$).

Costs and cost-effectiveness

Total cost for recruitment of 164 randomized families was \$90 982.38 (Table III). The recruitment method with the greatest contribution to total recruitment costs was targeted mailing, which cost \$45 746.78. For targeted mailings, postage was the single most expensive cost (\$18 415.20). Other than word of mouth, the two least expensive recruitment methods were internet presence and earning statements (both \$124.80).

Costs per enrolled and randomized family by recruitment method are also shown in Table III. The mean cost of recruitment per enrolled family was \$374.41, while the mean cost per randomized family was \$554.77. The methods of recruitment that were the least expensive per randomized family were internet presence and the advertisement on earnings statements. However, these methods yielded a very small number of enrolled (3 families) and randomized (2 families) families. Methods of recruitment that cost the most per randomized family were bus and TV advertisements (passive methods), which cost \$8 731.27, but yielded no families. Pediatrician referral and targeted mailings produced the greatest number of enrolled and randomized families at the most reasonable costs, with the cost for pediatrician referral being approximately six-times less than the cost for targeted mailings per enrolled (\$96.94 vs. \$557.89) and randomized family (\$145.95 vs. \$879.75).

Discussion

This paper describes number of families enrolled, proportion of families randomized, costs, and costeffectiveness of active and passive recruitment methods used to randomize 164 parent-child dyads into two childhood obesity interventions for children aged 4–9 years. Results indicated that no single method of recruitment produced large numbers of enrolled and randomized families, neither in total nor per month of use of recruitment method. Recruitment for the pediatric obesity intervention trials demanded a significant amount of financial resources and staff effort, as the mean cost per randomized family in the two trials was \$544.77.

For enrollment and randomization rates, pediatrician referral, an active form of recruitment, produced the largest numbers of families, which was approximately 1.7 times the size of the enrollment and randomization rates of targeted mailings, the recruitment strategy that produced the second largest enrollment and randomization rates. However, when these two methods were compared on the number of enrolled and randomized families obtained per month of use of each referral method, they were similar in the number of families produced (each produced approximately 6 families/month enrolled and approximately 4 families/month randomized). Passive methods of recruitment, particularly newspaper advertisements, produced the highest proportion of families that were converted from enrolled to randomized families (87.5%). While passive methods of recruitment produced families that appeared to be more committed through the recruitment process, the children from these families were not heavier than those children recruited through active methods.

Pediatrician referral was the most cost-effective recruitment strategy, as it produced a fair amount of enrolled and randomized families at a reasonable cost. Recruitment through pediatricians and clinics might be considered a “traditional” method to recruit participants for research trials (16). An apparent argument for recruitment through pediatric primary care practices is that pediatricians regularly meet with children and parents and are generally already trusted by families (17). However, there may be disadvantages to referral through pediatricians. First, although pediatricians are recommended to routinely assess height and weight and plot BMI of their patients on percentile charts (18,19), pediatricians may not routinely assess BMI and instead visually assess weight status in children (19,20). This may cause selection bias resulting in referral of only significantly obese children to interventions, whereas those children who are already overweight but leaner (BMI=85th percentile to 95th percentile) may be misclassified and parents not be made aware of their children’s weight status. Secondly, for this study, it is important to note that referral through pediatricians required continuous contact with practices, thus utilizing a significant amount of staff time, and that even with continuous contact with practices over the 22 months of recruitment, only 91 families were randomized into the trials from pediatrician referral.

Other methods we employed in the trials were passive forms of recruitment, such as newspaper, TV, and bus advertisements, as well as advertisements on earnings statements, on the Internet, in community centers, at community fairs, and by word of mouth. It has been reported that active recruitment methods yield less interested individuals for trials compared with passive recruitment methods (10). Passive recruitment efforts may produce participants that are more committed, leading to a higher rate of conversion of enrolled to randomized participants. Indeed, in this study a significantly larger portion of families who were recruited through passive as compared with active recruitment methods completed the initial screening and were randomized into the trial. However, as a whole, passive recruitment strategies produced a very small number of enrolled and randomized families. Moreover, two methods of passive recruitment, television and bus advertisements were fairly expensive, costing approximately \$8 700, and yielded no families. These methods of recruitment may have produced no families, as they require contact information for the study to be written down by potential participants so that this information can be used in the future, and thus added one more step for potential participants to take to be recruited into the trial.

Results from this study are striking in demonstrating that successful recruitment required continuous monitoring, an enormous amount of effort from staff, and a significant financial investment. This confirms previous reports on pediatric RCTs' challenges to recruit adequate numbers of participants in a given length of time while staying within budget (5,6). One outcome in this investigation that is different from other studies reporting on recruitment efforts in pediatric obesity RCTs is that this investigation was able to obtain a large portion of enrolled and randomized families from pediatrician referral, while other investigations have found pediatrician referral to be a poor method of recruitment, and instead found mailings and advertisements to be better methods of recruitment (5,6). Because pediatrician referral was being evaluated in one of the trials, continuous effort by staff needed to be allocated towards this strategy. This likely resulted in a larger amount of staff effort being put towards this recruitment method in the present study as compared with previous pediatric obesity trials where pediatrician referral was not being evaluated.

A limitation of the study was that although we obtained information on the recruitment method that caused the family to initiate contact we did not investigate whether families were exposed to only one method or several methods, or whether they were exposed to a certain method repeatedly (e.g., pediatrician encouraged family to participate multiple times, or targeted mailing reached household multiple times). Additionally, total costs of methods did not include phone screening time, and it is not known if some methods required more phone calls to make contact with families than other methods (i.e., did passive recruitment methods require more phone calls than active recruitment methods). Furthermore, implementation of recruitment strategies occurred at different time points over the two years and were used for differing lengths of time. For example, the pediatrician referral method was used consistently over the two years, whereas the television advertisement was used for two months. These differences in length of use were primarily due to cost of method per number of families that responded to the method. Finally, word of mouth is a recruitment strategy that can be conducted at little to no cost and could have been more strongly used in this investigation. It is likely that participating families know more families with children in the same age group and can attract others to the studies. In addition, it has been suggested previously that being referred by friends and family members may reduce anxiety and distrust towards research (21).

This investigation demonstrated that recruitment for clinical pediatric trials is challenging. The success of certain recruitment methods may depend on a number of factors, such as the population of interest, the location of the study, and the effort individuals have to make to partake in the study. In order to maximize recruitment numbers and obtain a heterogeneous sample, it is recommended to try several strategies. Active recruitment methods, such as pediatrician referral and targeted mailings, were shown to be the most successful in this investigation and should be considered when recruiting families for trials investigating pediatric obesity interventions.

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Figure 1.
Participant flow through each stage of recruitment.

Table I

Baseline characteristics of randomized families in trials 1 and 2 (January 2006–September 2007).

	Child (n=164)		Parent (n=164)	
	Mean (range)	Standard Deviation	Mean (range)	Standard Deviation
Age (years)	7.2 (4.1–9.9)	1.6	38.0 (24.6–54.7)	5.8
BMI ^a (kg/m ²)	24.0 (17.1–35.9)	4.0	32.9 (18.4–59.6)	8.4
zBMI	2.27 (0.89–5.19)	0.60		
	N	%	N	%
Obese ^b (%)	142	86.6	90	55.2
Obese ^c (%)	123	75.0		
Female	100	61.7	152	92.7
Race				
Caucasian	137	83.5	147	89.6
African American	13	7.9	10	6.1
Asian	4	2.4	2	1.2
American Indian or Alaskan native	1	0.6	0	0
More than one race	8	4.9	4	2.4
Other	1	0.6	1	0.6
Hispanic	24	14.6	25	15.2

^aBMI=body mass index.^bChildren: 95th percentile BMI; Parent: BMI ≥ 30.^cChildren who meet IOTF guidelines for obesity.

Table II

Number of enrolled and randomized families by recruitment method.

Recruitment method	Number of enrolled families (% of total)	Number of enrolled families/month of use of recruitment method	Number of randomized families (% of total)	Number of randomized families/month of use of recruitment method	Conversion rate (enrolled to randomized) ^a
Active methods					
Pediatrician referral	137 (56.4%)	6.1	91 (55.5%)	4.5	66.4%
Targeted mailing	82 (32.4%)	5.5	52 (31.7%)	3.5	63.4%
Passive methods					
Newspaper advertisements	13 (5.1%)	0.7	12 (7.3%)	0.6	92.3%
Bus advertisements	0 (0.0%)	0.0	0 (0.0%)	0.0	NA
Internet presence	2 (0.8%)	0.1	1 (0.6%)	0.05	50%
Earnings statements	1 (0.4%)	1.0	1 (0.6%)	1.0	100%
Fairs/community centers/schools	2 (0.8%)	0.2	2 (1.2%)	0.2	100%
Television advertisement	0 (0.0%)	0.0	0 (0.0%)	0.0	NA
Word of mouth	6 (2.4%)	0.3	5 (3.1%)	0.2	83.3%
Total	243	11.0	164	7.5	67.5%

NA=Not applicable.

^aChi-square indicated a main effect ($p < 0.01$) of recruitment method, with passive methods producing a higher conversion rate than active methods.

Table III

Total cost and cost per enrolled and randomized family by recruitment method.

Recruitment method	Total cost	Number of enrolled families	Cost/enrolled family	Number of randomized families	Cost/randomized family
Active methods					
Pediatrician referral	\$13 281.20	137	\$96.94	91	\$145.95
Targeted mailing	\$45 746.76	82	\$557.89	52	\$879.75
Passive methods					
Newspaper advertisements	\$19 878.55	13	\$1 529.12	12	\$1 656.55
Bus advertisements	\$2 646.60	0	NA	0	NA
Internet presence	\$124.80	2	\$62.40	1	\$124.80
Earnings statements	\$124.80	1	\$124.80	1	\$124.80
Fairs/community centers/schools	\$3 095.0	2	\$1 547.50	2	\$1 547.50
Television advertisement	\$6 081.67	0	NA	0	NA
Word of mouth	\$0.00	6	\$0.00	5	\$0.00
Total	\$90 982.38	243	\$374.41	164	\$554.77

Costs in USD; NA =not applicable as no participants were enrolled/randomized by this method.