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A successful approach to minimizing attrition in racial/ethnic minority, low-income populations

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ABSTRACT

Background: Recruiting and retaining minority participants in clinical trials continue to be major challenges. Although multiple studies document lower minority trial enrollment, much less is known about effective minority retention strategies. Our objectives were to evaluate an innovative approach to high RCT retention of minority children, and identify child/caregiver characteristics predicting attrition.
Methods: The Kids' HELP trial examined the effects of Parent Mentors on insuring uninsured minority children. We tested a retention strategic framework consisting of: 1) optimizing cultural/linguistic competency; 2) staff training on participant relationships and trust; 3) comprehensive participant contact information; 4) an electronic tracking database; 5) reminders for upcoming outcomes-assessment appointments; 6) frequent, sustained contact attempts for non-respondents; 7) financial incentives; 8) individualized rapid-cycle quality-improvement approaches to non-respondents; 9) reinforcing study importance; and 10) home assessment visits. We compared attrition in Kids' HELP vs. two previous RCTs in similar populations, and conducted bivariate and multivariable analyses of factors associated with Kids' HELP attrition.
Results: Attrition in Kids' HELP was lower than in two similar RCTs, at 10.9% vs. 37% and 40% ($P < 0.001$). After multivariable adjustment, missing the first outcomes follow-up assessment was the only factor significantly associated with attrition (relative risk = 1.5; 95% confidence interval, 1.1–2.0).
Conclusions: A retention strategic framework was successful in minimizing attrition in minority, low-income children. Participants missing first assessment appointments were at highest risk of subsequent attrition. These findings suggest that deploying this framework may help RCT retention of low-income minority children, particularly those at the highest risk of subsequent attrition.

1. Introduction

The recruitment and retention of racial/ethnic minority participants in clinical trials continue to be major challenges across a wide variety of conditions and healthcare settings. Multiple recent studies document that minority clinical-trial candidates are significantly less likely than whites to be approached about study participation and to be enrolled in clinical studies, including trials in the emergency department, for HIV/AIDS patients, for cancer

Abbreviations: CHIP, Children's Health Insurance Program; Kids' HELP, Kids' Health insurance by Educating Lots of Parents; RCT, randomized, controlled trial.

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patients, and in the evaluation of new molecular-entity drugs and biological products [1–4]. Although fewer studies have been conducted on racial/ethnic differences in participant retention in clinical trials, the evidence shows that retention rates in trials are significantly lower for minorities and those who speak a language other than English at home [5–7]. A recent review of childhood obesity studies also revealed that mean retention rates were lower in trials solely targeting Latinos and African-Americans [8].

Echoing these well-documented challenges in the literature of retention of minority children and their parents in clinical trials, two randomized, controlled trials (RCTs) by our team had attrition rates of 37–40% [9,10]. Prompted by these experiences and a review of the literature revealing that not enough is known about effective methods for minimizing attrition in minority children in clinical trials, our study aim was to develop, implement, and evaluate an innovative approach for achieving high retention rates in an RCT of an intervention targeting low-income minority children and their families. An additional goal was to identify child or caregiver characteristics at baseline associated with attrition at one-year follow-up of outcomes.

2. Methods

2.1. Strategic framework

Based on lessons learned from our team's prior RCTs targeting low-income, minority children [9,10], a strategic framework was developed to maximize retention in an RCT of the effects of Parent Mentors on insuring uninsured minority children called Kids' HELP (Kids' Health insurance by Educating Lots of Parents) [11]. The strategies in this framework were as follows:

- **Optimize cultural and linguistic competency**. The Kids' HELP trial target population was Latino and African-American uninsured children and their parents. To optimize cultural and linguistic competency throughout the trial, the four research staff hired for the trial were all bilingual Latinos or African-Americans, including a bilingual Latino research assistant responsible for assessing outcomes. This strategy was aimed at eliminating potential cultural and linguistic barriers to trial retention.
- **Research-staff training emphasized building participant relationships and trust.** It was theorized that participants would be less likely to dropout or be lost to follow-up if they had trusting relationships with staff.
- **Comprehensive contact information for participants and their relatives, friends, and neighbors**. Our prior experiences revealed that having only one telephone number for a participant increases the risk of dropout or loss to follow-up. To ensure multiple alternatives in the event of an initial failure to contact a participant, we collected mobile, landline, and work telephone numbers for participant caregivers, along with e-mail and postal addresses, if available. We also requested similar complete contact information for at least one relative and one friend or neighbor for each participant.
- **Electronic tracking database**. A detailed electronic tracking database was created to monitor study outcomes, adherence to monthly outcome phone calls, and participants at risk for loss to follow-up or currently lost to follow-up. The database also included the number of contact attempts, the mode of contact (telephone, text, e-mail, letter, or fax) of all contact attempts, and upcoming outcomes-assessment appointments with participants.
- **Reminders for upcoming outcomes-assessment appointments**. Participants were reminded about upcoming appoints for outcomes assessments with research staff via telephone messages, texts, and/or e-mails.
- **Frequent, sustained contact attempts for non-respondents**. For any participant who did not respond to a scheduled outcomes follow-up assessment, the outcomes researcher contacted the participant daily, varying the time of day for the subsequent contacts, as well as the modes of communication (mobile and landline telephones, texts, e-mails, and certified letters), and continued such contacts periodically until a response was obtained or the study ceased.
- **Incentives for every survey completed**. To compensate participants for their time and effort and incentivize them to complete all follow-up surveys, honoraria of $50 at enrollment, $5 for monthly follow-ups, and $10 for six- and 12-month surveys were provided.
- **Individualized rapid-cycle quality-improvement approach to non-respondents**. In weekly research-team meeting, all non-respondents were identified and discussed using an individualized rapid-cycle quality-improvement framework. Team members most familiar with the non-responding participant shared potential root causes for the non-response. The team then developed and implemented an action plan, evaluated the outcome at the next team meeting, and continued or modified the action plan, based on the results. Action plans included varying daily time of the phone call; using alternative phone numbers; contacting family members, friends, or neighbors; text messages; mailing a certified letter; having the recruitment research assistant who made the first contact with the participant reach out to the participant; leaving a voice mail about the importance of the study and participation; and making a home visit.
- **Reinforce the importance of the study**. In scheduling follow-up appointments and voice messages left for non-respondents, a script was developed which emphasized why the study was so important for children, families, and the community, and that participation would help us to insure more children and improve children's health, healthcare, and well-being.
- **Home visits as a last resort**. When repeated contacts using all other means were exhausted, research staff made one or more home visits to non-responding participants and their families. When families were not at home, a note regarding the importance of completing the follow-up was left, along with the business card of that particular research-team member.

2.2. Summary of design and methods of Kids' HELP trial

The Kids' HELP trial was the first RCT of the effectiveness and cost effectiveness of Parent Mentors (PMs) in insuring uninsured minority children [11]. PMs were experienced parents with at least one child covered by Medicaid or CHIP who received two days of training, then assisted families for one year with insurance applications, retaining coverage, medical and dental homes, and social determinants of health. Controls received traditional state Medicaid/CHIP outreach and enrollment efforts. The primary outcome was obtaining health insurance one year after enrollment. The PM intervention was more effective than traditional outreach/enrollment in insuring uninsured minority children [12]. The PM intervention also insured children faster, and was more effective in renewing coverage, improving access to medical and dental care, reducing out-of-pocket costs, achieving parental satisfaction and quality of care, and sustaining insurance after intervention cessation, and saved $6,045.22 per child insured per year [12]. Complete details on the design, methods, and results of the Kids' HELP trial

are available elsewhere [11–13].

2.3. Data collection

At baseline, all Kids' HELP trial participants completed a questionnaire which consisted of 82 questions regarding family, parental, and children's characteristics [11]. A researcher blinded to group allocation monitored trial outcomes monthly for 12 months [12]. Contacts with study families, withdrawals, and potential losses to follow-up were recorded in the electronic study database; reports from this database were then generated and reviewed and discussed in weekly meetings of the research team.

2.4. Analyses

All analyses were conducted using SAS 9.1© (Cary, NC). Bivariate analyses were performed to 1) compare attrition rates in the Kids' HELP trial and two prior community-based RCTs of interventions which also targeted minority children [9,10] (the first examined the effects of community-based case managers on insuring uninsured children [9] and the second evaluated the effects of Parent Mentors [trained parents who already have their own children with asthma] on improving asthma outcomes [10]); and 2) identify child and caregiver factors associated with attrition in the Kids' HELP trial. Pearson's Chi-square was used for categorical variables, and the non-parametric Wilcoxon test was used for continuous variables. Two-tailed P values are reported, with $P < 0.05$ considered statistically significant. In the bivariate analyses of factors associated with attrition, to adjust for multiple comparisons, Bonferroni-corrected P values were calculated and are provided for any findings with an initial $P < 0.05$.

Multivariable analyses were performed using multiple logistic regression and forward stepwise procedures. The primary outcome was attrition (defined as withdrawal of the child from the study by the caregiver or loss to follow-up of the participating family). The initial alpha-to-enter was set at 0.15. Factors in the bivariate analysis with a $P < 0.15$ for an association with attrition were forced into the multivariable model. The variance inflation factor was calculated to detect any multicollinearity among independent variables. The log likelihood chi-square tests, pseudo R-square, and Hosmer and Lemeshow's goodness-of-fit tests were used to select the best-fitting model. Logistic regression yields odds ratios rather than risk ratios, and when the outcome of interest is common in the study population, odds ratios may exaggerate risk associations. Established methods were used to directly estimate adjusted risk ratios and correct lower and upper limits of confidence intervals derived from adjusted odds ratios obtained from the logistic regression analysis [14–16].

2.5. Human and animal rights

The protocol for the Kids' HELP trial was approved by the University of Texas Southwestern Medical Center Institutional Review Board. Informed consent and assent (when indicated for older children) was obtained from all participants in their language of choice (English or Spanish). The study did not involve the use of animals in any way.

3. Results

3.1. Comparability of study populations in three RCTs

The study populations in the three RCTs were comparable (Table 1). The average child age ranged between 7.0 and 8.9 years, and 100% were racial/ethnic minority in all three trials. The mean primary-caregiver age (in years) was in the low to mid 30s, and the vast majority of caregivers were female (although data were not available on caregiver gender for one trial). In all three RCTs, 100% of study families resided in urban households. Approximately three-quarters of study households in all three trials had annual combined family incomes at or below the federal poverty threshold.

3.2. Comparison of attrition rates in three RCTs

The attrition rate in the Kids' HELP trial was significantly lower than the attrition rates of two similar community-based RCTs of interventions targeting low-income racial/ethnic minority children (Table 2). The Kids' HELP trial attrition rate was 10.9% (8.9% in the intervention group and 13.0% in the control group), compared with 37% in a case management trial for uninsured Latino children [9] and 40.4% in the Parents Helping Parents Fight Asthma trial [10] ($P < 0.001$).

3.3. Bivariate analysis of characteristics associated with attrition

A bivariate analysis (Table 3) revealed that missing the first outcomes follow-up contact was a significant predictor of subsequent participant attrition during the one-year outcomes follow-up period, with 66% in the attrition group missing the first follow-up, compared with only 39% among participants who were retained throughout the one-year follow-up period ($P = 0.001$). Another significant predictor of attrition was the caregiver reporting that

Table 1
Comparison of selected baseline characteristics in three randomized, controlled trials (RCTs) of interventions targeting the elimination of health and healthcare disparities in urban minority children.

	RCT					
	Kids' HELP (N = 266)		Insurance case-management (N = 275)		Asthma Parent Mentors (N = 220)	
Characteristic	Intervention group	Control group	Intervention group	Control group	Intervention group	Control group
Child age, average[a] (years)	7.0	7.0	8.9	8.9	7.1	7.3
Child race/ethnicity African-American or Latino	100%	100%	100%	100%	100%	100%
Primary caregiver age, mean (years)	37.5	35.7	36.7	36.7	32.5	31.3
Female primary caregiver	96%	95%	NA[b]	NA[b]	92%	91%
Urban household	100%	100%	100%	100%	100%	100%
Annual combined family income 0–100% of federal poverty threshold	72%	72%	69%	73%	82%	79%

[a] Median for Kids' HELP; mean for the other two RCTs.
[b] "NA" denotes not available; data on the gender of the primary caregiver were not collected in this trial.

Table 2
Comparison of attrition rates in three community-based, randomized, controlled trials of interventions targeting low-income racial/ethnic minority children.

Characteristic	Trial name and publication citation		
	Case management of uninsured children [9]	Parents Helping Parents Fight Asthma [10]	Kids' HELP [12]
Number of participants randomized[a]	275	220	266
Number of participants who withdrew or were lost to follow-up	102	89	29
Attrition rate[b]	37.1%[c]	40.4%[c]	10.9%

[a] The final number of participants randomized after all post-randomization exclusions of ineligible participants occurred.
[b] The number of participants who withdrew or were lost to follow-up over the one-year evaluation period divided by the number of participants randomized, multiplied by 100.
[c] $P < 0.001$ for comparison with attrition in the Kids' HELP trial.

Table 3
Bivariate analysis of characteristics of uninsured minority children and their parents in the Kids' HELP trial (N = 266) by attrition status.

Characteristic	Mean or %		
	No attrition (N = 237)	Attrition (N = 29)	*P*
Missed first follow-up contact	39%	66%	0.001[a]
Caregiver has no emotional worry or concern about child's physical health	23%	41%	0.03[b]
Type of insurance that uninsured child had in past			0.06
Medicaid	75%	52%	
CHIP	13%	30%	
Private	11%	19%	
Instituto Mexicano del Seguro Social[a]	1%	0%	
Primary caregiver employed	34%	50%	0.12
Primary caregiver born in US	48%	59%	0.28
Child born in US	97%	100%	0.35
Primary caregiver has limited English proficiency	47%	38%	0.36
Primary caregiver aware that child is eligible for Medicaid or CHIP	52%	41%	0.47
Primary caregiver's highest educational attainment			0.56
High-school graduate or higher	36%	41%	
Less than high-school graduate	64%	59%	
Caregiver worries about child's health more than other people	84%	79%	0.57
Gender of child			0.58
Male	50%	55%	
Female	50%	46%	
Child's health status not excellent/very good	39%	35%	0.61
Primary caregiver has health insurance	26%	30%	0.66
Primary caregiver's health status			0.69
Excellent	16%	9%	
Very good	23%	22%	
Good	39%	48%	
Fair	19%	22%	
Poor	4%	0%	
Mean age of caregiver in years (range)	36.6 (18–76)	34.6 (20–48)	0.73
Child ever had health insurance before	95%	93%	0.76
Child has limited English proficiency	34%	31%	0.77
Gender of primary caregiver			0.84
Male	4%	3%	
Female	96%	97%	
Mean age of child in years (range)	7.3 (1–18)	7.1 (1–18)	0.85
Primary caregiver married and living with spouse	36%	38%	0.86
Race/ethnicity of primary caregiver			0.89
Latino	64%	66%	
African-American	34%	31%	
White	2%	3%	
Median combined annual family income	$21,000	$21,847	0.92
Number of adults in household			0.93
1	30%	38%	
2	41%	38%	
>=3	29%	24%	
Median months without insurance	14	6	0.96
Number of children in household			0.97
1	28%	31%	
2	34%	41%	
>=3	38%	28%	
Race/ethnicity of child			0.99
Latino	65%	66%	
African-American	35%	34%	

[a] $P = 0.002$ after Bonferroni adjustment for multiple comparisons.
[b] $P = 0.06$ after Bonferroni adjustment for multiple comparisons.

she or he has no emotional worry or concern about the child's physical health, which was noted for 41% of the attrition group, but only 23% of the retention group ($P = 0.03$). There was a non-significant trend towards higher attrition for children who ever had Children's Health Insurance Program (CHIP) coverage (30% had ever had CHIP coverage in the attrition group vs. 13% in the retention group; $P = 0.06$) and families in which the primary caregiver was employed (primary caregiver employment was 50% in the attrition group vs. 34% of the retention group; $P = 0.12$). None of the remaining 22 child, caregiver, or family characteristics was significantly associated with attrition.

3.4. Multivariable analysis of characteristics associated with attrition

Multivariable analysis (Table 4) revealed that missing the first outcomes follow-up contact was significantly associated with attrition, with an adjusted relative risk of 1.5 (95% confidence interval, 1.1–2.0). After adjustment, the child ever having CHIP coverage, primary caregiver employment, and the primary caregiver has no emotional worry or concern about the child's physical health were not found to be significantly associated with attrition.

4. Discussion

A systematic, family-centered, culturally appropriate approach to retention in a community-based RCT of an intervention targeting low-income, minority children resulted in an attrition rate of 10.9%, a statistically significant reduction in comparison with attrition rates of 37–40% in prior RCTs [9,10] targeting similar at-risk populations. It is hypothesized that retention success in the Kids' HELP trial can be attributed to the 10-component strategic framework described in the Methods. In particular, we believe that the most crucial elements of retention success were: 1) building participant relationships and trust through culturally competent interactions with research staff from the same racial/ethnic backgrounds as participating families; 2) persistent maintenance of participant communication leveraging multiple possible modes of contact; 3) reinforcement of the importance of the study for children, families, and communities; 4) a systematic, electronic approach to tracking and following participants, especially those at highest risk for attrition; and 5) employing a rapid-cycle quality improvement approach to non-respondents.

Certain components of our retention strategic framework have been previously reported as effective in RCT retention in prior published studies and reviews of the literature. Cultural and linguistic competency have been noted to be critical to retention of minority participants in a variety of settings and populations, including in qualitative research [17], studies on minority girls and women [18], and evaluations of mental-health disparities for Latino children [19]. Research staff building relationships and trust has been cited as essential to retention in studies of minority girls and women [18] and of weight and hypertension management in primarily minority adults [20]. Comprehensive contact information for participants and their relatives, friends, and neighbors has been identified as crucial to retention in an analysis of trials by the NIH Behavior Change Consortium and two retention literature reviews. [21,22,23] Reminders also have been reported to enhance RCT retention in three systematic reviews [22–24]. Frequent, sustained contact attempts for non-respondents has been cited as important for retention in trials by the NIH Behavior Change Consortium [21]. Incentives have been identified in multiple studies as one of the most effective means of enhancing retention. [18,21–26] Reinforcing the importance/benefits of the trial also has been ascertained to be useful in RCT retention [21–23]. Home visits as a last resort were found to enhance retention in RCTs of interventions targeting childhood obesity [26] and intraoperative hemodynamic management for patients undergoing coronary-artery bypass-graft surgery [27].

Two components of our retention strategic framework have not, to our knowledge, been previously reported in prior published studies and reviews of the literature on RCT participant retention. Two prior articles noted the importance of developing either a participant tracking protocol [26] or tracking system using calendars or unspecified computer software [21]. Our electronic tracking database was unique in being multi-functional by addressing monitoring of outcomes, adherence to outcome phone calls, and participants at risk for loss to follow-up or currently lost to follow-up. An additional innovation of the database was the tracking of the number of contact attempts, modes of contacts, and imminent outcomes-assessments appointments with participants. The second unique component of the Kids' HELP retention strategic framework was the individualized rapid-cycle quality-improvement approach to non-respondents. A major focus of the Kids' HELP weekly research-team meetings was identifying and discussing all non-respondents using an individualized rapid-cycle quality-improvement framework. This resulted in identification of all potential root causes for non-response, development and implementation of an action plan, ongoing evaluation of response outcomes at the next team meeting, and continuation or modification of the action plan, based on the results. It is our impression that this innovation was one of the most powerful tools for reducing attrition in the Kids' HELP trial, and could prove useful in maximizing retention in other RCTs.

The study findings revealed that participants who miss the first follow-up outcomes assessment are at significantly higher risk of future attrition than those completing the first assessment. Attrition occurred in approximately two-thirds of participants missing the first outcomes assessment appointment, compared with about one-third of those completing this assessment, and missing the first assessment appointment conferred approximately twice the adjust relative risk of subsequent attrition. These findings complement prior published work on a longitudinal birth cohort study which showed that mothers who did not complete the first study event were over eight times more likely to subsequently be lost to follow-up or withdraw [28]. The results of that study and our Kids' HELP trial make intuitive sense, given that past behavior often predicts future behavior, as has been shown in the psychology literature [29]. These findings may prove particularly useful in identifying trial participants at greatest risk of subsequent attrition,

Table 4
Multivariable analysis of factors associated with attrition in the Kids' HELP trial.

Factor	Adjusted relative risk of subsequent attrition[a] (95% confidence interval)
Missed first outcomes follow-up contact	1.5 (1.1, 2.0)
Child ever had CHIP coverage	2.5 (0.98, 3.8)
Primary caregiver employed	1.2 (0.7, 1.9)
Caregiver has no emotional worry or concern about child's physical health	1.1 (0.99, 1.2)

[a] During the one-year outcomes follow-up period.

and targeting them for more intensive retention strategies.

In contrast to prior work on attrition in an RCT [30] and a prospective observational study [28], maternal age, marital status, and the number of children in the household were not found to be significantly associated with attrition in the Kids' HELP trial. This may reflect that those studies focused on substantially different objectives and populations—reducing infant mortality through a maternal parenting intervention and identifying factors predicting future asthma in a birth cohort—and that some attrition predictors, therefore, may be study-specific. Of note, our bivariate analyses revealed that attrition was significantly higher among caregivers with no emotional worry or concern about their child's physical health, compared with caregivers with these worries/concerns. Although this finding was no longer significant after adjustment in the multivariable analysis, it suggests the study-specific possibility that parents less concerned about their child's health might be less likely to be interested in continuing in a study of an intervention to insure uninsured children. One potential retention lesson for RCT research teams, therefore, may be to monitor both for study-specific reasons for attrition, as well as cross-cutting factors, such as missing the first follow-up appointment.

Certain study limitations should be noted. The Kids' HELP trial was conducted in predominantly low-income, Latino and African-American communities in an urban setting. The results, thus, may not necessarily generalize to children and families from other income strata or racial/ethnic groups, or residing in suburban or rural areas.

5. Conclusion

A 10-component retention strategic framework was successful in minimizing attrition in racial/ethnic minority, low-income populations, achieving an attrition rate of 10.9%, which was significantly lower than the 37%–40% attrition rates of two prior RCTs targeting similar populations at high risk for attrition. The strategic framework consists of: 1) optimize cultural and linguistic competency; 2) research-staff training emphasizing building participant relationships and trust; 3) comprehensive contact information for participants and their relatives, friends, and neighbors; 4) an electronic tracking database; 5) reminders for upcoming outcomes-assessment appointments; 6) frequent, sustained contact attempts for non-respondents; 7) incentives for every survey completed; 8) an individualized rapid-cycle quality-improvement approach to non-respondents; 9) reinforce the importance of the study; and 10) home visits as a last resort. We also found that participants who miss the first outcomes-assessment appointment are at a significantly higher risk of future attrition than those completing the first assessment. The study findings suggest that deploying the 10-component Kids' HELP retention strategic framework can help to minimize attrition in RCTs targeting low-income minority children, particularly participants identified early on in a trial to be at the highest risk of subsequent attrition, including participants and families who miss the first outcomes-assessment contact.

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Conflict of interest

The authors report no conflict of interest.

Clinical trial registration

The Kids' HELP trial is registered with ClinicalTrials.gov, identifier NCT01264718.

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