

Proactive recruitment predicts participant retention to end of treatment in a secondhand smoke reduction trial with low-income maternal smokers

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Abstract

Improving smoking intervention trial retention in underserved populations remains a public health priority. Low retention rates undermine clinical advancements that could reduce health disparities. To examine the effects of recruitment strategies on participant retention among 279 low-income, maternal smokers who initiated treatment in a 16-week behavioral counseling trial to reduce child secondhand smoke exposure (SHSe). Participants were recruited using either reactive strategies or methods that included proactive strategies. Logistic regression analysis was used to test associations among retention and recruitment method in the context of other psychosocial and sociodemographic factors known to relate to retention. Backwards stepwise procedures determined the most parsimonious solution. Ninety-four percent of participants recruited with proactive + reactive methods were retained through end of treatment compared to 74.7% of reactive-recruited participants. Retention likelihood was five times greater if participants were recruited with proactive + reactive strategies rather than reactive recruitment alone (odds ratio [OR]=5.36; confidence interval [CI], 2.31–12.45). Greater knowledge of SHS consequences (OR=1.58; CI, 1.07–2.34) was another significant factor retained in the final LR model. Proactive recruitment may improve retention among underserved smokers in behavioral intervention trials. Identifying factors influencing retention may improve the success of recruitment strategies in future trials, in turn, enhancing the impact of smoking interventions.

KEYWORDS

Retention, Recruitment, Underserved, Secondhand smoke

INTRODUCTION

Improving smoking interventions to reduce health disparities in underserved populations at increased risk for tobacco-related disease remains a public health priority. Unfortunately, clinical trials that purposively enroll high-risk and underserved smokers continue to be challenged with retaining partic-

Implications

Practice: Smoking intervention providers could consider partnering with community agencies to design and implement proactive referral strategies given that these strategies may facilitate enrollment as well as retention of clients through end of treatment.

Policy: Providing resources for strategic intervention recruitment and retention efforts that target underserved smokers would improve the public health impact of smoking interventions in populations with the greatest tobacco-related morbidity and mortality risk.

Research: To facilitate retention of low-income, underserved participants in community-based smoking intervention trials, the results suggest the need to develop and implement clinic-tailored, proactive recruitment strategies.

ipants, a consequence that erodes statistical power [1], threatens study validity [2, 3], and undermines clinical advancements that could guide the reduction of health disparities. Smoking intervention trials typically demonstrate retention as low as 50% [4–6] with lower retention rates observed among underserved populations [2, 7–11] and smokers known to have increased difficulty quitting, such as women [12, 13] (low income, minority women in particular [14]). Researchers have explored factors that influence underserved smokers' *enrollment* in clinical trials [9, 10, 15] including studies evaluating effects of different recruitment strategies [16–20]. However, little is known about how different recruitment methods influence participant retention [21, 32]. Across populations, factors such as education [7, 22, 23], income [22, 24–26], older age [27, 28], and male gender [29–31] have been predictive of retention. Among women in particular, psychosocial factors that relate to smoking (e.g., depressive symptoms, weight concerns) [32–34] may influence retention during smoking intervention trials [35–37].

Reasons for the dearth of research in this area include practical as well as research design limitations that prevent researchers' from attempting systematic, prospective study of recruitment-retention associations with other factors. For example, there are no known large scale, funded randomized trials that have supported prospective analyses of the effects of recruitment type on retention; and it is unlikely that any trial would be funded that focuses on retention as a primary clinical trial outcome. Nonetheless, exploring predictors of retention remains a critical step toward improving methods for future studies. Thus, it would be informative to study the influence of different recruitment strategies on patient retention in an ongoing secondhand smoke exposure (SHSe)-reduction trial. With this rationale in mind, the purpose of the present study was to examine effects of recruitment strategies on patient retention through the end of treatment (EOT) in a behavioral counseling intervention trial targeting underserved maternal smokers.

METHODS

Sample

Data for the current study were obtained from a larger IRB-approved randomized behavioral counseling trial to reduce children's SHSe. Participants included 279 volunteer maternal smokers who had initiated treatment. The trial implemented purposive sampling to reach a target, underserved population. Eligible participants were over 17 years old, smoked over five cigarettes daily, and had babies exposed to at least two of their cigarettes per day. Exclusion criteria included pregnancy, active self-reported psychiatric diagnosis, and non-proficiency in English.

Recruitment strategies

Reactive recruitment

These strategies were utilized from September 2004 to October 2006. They included 15, multi-day advertisements in free city and community newspapers, posters with pull tabs on mass transit bus and subway cars for two 5-week periods, and program brochures and posters continuously displayed in target community laundromats, three pediatric primary care clinics, and seven Women, Infant, and Children (WIC) clinics. All clinics served medically underserved communities in North and West Philadelphia. The principal investigator (PI) provided clinic staff with a presentation about SHSe dangers, SHSe-reduction advice and referral information to be provided to inquiring maternal smokers.

Proactive recruitment

Proactive strategies were implemented during an equivalent period from November 2006–November 2008. During this period, advertising resources were replaced by personnel resources and clinic incentives

to facilitate the proactive, clinic-partnered recruitment approach. These resources enabled the PI and WIC executive director to collaboratively design clinic-specific, culturally sensitive recruitment training to facilitate WIC staff assistance in the active recruitment process. "Culturally sensitive" refers to our efforts in designing and implementing recruitment procedures that simultaneously considered the types of strategies that would work within the organizational culture (e.g., promotion of maternal and child health, improving the quality of client care and services) as well as the types of procedures to which the clientele would be most likely to respond favorably within their socio-cultural milieu. Recruitment training encouraged staff to actively assess maternal smoking with a focus on SHSe and child health during routine client visits and to provide referral information about our clinical trial to all identified maternal smokers. Project staff visited the seven clinics weekly to support WIC staff efforts, collecting pre-screening forms and assisting them with in-person recruitment. Research project staff also provided periodic non-contingent refreshments (e.g., pizza, donuts) and clinic incentives tied to accrual achievements (e.g., staff room microwave).

Retention strategies

Intensive retention strategies were used throughout the entire, 4-year study and did not vary between the two recruitment periods. Protocols included updating multiple contact points from participants and consenting collaterals at each interaction, scheduling all meetings at participants' preferred location (home, clinic) and times, and reimbursing patients for transportation costs. Patients received appointment reminders and "supplies" with staff contact information (e.g., bibs, magnets, calendars, cups). Assessment compensation was \$20 for the baseline assessment (pre-treatment) and \$50 for the 16-week EOT assessment.

Data collection

After completing eligibility screening interviews, eligible participants were scheduled for a 75-min in-home baseline interview to collect smoking, SHSe, psychosocial and child health histories, plus children's urine samples for cotinine to validate reported SHSe. After baseline, patients were randomized into one of two no-cost treatment conditions: either behavioral counseling (two in-home sessions, seven telephone sessions, and four educational mailings), or self-help control (identical manual as counseling mailings, three retention calls, and seven retention postcards that controlled for contact). Treatment started approximately 2 weeks post-baseline and was determined by completion of the first counseling session, or by telephone verification of receipt of the mailed control manual. Participants completed 45-min EOT assessments 16 weeks after treatment started.

Measures

The criterion variable, retention, was measured as a dichotomous factor (1 = retained; 0 = not retained). Participants were not retained if repeated contact attempts were unsuccessful from 2 weeks before to 4 weeks after the projected EOT assessment date, or if the patient did not show for a scheduled assessment more than twice without a legitimate conflict.

Recruitment type (1 = proactive, 0 = reactive) was the primary predictor variable. Additional covariates included: treatment assignment, demographics (e.g., age, income), maternal smoking history, current cigarettes smoked per day, number of smokers in the home, child SHSe locations and sources, and nicotine dependence as measured by the Fagerström Test for Nicotine Dependence (FTND) [41]; maternal-reported psychosocial variables included social support, depressive symptoms, and perceived life stress. Maternal depressive symptoms were measured as a continuous variable using the Center for Epidemiologic Studies Depression Scale (CES-D) [42]; general social support was measured by the global score of the Interpersonal Support Evaluation List [43]. Maternal knowledge about SHSe consequences, maternal-reported child health indices (e.g., existing medical diagnoses), and reported nuisance barriers to retention (e.g., frequency of residential moves and phone disconnection, season at enrollment, history of substance abuse, and current alcohol consumption) were also assessed. These assessments and methods have been reliable and valid in previous trials with low income smokers [44, 45].

Statistical analyses

Prior to analyses, data were summarized, screened for errors, checked for outliers, and tested to determine if they met distributional assumptions. Income, education, marital status, maternal age, and number of smokers in the home were dichotomized to aid interpretation of multivariate analyses. Logistic regression was used to test the recruitment-retention association in the context of the covariates listed above. Variables with bivariate association $p \leq 0.25$ were retained for backwards stepwise logistic regression procedures ($p=0.1$ to enter, and $p=0.2$ to remove) to determine the most parsimonious solution. Analyses were conducted using STATA software (Stata Corporation, College Station, TX). Stata automatically tests for multi-collinearity in multivariate modeling analyses using a meta command. If it discovers multi-collinearity, it removes one of the variables before proceeding.

RESULTS

Sample characteristics

Eligible participant baseline characteristics in Table 1 suggest a fairly homogeneous sample, reflecting success in purposive sampling. Among the 142 participants recruited using only reactive recruit-

ment methods and initiating treatment, 74.4% were retained to EOT. Of the 137 initiating treatment following proactive + reactive methods, 94.2% were retained to EOT.

Logistic regression

Table 2 shows variables entered in step 1 with the final model in bold. Treatment assignment, as well as marital status and cigarettes smoked per day (two variables with significant differences between recruitment groups as shown in Table 1) are not included in the Table 2 model because their association with retention demonstrated p values greater than 0.25. There was no evidence of multicollinearity in the model.

The final model shows that proactive recruitment contributed a 5-fold increase in retention likelihood compared to reactive recruitment when controlling for other retention-related covariates. Maternal belief that SHSe harms children's health contributed unique variance, while older age and lower income were non-significant factors retained in the model.

DISCUSSION

This study examined participant retention in a behavioral counseling trial to prevent babies' SHSe in an underserved community of low income, mostly single, African American mothers. Multivariate results suggest a large effect of proactive recruitment on participant retention in the context of other factors known to influence retention. Marital status, cigarettes smoked per day, and number of mothers' cigarettes to which child was exposed per day differed between the two recruitment groups (Table 1); however, none of these variables were retained in the final logistic regression model of retention. Moreover, factors known to be associated with retention in smoking trials, particularly nicotine dependence, maternal age, and child age, were not retained in the final model. To our knowledge, there are no previous studies that have examined the effects of clinic-tailored, proactive recruitment strategies compared to traditional, reactive strategies on clinical trial retention in an underserved population of smokers. While it is possible that some factors previously known to associate with retention dropped out of our analyses because of limited variability due to purposive sampling (e.g., child age), our results suggest that proactive recruitment and to a lesser extent, greater maternal knowledge about the harms of child SHSe, may have a much larger impact on retention of underserved smokers in a clinical trial than these other factors.

Because our proactive recruitment components emphasized a research staff-WIC staff partnership that coordinated clinic-specific recruitment activities and incentivized WIC staff's recruitment efforts, we suggest that associative learning theories and the

Table 1 | Sample characteristics at screening

| | Reactive (M,SD ^a) | Proactive + reactive (M, SD ^a) | Reactive (%) | Proactive + reactive (%) |
|---|----------------------------------|---|-----------------|-----------------------------|
| Mom age (years) | 30.10 (7.99) | 29.29 (7.79) | | |
| Child age (months) | 20.25 (15.20) | 17.35 (13.49) | | |
| Mother's race | | | | |
| African American | | | 88.9 | 86.9 |
| Other | | | 11.1 | 13.1 |
| Marital status | | | | |
| Married/living with partner | | | 86.1 | 75.2 |
| Single | | | 13.9 | 24.8* |
| Income | | | | |
| \$15,000 or below | | | 72.3 | 73.9 |
| Above \$15,000 | | | 27.7 | 26.1 |
| Education | | | | |
| <high school degree | | | 53.8 | 60.1 |
| High school and above | | | 46.2 | 39.9 |
| # of smokers in the home | | | | |
| One smoker | | | 51.4 | 45.1 |
| Two or more smokers | | | 48.6 | 54.9 |
| Average no. of cigarettes smoked per day | 10.34 (5.73) | 13.92 (7.41)** | | |
| Avg. no. of mom's cigarettes child exposed per day | 4.21 (3.62) | 6.50 (4.90)** | | |
| Baseline CES-D Score | 19.27 (10.60) | 19.44 (10.52) | | |
| Baseline ISEL score | 37.13 (7.14) | 37.70 (6.44) | | |
| FTND score | 3.89 (2.04) | 4.24 (2.07) | | |

CES-D Center for Epidemiologic Studies on Depression Scale, ISEL Interpersonal Support Evaluation List, FTND Fagerström Test for Nicotine Dependence

^a M mean, SD standard deviation

* $p < 0.05$; ** $p < 0.01$

Behavioral Ecological Model (BEM) [38–40] provide a suitable framework for interpreting the results of this study. Associative learning theories assert that patient retention can be facilitated by implementing reinforcing consequences for ongoing participation that are delivered at individual, family, or clinic levels. The simplest examples in smoking intervention trials would include monetary incentives or

social reinforcement (e.g., praise) provided to individuals and families for ongoing participation, or clinic/employee incentives for completion of referrals and follow-up services. The BEM frames how proactive recruitment could promote retention through reinforcement across layers of social complexity. For example, work-related incentives offered to clinic staff could increase their frequency

Table 2 | Logistic regression model of participant retention (1 = retained, 0 = not retained)

| Predictor | Univariate analyses | | Final multivariate models | |
|-------------------------------------|---------------------|----------|---------------------------|----------|
| | OR (CI) | <i>p</i> | OR (CI) | <i>p</i> |
| Recruitment Type | 5.46 (2.43–12.5) | 0.00 | 5.36 (2.31–12.45) | >0.001 |
| Know SHS harms child health | 1.52 (1.05–2.22) | 0.03 | 1.58 (1.07–2.34) | 0.02 |
| Mothers' Age (median split) | 1.32 (0.67–2.60) | 0.42 | 1.59 (0.76–3.35) | 0.22 |
| Income over \$15,000 | 1.01 (0.47–2.14) | 0.98 | 0.97 (0.43–2.17) | 0.94 |
| Male Children | 1.32 (0.98–1.79) | 0.07 | <i>x</i> ^a | |
| Times received SHSe advice | 1.14 (0.95–1.37) | 0.17 | <i>x</i> | |
| Recruitment Season | 1.27 (0.95–1.67) | 0.11 | <i>x</i> | |
| Total number of Children in home | 1.16 (0.94–1.45) | 0.16 | <i>x</i> | |
| Baby older than 2 years old | 1.85 (0.70–4.00) | 0.11 | <i>x</i> | |
| Baby saw doctor due to sickness | 0.50 (0.23–1.12) | 0.09 | <i>x</i> | |
| SHSe (cigs/day) from mom in home | 1.11 (0.98–1.24) | 0.09 | <i>x</i> | |
| SHSe (cigs/day) fm visitors in home | 1.30 (0.89–1.88) | 0.17 | <i>x</i> | |
| SHSe (cigs/day) from all sources | 1.06 (0.99–1.14) | 0.07 | <i>x</i> | |

Recruitment type coded: 1 proactive + reactive, 0 Reactive

^a "*x*" represents variables not retained in final model

of explicitly providing positive social reinforcement to clients who participate in smoking intervention studies. Such reinforcement from staff would serve to sustain smokers' behavior change efforts which, in turn, would further reinforce staff engagement with clients specific to tobacco intervention.

In short, the clinic-specific partnerships improved our working understanding of accrual barriers and organization-level social contingencies that could reinforce WIC staff adherence to SHSe-related assessments, advice, and referral. This collaborative effort to improve client care along with reinforcement of staff's SHSe advice and referral actions through clinic-level incentives may have modified social norms about clinics' partnerships with a university-driven clinical trial. Subsequently, this shift in social norms may have added credibility to advice about active participation in our program.

In our interpretation, the association between retention and greater knowledge of SHS consequences in the logistic regression model provides additional justification for establishing intervention and research partnerships with community agencies embedded within underserved neighborhoods. Community workers can provide a culturally knowledgeable and trusted mouthpiece to disseminate basic SHSe and health education in addition to providing ongoing support for smoking behavior change during the course of behavioral treatment. This type of health education may play a motivating role that sensitizes the community to the costs of SHSe, thereby setting the stage for cooperation with formal interventions that may be critical to achieve substantive behavior change [46].

Limitations

This study's accrual protocols did not include procedures to interview participants after they dropped out, information that would further enhance our understanding about behavioral counseling participant retention. Many new community-based behavioral intervention trials, such as this one, employ modifications in recruitment methods during the course of the trial in order to improve enrollment. Thus, our study reflects a naturalistic design that included systematic addition of proactive recruitment protocols. Such an approach lacks a reversal design that controls for history and other temporal biases, thereby limiting interpretation of causality. These design constraints may underestimate the effects of reactive recruitment, as it is conceivable that reactive strategies could have worked better had we simply allowed for longer implementation of these methods and the latent effects of a growing word-of-mouth reputation and not added proactive strategies. However, we believe that such an approach would have been less likely to produce such a large effect in retention between the two time points as observed in our study.

Short of a randomized controlled trial of recruitment procedures addressing potential sources of bias, any study examining effects of systematic changes in recruitment strategies are not equipped to avoid these sources of confounding. While randomized controlled trial (RCT) designs remain the gold standard for testing intervention effects, it remains impractical to conduct long-term trials to answer some research questions. Instead, natural experiments and cross-sectional designs such as this, offer powerful means of approximating an RCT and advancing behavioral science within the constraints of time, cost and social standards. Lastly, some could argue that our study targeted a specific high-risk population, conceivably limiting generalizability of results. However, empirical results from small samples of subpopulations may be quite robust with respect to estimates of logical, theory-based associations even if they are less likely to generalize for purposes of estimating population prevalence and incidence rates [47].

CONCLUSIONS

If replicated, factors retained in our multivariate models are likely to be robust indicators of patient retention in populations subject to the stress and challenges of poverty and minority status. Federal funding agencies require inclusion of minorities in clinical trials (unless sufficient rationale is provided) and emphasize the priority of targeting underserved, high risk populations to reduce health disparities. Therefore, it is essential to continue to examine factors that influence retention to guide future clinical trials that require long-term contact to promote health behavior change, such as smoking. Given recent calls for testing intensive, multilevel smoking interventions for underserved, high risk populations of smokers, future research could test the utility of proactive and collaborative partnerships similar to ones in this study, but that merge community clinic-level provision of low-intensity tobacco education and referrals with behavioral health partners' delivery of more intensive smoking intervention components.

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